Original Application
-COPY-

AxelaCare Health Solutions LLC (East TN)

CN1702-008

DSG Development Support Group

FEB 13 '17 PM2:04

February 12, 2017

Melanie Hill, Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application Submittal
AxelaCare Health Solutions--Expansion of Home Health Service Area
East Tennessee

Dear Mrs. Hill:

This letter transmits an original and two copies of the subject application. The affidavit and filing fee are enclosed.

I am the contact person for this project. Brant Phillips is legal counsel. Please advise me of any additional information you may need. We look forward to working with the Agency on this project.

Respectfully,

John Wellborn

John Wellborn
Consultant

4219 Hillsboro Road, Suite 203
Nashville, TN 37215

jwdsg@comcast.net

Tel 615.665.2022
Fax 615.665.2042

FEB 13 '17 PM 2:04

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

JOHN WELLBORN, being first duly sworn, says that he is the lawful agent of the applicant named in this application, that this project will be completed in accordance with the application to the best of the agent's knowledge, that the agent has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete to the best of the agent's knowledge.

John Wellborn
SIGNATURE/TITLE
CONSULTANT

Sworn to and subscribed before me this 13th day of February (Month), 2017 (Year) a Notary

Public in and for the County/State of DAVIDSON

NOTARY PUBLIC

My commission expires July 2 (Month/Day), 2018 (Year).

JAN M. DANFORTH
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
My Commission Expires July 2, 2018

AXELACARE
HEALTH SOLUTIONS

CERTIFICATE OF NEED APPLICATION TO ADD EAST TENNESSEE COUNTIES TO ITS HOME HEALTH SERVICE AREA

LIMITED TO HOME INFUSION OF IMMUNE GLOBULIN MEDICATIONS

Submitted February 2017

CERTIFICATE OF NEED APPLICATION

SECTION A: APPLICANT PROFILE

1. Name of Facility, Agency, or Institution

AxelaCare Health Solutions		
Name		
5100 Poplar Avenue, 27th Floor, Suite 2739		Shelby
Street or Route		*County*
Memphis	TN	38137
City	*State*	*Zip Code*
www.AxelaCare.com		
Website Address		

2. Contact Person Available for Responses to Questions

John Wellborn		Consultant	
Name		*Title*	
Development Support Group		jwdsg@comcast.net	
Company Name		*E-Mail Address*	
4219 Hillsboro Road, Suite 210	Nashville	TN	37215
Street or Route	*City*	*State*	*Zip Code*
CON Consultant	615-665-2022	615-665-2042	
Association With Owner	*Phone Number*	*Fax Number*	

NOTE: **Section A** is intended to give the applicant an opportunity to describe the project. **Section B** addresses how the project relates to the criteria for a Certificate of Need by addressing: Need, Economic Feasibility, Contribution to the Orderly Development of Health Care, and Quality Measures. Please answer all questions on 8.5" X 11" white paper, clearly typed and spaced, single-sided, in order and sequentially numbered. In answering, please type the question and the response. All questions must be answered. If an item does not apply, please indicate "N/A" (not applicable). Attach appropriate documentation as an Appendix at the end of the application and reference the applicable Item Number on the attachment, i.e., Attachment A.1, A.2, etc. The last page of the application should be a completed and signed notarized affidavit.

3. SECTION A: EXECUTIVE SUMMARY

A. Overview

Please provide an overview not to exceed three pages in total, explaining each numbered point.

(1) Description (Address the establishment of a health care institution, initiation of health services, bed complement changes, and/or how this project relates to any other outstanding but unimplemented certificates of need held by the applicant.)

Specialty home infusion is the process of providing very specialized medications intravenously in a patient's home, with the presence and support of a skilled registered nurse (R.N.) who works under the direction of the patient's referring physician. This is a very specialized therapy needed by a small group of seriously ill patients. It requires prolonged hours of onsite, in-home skilled nursing care, often on several consecutive days each month. Almost no nursing agencies are willing or able to staff for this type of therapy routinely -- especially since patient demand is small due to lack of Medicare reimbursement except when the infusion patient is totally homebound and, therefore, qualifies for Medicare reimbursement.

In 2016, AxelaCare Health Solutions, the applicant, requested CON approval to establish a home health agency to serve 21 West Tennessee counties. Its scope of service was to be limited to the home infusion of specialized immune globulin pharmaceuticals and nursing services necessary to provide for that specific type of infusion therapy.

The CON Board unanimously approved the application.

The approved application stated that, in two subsequent applications, AxelaCare would propose extending this limited home health service to all other Tennessee counties. This present application is to expand AxelaCare's authorized service area to cover 34 additional East Tennessee counties. A companion application has been filed simultaneously to serve 40 counties of East Tennessee. If both are approved, AxelaCare's specialized home health nurses will be able to meet specialized patient needs for immune globulin infusions in all 95 Tennessee counties.

As in the approved West Tennessee project, this service will be provided only to a very small number of patients whose physicians have prescribed infusion of specialized immune globulin medications. The non-homebound patients served by the project will not be eligible for Medicare or TennCare reimbursement for this home care service under existing reimbursement rules. The service, therefore, is proposed for privately insured patients, and a small number of charity patients. The same was true of the approved West Tennessee application.

The applicant home health agency, which expects to achieve State licensure for West Tennessee by February 2017, will maintain its principal office in Memphis/Shelby County and will provide home nursing service through R.N. field staff residing in one or more counties in East Tennessee to ensure appropriate drive time accessibility to the patients they serve.

Branch offices are not necessary for nurse training and support, which will be delivered in the field. As in other technologically advanced companies, principal office employees linked electronically will provide staff recruitment, training, scheduling, business management and other components of the program, both in Memphis and in varying locations in East Tennessee. Significant additional description of the project and its importance to patient care is provided in Attachment Section A-3A(1).

(2) Ownership Structure

AxelaCare Health Solutions LLC ("AxelaCare") is the Certificate of Need applicant. The applicant LLC is wholly owned by UnitedHealth Group Incorporated through several wholly owned intermediary corporations and LLC's, which are shown in the organization chart in Attachment A.4 of the application. No other facilities or entities in Tennessee are owned by the applicant.

AxelaCare is America's fourth largest provider of home infusion medications and services. It is a leader in research partnerships in this field of medicine. AxelaCare is accredited by the Joint Commission and holds the Joint Commission's Gold Seal of Approval based on the recognized quality of its programs. AxelaCare's National Pharmacy Program (which supports this project by providing medications to the home health team) is accredited by URAC (originally named the Utilization Review Accreditation Program), a distinction that it earned with a 100% score on its accreditation surveys. Additional information on URAC is provided in the Attachments to the application.

AxelaCare is both a licensed pharmaceutical provider and a home health services provider. As a provider of medications AxelaCare pharmacies prepare and ship home infusion pharmaceuticals to patients in 48 States. As a services provider in 17 States (through 33 branch offices) AxelaCare operates a full-scope program that integrates (a) the AxelaCare Pharmacy with (b) AxelaCare clinical teams of pharmacists and skilled home infusion nurses who manage the infusion of those medications in patients' homes, as directed by their physicians. AxelaCare nurses and pharmacists in all 17 states are available 24/7 for patient assistance and for consultation with referring physicians -- before, during and after the patient's infusion.

(3) Service area

The proposed service area consists of 34 East Tennessee counties. They are Anderson, Bledsoe, Blount, Bradley, Campbell, Carter, Claiborne, Cocke, Cumberland, Grainger, Greene, Hamblen, Hamilton, Hancock, Hawkins, Jefferson, Johnson, Knox, Loudon, McMinn, Marion, Meigs, Monroe, Morgan, Polk, Rhea, Roane, Scott, Sequatchie, Sevier, Sullivan, Unicoi, Union, and Washington Counties.

(4) Existing similar service providers

Publicly available data sources do not provide patient care data specific to patients receiving immune globulin infusions. The applicant knows of 76 home health agencies serving the area, but it has not been able to identify one other agency that meets all four of the criteria for optimal care that are stated below in Section B(1) "Need" immediately after this Executive Summary.

(5) Project cost

The estimated $70,000 cost of the project is very minimal. The principal office already exists, so there are no facility costs. The proposed capital cost is almost entirely the potential cost of the CON process.

(6) Funding

This will be funded by cash transfers from UnitedHealth Group Incorporated to Briova Rx Infusion Services, the applicant's immediate parent company.

(7) Financial feasibility, including when the proposal will realize a positive financial margin; and

As with the approved West Tennessee application, the AxelaCare home health nursing service that is proposed in this application will operate at a financial loss from a stand-alone perspective. However, AxelaCare's Kansas-based specialty pharmacy that provides the medication for the infusion is already licensed to operate anywhere in Tennessee and that component of the project is profitable enough to absorb losses on the actual home delivery component. From the applicant's perspective, as well as from a business perspective, there will be a positive operating margin when those two components of this project's care delivery are combined for purposes of financial feasibility evaluation.

To illustrate this, the applicant has provided several sets of Projected Data Charts: for the proposed nursing service alone; for the proposed pharmaceutical component alone; for the two of those combined, and for the approved West Tennessee operation combined with the proposed nursing and pharmaceutical operations in East Tennessee. The combined services show a positive cash flow and positive operational margins in Year One and thereafter.

(8) Staffing

In Year Two, this project will require 10 FTE's of new personnel. This includes 3.0 skilled care field R.N. FTE's in East Tennessee, and 0.5 of a RN Nurse Director FTE based at the principal office in Memphis but also doing patient care in East Tennessee. Other staff include non-clinical staff in Memphis and at the Regional Pharmacy in Kansas.

B. Rationale for Approval

A certificate of need can only be granted when a project is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, will provide health care that meets appropriate quality standards, and will contribute to the orderly development of adequate and effective health care in the service area. This section should provide rationale for each criterion using the data and information points provided in Section B of this application. Please summarize, in one page or less, each of the criteria.

(1) Need

Referring physicians who prescribe specialty infusion medications provided by AxelaCare can face undesirable delays in finding home health agencies that can administer specialty infusion care to their patients in a timely and optimal manner.

These referring physicians and their patients need an agency that is prepared to do all of the following: (a) start infusions in the patient's home promptly upon request; (b) provide highly skilled nurses specialized in specialty infusion; (c) provide both onsite and post-treatment data communication to the physician and pharmacist responsible for the patient; and (d) serve their East Tennessee patients who live in remote rural areas. All four criteria must be met for optimal care of this unique patient population.

Yet, out of the 76 home health agencies currently serving the East Tennessee service area, few if any appear to meet all four criteria. In January 2017, AxelaCare conducted a phone survey of 74 of the 76 agencies licensed for any of the counties in this service area (excluding agencies serving only high-risk pregnant women). Almost every agency provided a telephone response; responses are summarized in a table beginning on the third following page.

Only 5 of the surveyed providers (two of which are under common ownership) indicated an ability to infuse IG patients. Of those 5, only 1 is licensed to serve the entire service area. This single agency reported having only 1 IVIG nurse. The remaining 4 agencies have only limited coverage of the service area counties -- with none licensed for more than 6 (18%) of the service area's 34 counties. This demonstrates a gap of home care for a small group of IG patients with serious needs, and a lack of reasonable choice of provider for this service.

One problem is that very few home health agencies are willing and able to routinely staff for the specialized skilled nursing care required to perform IVIG infusions at home. Optimal nursing care for IVIG infusion requires significant nursing experience and training. Such care and administration of IVIG requires the nurse to be placed for long hours, generally 4-6 hours per treatment day, with the patient being treated over several consecutive treatment days, during which continuous monitoring of patient responses is required. Few agencies are willing to make such long time commitments of their nursing staff.

Due to the difficulty of finding agencies with staff to perform this type of specialty home infusion, physicians often cannot start the infusion as quickly as the patient requires it. This can force patients either to incur the burden of commuting to a freestanding or outpatient infusion center or on occasion to remain in a hospital extra days while waiting for home infusion to be arranged. Extra time in a hospital bed drives up costs. Reliance on facilities outside the patient home requires frequent and burdensome commuting on multiple days. Commuting imposes on these immune-compromised patients a risk of contracting opportunistic infections through exposure to other persons. Commuting is also less convenient and typically more expensive than

obtaining infusion care in one's home. (For these reasons, Medicare is conducting a Congressionally-mandated study to evaluate whether to extend reimbursement coverage from their homebound enrollees to their non-homebound enrollees.)

A third consideration is how home infusion care can be improved by granting this application. AxelaCare may be the only provider with advanced technology -- CareExchange-- that allows the nurse in the home to continuously record and transmit patient response data over the internet to the supervising physician and the AxelaCare pharmacist ***during treatment.***

With such "real-time" data, both the AxelaCare infusion pharmacist (available 24/7 in Kansas) and the referring specialist physician can evaluate patient reactions to the medication as it is being delivered (as well as afterward). They can immediately direct appropriate adjustments, such as variations in the dosing rate or dosing amount, as indicated by digitally documented patient reactions. The infusion nurse can identify and discuss issues with them during, as well as after, infusion, and the pharmacist and/or nurse can telephonically alert the physician to patient response issues and can discuss modifications of the treatment.

CareExchange's capturing and analysis of patient response data during the dosing cycle, and its rapid communication to the treatment team, helps both the patient and the referring physician. The technology tracks patient progress and changes in the patient's condition. It establishes baseline and trending information to compare those changes. From the ***patient's*** perspective, it ensures that patients can receive immediate optimal adjustments in dosage amounts and timing for maximum effectiveness of the infusion session. From the ***physician's*** perspective, it provides real-time infusion response data between patient office visits to help manage the patient's condition; it allows rapid adjustment of the prescribed therapy to find the most effective dose; and it gives a better understanding of how the therapy is working and how it might work for other patients with similar conditions. After treatments, AxelaCare's tablet-based software uploads its clinical data to a secure AxelaCare database that is made available for medical research. So from a ***research*** perspective, the steadily growing AxelaCare central database of patient responses to these new pharmaceuticals provides academic and other researchers with a unique source of clinical information that is very valuable.

At an annual caseload of only 35 patients in Year Two, this project can greatly improve care for immune-compromised patients with very special needs, without having any significant adverse impact on existing home health providers, who collectively served approximately 69,000 patients in 2015 in this East Tennessee service area.

(2) Economic Feasibility

The AxelaCare home health nursing service that is proposed in this application will operate at a financial loss. However, AxelaCare's Kansas-based specialty pharmacy that provides the medication to the service is already licensed and operating throughout Tennessee; and it will be profitable enough to absorb those losses. From the applicant company's perspective, as well as from a business perspective, there will be a positive operating margin when those two components of this project's care delivery are combined for purposes of evaluating financial feasibility.

To document that, the applicant has provided several sets of Projected Data Charts: for the regional nursing service alone; for the regional pharmaceutical component alone; for those

two combined to provide actual patient care, and for the entire West and East Tennessee regions with both components combined. The latter three all show a positive cash flow and positive operational margin in Year One and thereafter.

(3) Appropriate Quality Standards

AxelaCare is America's fourth largest provider of home infusion medications and services. It is a leader in research partnerships in this field of medicine. AxelaCare is accredited by the Joint Commission, and holds the Joint Commission's Gold Seal of Approval based on the recognized quality of its programs. AxelaCare's National Pharmacy Program (which supports this project by providing medications to the home health team) is accredited by URAC (originally named the Utilization Review Accreditation Program), a distinction that it earned with a 100% score on its accreditation surveys. Additional information on URAC is provided in the Attachments to the application.

(4) Orderly Development of adequate and effective health care

In 2016, AxelaCare Health Solutions requested approval to establish a limited home health agency to serve 21 West Tennessee counties. Its scope of service was to be limited to the infusion of specialized immune globulin pharmaceuticals, and nursing services necessary for that therapy. The CON Board unanimously approved the application with the requested restriction.

That approved application stated that AxelaCare would file two subsequent applications to extend this limited home health service to all other Tennessee counties. Encouraged by the West Tennessee approval, and consistent with its commitment to the Board, in this application AxelaCare is proposing to continue to extend the West Tennessee service in an orderly development through Middle and East Tennessee. This current application is to cover 34 additional East Tennessee counties. A companion application is being filed simultaneously to serve 40 counties of Middle Tennessee. If both are approved, AxelaCare's specialized home health nurses will be able to meet patient needs for immune globulin infusions in all 95 Tennessee counties.

C. Consent Calendar Justification

If consent calendar is requested, please provide the rationale for an expedited review. A request for Consent Calendar must be in the form of a written communication to the Agency's Executive Director at the time the application is filed.

Not applicable.

Axelacare Survey List--East Tennessee Home Health Agencies (74 Surveyed)								
Health Statistics ID Number	County of Parent Office	License Number	Home Health Agency Name	Agency License Number	Does Agency Infuse IG Patients?	If yes, through your own nurses? If no, is it from lack of nurses, and/or from not having adopted a Standard of Practice (SOP) for IG infusions?	Counties Covered in 34-County AxelaCare Service Area	AxelaCare Comments
82051	Sullivan	249	Advanced Home Care, Inc.	249	NO	NO SOP		
30021	Greene	86	Advanced Home Care, Inc.	86	NO	NO SOP		
26054	Franklin	82	Amedisys Home Care	82	NO	NO NURSE		
33103	Hamilton	113	Amedisys Home Health	113	NO	NO NURSE		
67024	Overton	191	Amedisys Home Health	191	NO	NO NURSE		
90121	Washington	273	Amedisys Home Health	273	NO	NO NURSE		
10031	Carter	23	Amedisys Home Health Care	23	NO	NO NURSE		
32102	Hamblen	91	Amedisys Home Health Care	91	NO	NO NURSE		
47202	Knox	150	Amedisys Home Health Care	150	NO	NO NURSE		
75064	Rutherford	5	Amedisys Home Health Care	5	NO	NO NURSE		
13022	Claiborne	25	Amedisys Home Health of Tennessee	25	NO	NO NURSE		
05012	Blount	213	Blount Memorial Hospital Home Health Services	213	NO	NO SOP		
47062	Knox	144	Camellia Home Health of East Tennessee	144	NO	NO SOP		
19724	Davidson	295	Careall	295	YES	1 PRN NURSE	1	These Careall agencies collectively are not
47232	Knox	131	Careall Home Care Services	131	YES	1 PRN NURSE	6	licensed for 80% of service area counties.
89074	Warren	265	Careall Home Care Services	265	NO	NO NURSE		
33253	Hamilton	103	CHI Memorial Health at Home	103	NO	NO SOP		
01032	Anderson	1	Clinch River Home Health	1	NO	NO SOP		
33213	Hamilton	98	Continuecare Healthservices, Inc. I	98	NO	NO SOP		
33383	Hamilton	108	Continuecare Healthservices, Inc. II	108	NO	NO SOP		
19734	Davidson	624	Coram CVS Specialty Infusion Services	624	YES	IVIG TEAM/MEDS	6	Not licensed for 82% of service area counties.
47402	Knox	133	Covenant Homecare	133	NO	NO SOP		
14024	Clay	135	Cumberland River Homecare	135	NO	NO SOP		
52024	Lincoln	161	Deaconess Homecare	161	NO	NO NURSE		
76032	Scott	211	Deaconess Homecare	211	NO	NO NURSE		
95034	Wilson	282	Deaconess Homecare I	282	NO	NO NURSE		
47222	Knox	132	East Tennessee Children's Hospital Home Health	132	NO	NO SOP		
19494	Davidson	42	Elk Valley Health Services	42	NO	NO NURSE		
26024	Franklin	83	Encompass Home Health of Tennessee	83	NO	NO NURSE		
06043	Bradley	13	Family Home Care - Cleveland	13	NO	NO SOP		
33093	Hamilton	100	Gentiva Health Services	100	NO	NO NURSE		
47042	Knox	142	Gentiva Health Services	142	NO	NO NURSE		
82061	Sullivan	251	Gentiva Health Services	251	NO	NO NURSE		
47182	Knox	149	Gentiva Health Services 2 (Girling Health Services)	149	NO	GOING OOB		
33083	Hamilton	115	Guardian Home Care, LLC	115	NO	NO SOP		
34011	Hancock	117	Hancock County Home Health and Hospice Agency	117	NO	NO SOP		
71014	Putnam	197	Highland Rim Home Health Agency	197	NO	NO NURSE		
33363	Hamilton	338	Home Care Solutions	338	NO	NO NURSE		
19544	Davidson	56	Home Care Solutions, Inc.	56	YES	1 NURSE	34	Only 1 IVIG-qualified nurse for 34 counties.
06063	Bradley	14	Home Health Care of East Tennessee, Inc.	14	NO	NO NURSE		
01052	Anderson	148	The Home Option by Hardin Health Care	148	NO	NO SOP		
37021	Hawkins	320	Hometown Home Health, Inc.	320	NO	NO SOP		
	Knox	633	Implanted Pump Management	633	NO	NO SOP		
62052	Monroe	190	Intrepid USA Healthcare Services	190	NO	NO NURSE		
71084	Putnam	198	Intrepid USA Healthcare Services	198	NO	NO NURSE		
89064	Warren	263	Intrepid USA Healthcare Services	263	NO	NO NURSE		
46031	Johnson	130	Johnson County Home Health.	130	NO	NO SOP		
30041	Greene	88	Laughlin Home Health Agency	88	NO	NO SOP		
33433	Hamilton	613	Maxim Healthcare Services	613	NO	NO NURSE		
47432	Knox	2	Maxim Healthcare Services, Inc.	2	NO	NO NURSE		
	Washington	629	Maxim Healthcare Services	629	NO	NO NURSE		
90081	Washington	269	Medical Center Homecare - Kingsport	269	NO	NO NURSE		
90091	Washington	271	Medical Center Homecare Services	271	NO	NO NURSE		
33033	Hamilton	111	NHC Homecare	111	NO	NO SOP		
47012	Knox	143	NHC Homecare	143	NO	NO SOP		
54043	McMinn	166	NHC Homecare	166	NO	NO SOP		
75024	Rutherford	208	NHC Homecare	208	NO	NO SOP		
90131	Washington	267	NHC Homecare	267	NO	NO SOP		
	Davidson	632	Pentec Health	632	NO	NON CLIN		
32132	Hamblen	10	Premier Support Services, Inc.	10	NO	NO SOP		
30051	Greene	87	Procare Home Health Services	87	YES	1 NURSE	6	Not licensed for 82% of service area counties.
01042	Anderson	620	Professional Case Management of Tennessee	620	NO	NO SOP		
96030	ondon Co, K	298	Professional Home Health Care Agency	298	NO	NO SOP		
25044	Fentress	287	Quality Home Health	287	NO	NO SOP		
25034	Fentress	80	Quality Private Duty Care	80	NO	NO NURSE		
15032	Cocke	27	Smoky Mountain Home Health and Hospice	27	NO	NO SOP		
07032	Campbell	16	Sunbelt Homecare	16	NO	NO SOP		
16034	Coffee	29	Suncrest Home Health	29	NO	NO SOP		
13032	Claiborne	93	Suncrest Home Health and Hospice	93	NO	NO SOP		
62062	Monroe	189	Sweetwater Hospital Home Health	189	NO	NO SOP		
33303	Hamilton	109	Tennessee Home Health	109	NO	NO SOP		

Axelacare Survey List--East Tennessee Home Health Agencies (74 Surveyed)								
Health Statistics ID Number	County of Parent Office	License Number	Home Health Agency Name	Agency License Number	Does Agency Infuse IG Patients?	If yes, through your own nurses? If no, is it from lack of nurses, and/or from not having adopted a Standard of Practice (SOP) for IG infusions?	Counties Covered in 34-County AxelaCare Service Area	AxelaCare Comments
47092	Knox	151	Tennova Healthcare Home Health	151	NO	NO NURSE		
32122	Hamblen	153	Univ. of TN Med Cntr Home Health / Hospice Service	153	NO	NO NURSE		
47132	Knox	156	UTMCK - Home Care Services: Hospice & Home Care	156	NO	NO SOP		

SECTION A (CONTINUED): PROJECT DETAILS

4.A. Owner of the Facility, Agency, or Institution

AxelaCare Health Solutions, LLC	913-747-3717
Name	*Phone Number*

c/o Office of General Counsel, AxelaCare, 15529 College Blvd	Johnson (KS)
Street or Route	*County*

Lenexa	Kansas	66219
City	*State*	*Zip Code*

B. Type of Ownership or Control (Check One)

A. Sole Proprietorship		F. Government (State of TN or Political Subdivision)	
B. Partnership		G. Joint Venture	
C. Limited Partnership		H. Limited Liability Company	X
D. Corporation (For-Profit)		I. Other (Specify):	
E. Corporation (Not-for-Profit)			

Attach a copy of the partnership agreement, or corporate charter and certificate of corporate existence. Please provide documentation of the active status of the entity from the TN Secretary of State's website hpps://tnbear.tn.gov/Ecommerce/FilingSearch.aspx.

See Attachment Section A-4A.

Describe the existing or proposed ownership structure of the applicant, including an ownership structure organizational chart. Explain the corporate structure and the manner in which all entities of the ownership structure relate to the applicant. As applicable, identify the members of the ownership entity and each member's percentage of ownership, for those members with 5% ownership (direct or indirect) interest.

An organization chart is included in Attachment Section A-4A. The applicant is wholly owned by BriovaRx Infusion Services, Inc., which still uses its former name of AxelaCare Holdings, Inc. BriovaRx is wholly owned through a wholly owned chain of subsidiaries by UnitedHealth Group Incorporated, the ultimate parent company.

5A. Name of Management/Operating Entity (If Applicable) Not Applicable.

Name

Street or Route *County*

City *State* *Zip Code*

Website Address

For new facilities or existing facilities without a current management agreement, attach a copy of a draft management agreement that at least includes the anticipated scope of management services to be provided, the anticipated term of the agreement, and the anticipated management fee payment methodology and schedule. For facilities with existing management agreements, attach a copy of the fully executed final contract.

Not applicable.

6A. Legal Interest in the Site of the Institution (Check One)

A. Ownership		D. Option to Lease	
B. Option to Purchase		E. Other (Specify):	
C. Lease of ____ Years			

Check appropriate line above: For applicants or applicant's parent company/owner that currently own the building/land for the project location, attach a copy of the title/deed. For applicants or applicant's parent company/owner that currently lease the building/land for the project location, attach a copy of the fully executed lease agreement. For projects where the location of the project has not been secured, attach a fully executed document including Option to Purchase Agreement, Option to Lease Agreement, or other appropriate documentation. Option to Purchase Agreements must include anticipated purchase price. Lease/Option to Lease Agreements must include the actual/anticipated term of the agreement and actual/anticipated lease expense. The legal interests described herein must be valid on the date of the Agency's consideration of the certificate of need application.

Not applicable. Implementation of the project requires no additional facilities.

6B. Attach a copy of the site's plot plan, floor plan, and if applicable, public transportation route to and from the site, on an 8.5" X 11 sheet of white paper, single-sided. Do not submit blueprints. Simple line drawings should be submitted and need not be drawn to scale.

(1) Plot Plan must include:

a. Size of site (in acres);
b. Location of structure on the site;
c. Location of the proposed construction/renovation; and
d. Names of streets, roads, or highways that cross or border the site.

Not applicable. Implementation of the project requires no additional facilities.

(2) Attach a floor plan drawing for the facility, which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. On an 8.5" X 11" sheet of paper or as many as necessary to illustrate the floor plan.

Not applicable. Implementation of the project requires no additional facilities.

(3) Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

Public transportation is not relevant to this proposal, which calls for nurses to drive to the patient's home, rather than having the patient drive or bus to a remote facility.

The drive time from the applicant's principal office in Memphis to East Tennessee patients is not relevant. The site of service is the patient's home. The service comes to the patient.

For this project, AxelaCare will recruit R.N.'s who reside within a reasonable drive time of its East Tennessee counties--either within East Tennessee or in nearby counties. It is for these nurses to determine what is a reasonable drive time for them, during their employment process. In AxelaCare's experience, most recruited nurses do not consider drive times of up to one or two hours to be excessive.

For the nurses, highway access throughout East Tennessee is excellent. Both interstate roadways and Federal and State roadways connect East Tennessee communities. A description of East Tennessee highways between county seats of 34 counties would be very extensive and, hopefully, not necessary for this application.

Though a formal recruitment plan is premature prior to being granted CON approval, representative East Tennessee communities in which AxelaCare will seek R.N. employees for this project would likely include cities such as Knoxville and Johnson City.

To illustrate regional accessibility from just one of these cities, the table on the following page provides drive time data to selected service area communities, starting from the reasonably central location of Knoxville, in Knox County. These drive times in fact are acceptable to most recruited nurses, in AxelaCare's experience. Their average drive time from Knoxville is approximately 71 minutes.

Table Need-A6(B)3: Mileage and Drive Times Between Knoxville and Major Communities in the Primary Service Area			
County	**Community**	**Distance in Miles**	**Drive Time in Minutes**
Anderson	Oak Ridge	25.2	32 min.
Bledsoe	Pikeville	92.5	97 min.
Blount	Maryville	17.8	23 min.
Bradley	Cleveland	83.7	79 min.
Campbell	LaFollette	38.9	43 min.
Carter	Elizabethton	115	110 min.
Claiborne	Tazewell	47.4	64 min.
Cocke	Newport	48.6	48 min.
Cumberland	Crossville	69.6	67 min.
Grainger	Rutledge	33.7	39 min.
Greene	Greeneville	70.1	68 min.
Hamblen	Morristown	48.7	50 min.
Hamilton	Chattanooga	112.0	101 min.
Hancock	Sneedville	69.2	84 min.
Hawkins	Rogersville	65.2	77 min.
Jefferson	Jefferson City	28.7	35 min.
Johnson	Mountain City	154.0	152 min.
Knox	Knoxville	NA	NA
Loudon	Loudon	33.9	37 min.
McMinn	Athens	58.6	59 min.
Marion	Jasper	136.0	124 min.
Meigs	Decatur	66.0	63 min.
Monroe	Sweetwater	45.8	46 min.
Morgan	Wartburg	46.3	60 min.
Polk	Benton	81.7	88 min.
Rhea	Dayton	80.5	82 min.
Roane	Rockwood	47.5	49 min.
Scott	Oneida	61.0	65 min.
Sequatchie	Dunlap	115.0	120 min.
Sevier	Sevierville	29.2	33 min.
Sullivan	Kingsport	101.0	93 min.
Unicoi	Erwin	100.0	108 min.
Union	Maynardville	26.0	37 min.
Washington	Johnson City	106	97 min.
AVERAGES		**57.8**	**71 min.**

Source: Google Maps, February 2017.

7. Type of Institution (Check as appropriate—more than 1 may apply)

A. Hospital (Specify):		H. Nursing Home	
B. Ambulatory Surgical Treatment Center (ASTC) Multi-Specialty		I. Outpatient Diagnostic Center	
C. ASTC, Single Specialty		J. Rehabilitation Facility	
D. Home Health Agency	X	K. Residential Hospice	
E. Hospice		L. Non-Residential Substitution-Based Treatment Center for Opiate Addiction	
F. Mental Health Hospital		M. Other (Specify):	
G. Intellectual Disability Institutional Habilitation Facility ICFF/IID			

8. Purpose of Review (Check as appropriate—more than 1 may apply)

A. New Institution		F. Change in Bed Complement *Please note the type of change by underlining the appropriate response: Increase, Decrease, Designation, Distribution, Conversion, Relocation*	
B. Modifying an ASTC with limitation still required per CON		G. Satellite Emergency Department	
C. Addition of MRI Unit		H. Change of Location	
D. Pediatric MRI		I. Other (Specify): Expansion of authorized service area of an approved and existing home health agency.	
E. Initiation of Health Care Service as defined in TCA Sec 68-11-1607(4) (Specify)			

9. Medicaid/TennCare, Medicare Participation

MCO Contracts (Check all that apply): None
____Amerigroup ____United Healthcare Community Plan _____BlueCare _____TennCare Select
Medicare Provider Number: project not eligible for a Medicare number
Medicaid Provider Number: project not eligible due to unavailability of Medicare no.
Certification Type: NA
If a new facility, will certification be sought for Medicare or for Medicaid/TennCare?
Medicare Yes ___ No X N/A ___
Medicaid/TennCare Yes ___ No X N/A ___

10. Bed Complement Data

Not Applicable

A. Please indicate current and proposed distribution and certification of facility beds.)

	Beds Currently Licensed	Beds Staffed	Beds Proposed	*Beds Approved	**Beds Exempt	TOTAL Beds at Completion
1. Medical						
2. Surgical						
3. ICU/CCU						
4. Obstetrical						
5. NICU						
6. Pediatric						
7. Adult Psychiatric						
8. Geriatric Psychiatric						
9. Child/Adolescent Psychiatric						
10. Rehabilitation						
11. Adult Chemical Dependency						
12. Child/Adolescent Chemical Dependency						
13. Long-Term Care Hospital						
14. Swing Beds						
15. Nursing Home SNF (Medicare Only)						
16. Nursing Home NF (Medicaid Only)						
17. Nursing Home SNF/NF (dually certified MCare/Maid)						
18. Nursing Home-Licensed (Noncertified)						
19. ICF/IID						
20. Residential Hospice						
TOTAL						

** Beds approved but not yet in service* *** Beds exempted under 10%/3 yrs provision*

B. Describe the reasons for change in bed allocations and describe the impact the bed changes will have on the applicant facility's existing services.

Not applicable.

C. Please identify all the applicant's outstanding Certificate of Need projects that have a licensed bed change component. If applicable, complete the chart below.

Not applicable. No beds are involved in the applicant's current CON.

11. Home Health Care Organizations – Home Health Agency, Hospice Agency (excluding Residential Hospice), identify the following by checking all that apply:

See Table on following page.

	Existing Licensed County	Parent Office County	Proposed Licensed County		Existing Licensed County	Parent Office County	Proposed Licensed County
Anderson	☐	☐	X	Lauderdale	X	☐	☐
Bedford	☐	☐	☐	Lawrence	☐	☐	☐
Benton	X	☐	☐	Lewis	☐	☐	☐
Bledsoe	☐	☐	X	Lincoln	☐	☐	☐
Blount	☐	☐	X	Loudon	☐	☐	X
Bradley	☐	☐	X	McMinn	☐	☐	X
Campbell	☐	☐	X	McNairy	X	☐	☐
Cannon	☐	☐	☐	Macon	☐	☐	☐
Carroll	X	☐	☐	Madison	X	☐	☐
Carter	☐	☐	X	Marion	☐	☐	X
Cheatham	☐	☐	☐	Marshall	☐	☐	☐
Chester	X	☐	☐	Maury	☐	☐	☐
Claiborne	☐	☐	X	Meigs	☐	☐	X
Clay	☐	☐	☐	Monroe	☐	☐	X
Cocke	☐	☐	X	Montgomery	☐	☐	☐
Coffee	☐	☐	☐	Moore	☐	☐	☐
Crockett	X	☐	☐	Morgan	☐	☐	X
Cumberland	☐	☐	X	Obion	X	☐	☐
Davidson	☐	☐	☐	Overton	☐	☐	☐
Decatur	X	☐	☐	Perry	☐	☐	☐
DeKalb	☐	☐	☐	Pickett	☐	☐	☐
Dickson	☐	☐	☐	Polk	☐	☐	X
Dyer	X	☐	☐	Putnam	☐	☐	☐
Fayette	X	☐	☐	Rhea	☐	☐	X
Fentress	☐	☐	☐	Roane	☐	☐	X
Franklin	☐	☐	☐	Robertson	☐	☐	☐
Gibson	X	☐	☐	Rutherford	☐	☐	☐
Giles	☐	☐	☐	Scott	☐	☐	X
Grainger	☐	☐	X	Sequatchie	☐	☐	X
Greene	☐	☐	X	Sevier	☐	☐	X
Grundy	☐	☐	☐	Shelby	X	X	☐
Hamblen	☐	☐	X	Smith	☐	☐	☐
Hamilton	☐	☐	X	Stewart	☐	☐	☐
Hancock	☐	☐	X	Sullivan	☐	☐	X
Hardeman	X	☐	☐	Sumner	☐	☐	☐
Hardin	X	☐	☐	Tipton	X	☐	☐
Hawkins	☐	☐	X	Trousdale	☐	☐	☐
Haywood	X	☐	☐	Unicoi	☐	☐	X
Henderson	X	☐	☐	Union	☐	☐	X
Henry	X	☐	☐	Van Buren	☐	☐	☐
Hickman	☐	☐	☐	Warren	☐	☐	☐
Houston	☐	☐	☐	Washington	☐	☐	X
Humphreys	☐	☐	☐	Wayne	☐	☐	☐
Jackson	☐	☐	☐	Weakley	X	☐	☐
Jefferson	☐	☐	X	White	☐	☐	☐
Johnson	☐	☐	X	Williamson	☐	☐	☐
Knox	☐	☐	X	Wilson	☐	☐	☐
Lake	X	☐	☐				

12. INSERT COST PSF TABLE

Not applicable; this is a service project that does not include a proposed facility.

13. MRI, PET, and/or LINEAR ACCELERATOR

Describe the acquisition of any Magnetic Resonance Imaging (MRI) scanner that is adding an MRI scanner in counties with population less than 250,000, or is initiating pediatric MRI in counties with population greater than 250,000, and/or describe the acquisition of any Positron Emission Tomography (PET) unit or Linear Accelerator unit if initiating the service by responding to the following:

A. Complete the Chart below for acquired equipment. Not applicable.

LINEAR ACCELERATOR	
Mev:	Total Cost*: $
Types: (indicate one)	By Purchase? __
__ SRS	By Lease? __
__ IMRT	
__ IGRT	Expected Useful Life (yrs): __
__ Other :	New? __
	Refurbished? __
	If not new, how old (Yrs)? __

MRI	
Tesla:	Total Cost*: $
Magnet: (indicate one)	By Purchase? __
__ Breast	By Lease? __
__ Extremity?	
__ Open?	Expected Useful Life (yrs): __
__ Short Bore?	New? __
__ Other -- _____	Refurbished? __
	If not new, how old (Yrs)? __

PET	
PET Only? __	Total Cost*: $
	By Purchase? __
PET/CT? __	By Lease? __
PET/MRI? __	Expected Useful Life (yrs): __
	New? __
	Refurbished? __
	If not new, how old (Yrs)? __

**As defined by Agency Rule 0720-9-.01(13)*

B. In the case of equipment purchase, include a quote and/or proposal from an equipment vendor. In the case of equipment lease, provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments along with the fair market value of the equipment.

Not applicable. No major medical equipment is proposed.

C. Compare the lease cost of the equipment to its fair market value. Note: Per Agency rule, the higher cost must be identified in the project cost chart.

Not applicable. No major medical equipment is proposed.

D. Schedule of Operations:

Location	Days of Operation (Sun-Sat)	Hours of Operation
Fixed Site (Applicant)		
Mobile Locations		
Applicant		
Name of other location		
Name of other location		

Not applicable to a home health service.

E. Identify the clinical applications to be provided, that apply to the project.

Not applicable; the project contains no major medical equipment.

F. If the equipment has been approved by the FDA within the past five years, provide documentation of the same.

Not applicable; the project contains no major medical equipment.

SECTION B: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with T.C.A. § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, will provide health care that meets appropriate quality standards, and will contribute to the orderly development of health care." Further standards for guidance are provided in the State Health Plan developed pursuant to T.C.A. § 68-11-1625.

The following questions are listed according to the four criteria: (1) Need, (2) Economic Feasibility, (3) Applicable Quality Standards, and (4) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. *Please type each question and its response on an 8 1/2" x 11" white paper, single-sided.* All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer, unless specified otherwise. ***If a question does not apply to your project, indicate "Not Applicable (NA)."***

NEED

1. Provide a response to each criterion and standard in Certificate of Need categories in the State Health Plan that are applicable to the proposed project. Criteria and standards can be obtained from the THSDA or found on the agency's website at http://tjn.gov/hsda/article/hsda-criteria-and-standards.

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA
FOR
HOME HEALTH SERVICES

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA
FOR
HOME HEALTH SERVICES

Standards and Criteria--State Health Plan

1. Determination of Need: In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county. This 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed Service Area.

2. The need for home health services should be projected three years from the latest available year of final JAR data.

3. The use rate of existing home health agencies in each county of the Service Area will be determined by examining the latest utilization rate as calculated from the JARs of existing home health agencies in the Service Area. Based on the number of patients served by home health agencies in the Service Area, an estimation will be made as to how many patients could be served in the future.

Following this page is a table of the TDOH need methodology, projecting home health agency needs by service area county to 2020, which is the 3-year planning horizon specified above. The table indicates a surplus capacity of 23,515 patients, based on the 1.5% criterion and the most recent (2015) JAR home health data.

This projected surplus is neither accurate nor relevant to this highly specialized project.

First, the projection methodology is stated as a "general guideline" and it uses a simple 1.5% "need" planning factor for each county's population. A one-size-fits-all methodology is not helpful to identify the needs of such a small and highly specialized group as immune-compromised patients who require IVIG therapy.

Second, the State Plan projection methodology may be unreliable. In 2015, there were 68,979 actual home health agency patients served in the area, which is an evidence-based indicator of need. That actual utilization was 79% greater than the 38,632 "patient need" projected by the State Plan formula for CY2018. This confirms that the agency's inquiry should not end with the projection methodology. The service area population is both aging and increasing. This suggests that more patients will need to be served in CY2018 than in CY2015 -- not fewer.

Joint Annual Report of Home Health Agencies - 2015 Final*
Comparison of Population Based Need Projection vs. Actual Utilization (2020 vs. 2015)**
Axelacare--East Tennessee

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2015 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Anderson	20	18	2,561	77,285	0.0331370900	79,061	2,620	1,186	(1,409)
Bledsoe	12	9	425	13,216	0.0321579903	13,481	434	202	(231)
Blount	19	18	3,029	131,578	0.0230205657	139,725	3,217	2,096	(1,119)
Bradley	17	17	2,501	104,477	0.0239382831	109,706	2,626	1,646	(981)
Campbell	22	20	1,725	41,357	0.0417099886	41,787	1,743	627	(1,117)
Carter	10	10	1,942	58,052	0.0334527665	58,375	1,953	876	(1,077)
Claiborne	22	19	1,801	33,546	0.0536874739	34,713	1,864	521	(1,342)
Cocke	16	14	1,272	36,775	0.0345887152	37,663	1,303	565	(738)
Cumberland	18	16	1,838	60,949	0.0301563602	65,575	1,978	984	(994)
Grainger	20	17	846	23,695	0.0357037350	24,577	877	369	(509)
Greene	18	16	2,289	71,945	0.0318159705	74,656	2,375	1,120	(1,257)
Hamblen	20	18	2,606	64,894	0.0401577958	67,028	2,692	1,005	(1,686)
Hamilton	17	16	8,287	352,955	0.0234789137	368,666	8,656	5,530	(3,126)
Hancock	11	10	643	6,930	0.0927849928	7,007	650	105	(545)
Hawkins	19	19	2,236	58,486	0.0382313716	59,784	2,286	897	(1,389)
Jefferson	18	17	1,583	55,028	0.0287671731	58,372	1,679	876	(804)
Johnson	7	6	787	18,716	0.0420495832	19,112	804	287	(517)
Knox	21	21	9,278	460,612	0.0201427666	488,993	9,850	7,335	(2,490)
Loudon	22	21	1,531	53,324	0.0287112745	57,923	1,663	869	(788)
McMinn	20	19	1,501	54,096	0.0277469684	55,724	1,546	836	(756)
Marion	18	16	678	28,554	0.0237444841	28,633	680	429	(251)
Meigs	19	19	371	12,151	0.0305324665	12,462	380	187	(195)
Monroe	19	17	1,203	47,421	0.0253685076	50,062	1,270	751	(528)
Morgan	20	15	526	23,168	0.0227037293	24,288	551	364	(187)
Polk	10	10	419	17,339	0.0241651768	17,812	430	267	(171)
Rhea	18	16	808	33,598	0.0240490505	35,216	847	528	(320)
Roane	23	20	2,060	55,411	0.0371767339	56,301	2,093	845	(1,229)
Scott	18	17	824	22,776	0.0361784334	23,224	840	348	(496)
Sequatchie	15	13	435	15,548	0.0279778750	16,943	474	254	(220)
Sevier	17	16	2,308	99,290	0.0232450398	108,468	2,521	1,627	(892)
Sullivan	14	14	5,685	158,679	0.0358270471	159,749	5,723	2,396	(3,327)
Unicoi	10	9	486	18,760	0.0259061834	19,150	496	287	(209)
Union	18	16	528	19,781	0.0266922805	20,320	542	305	(238)
Washington	16	14	3,967	132,015	0.0300496156	140,905	4,234	2,114	(2,121)
Need/Surplus			**68,979**	**2,462,407**		**2,575,461**	**71,897**	**38,632**	**(33,259)**

*Applicant's compilation of most recent year of final Joint Annual Report data for Home Health Agencies (2015)
Data is projected based on the year the Home Health data was **finalized**, not the actual year of Home Health data.

Population Data Source: The University of Tennessee Center for Business and Economic Research (UTCBER) Projection Data Files, reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment.

Note: Population data will not match the UTCBER data exactly due to rounding.

4. County Need Standard: The applicant should demonstrate that there is a need for home health services in each county in the proposed Service Area by providing documentation (e.g., letters) where: a) health care providers had difficulty or were unable successfully to refer a patient to a home care organization and/or were dissatisfied with the quality of services provided by existing home care organizations based on Medicare's system Home Health Compare and/or similar data; b) potential patients or providers in the proposed Service Area attempted to find appropriate home health services but were not able to secure such services; c) providers supply an estimate of the potential number of patients that they might refer to the applicant.

The applicant has submitted letters of support from area physicians and patients who cite the need for the project due to difficulty of finding home health providers in this service area that are able and willing to respond timely to their patients' needs with the level of service that AxelaCare proposes to provide.

Physicians are not willing to project their potential IVIG referrals to AxelaCare or to disclose their current referrals to specific providers. Nor is the applicant able to break down the number of cases by "service category" within the overall category of immune globulin therapy. As one can see from UnitedHealth's clinically complex IG Policy document in the Attachments, it would not be feasible for the applicant to project cases by the many disease types beyond the single category of immune globulin therapy. There is no publicly available source known to the applicant that provides such a breakdown.

What is known, however, is that almost all referrals come from specialists in neurology and allergy/immunology practices. The AxelaCare home health referrals that were being subcontracted to other agencies Statewide during the month of January consisted of 23 neurology referrals and 28 immunology/allergy referrals.

5. Current Service Area Utilization: The applicant should document by county: a) all existing providers of home health services within the proposed Service Area; and b) the number of patients served during the most recent 12-month period for which data are available. To characterize existing providers located within Tennessee, the applicant should use final data provided by the JARs maintained by the Tennessee Department of Health. In each county of the proposed Service Area, the applicant should identify home health agencies that have reported serving 5 or fewer patients for each of the last three years based on final and available JAR data. If an agency in the proposed Service Area who serves few or no patients is opposing the application, that opponent agency should provide evidence as to why it does not serve a larger number of patients.

The applicant submitted three years of JAR-reported patient data for every home health agency with authorization to provide home care to patients in any of the counties in the project service area. The applicant also provided the patients each agency served in CY2015 within this project's service area. The Tables are in the Attachments. None of the identified agencies that were operational in 2013-2015 reported serving fewer than six patients in each of those years.

6. Adequate Staffing: Using TDH Licensure data, the applicant should document a plan demonstrating the intent and ability to recruit, hire, train, assess competencies of, supervise, and retain the appropriate numbers of qualified personnel to provide the services

described in the application and document that such personnel are available to work in the proposed Service Area. The applicant should state the percentage of qualified personnel directly employed or employed through a third party staffing agency.

AxelaCare has extensive experience in recruiting, employing, training, assessing the competencies of, supervising and retaining skilled nursing staff to specifically manage IVIG care in the patients' homes.

AxelaCare is America's fourth largest provider of home infusion medications and services. It is a leader in research partnerships in this field of medicine. AxelaCare is accredited by the Joint Commission, and holds the Joint Commission's Gold Seal of Approval based on the recognized quality of its programs. AxelaCare's National Pharmacy Program (which supports this project by providing medications to the home health team) is accredited by URAC (originally named the Utilization Review Accreditation Program), a distinction that it earned with a 100% score on its accreditation surveys. Additional information on URAC is provided in the Attachments to the application.

AxelaCare is both a licensed pharmaceutical provider and a home health services provider. As a provider of medications, AxelaCare pharmacies prepare and ship home infusion pharmaceuticals to patients in 48 States. As a services provider in 17 States (through 33 branch offices) AxelaCare operates a full-scope program that integrates (a) the AxelaCare Pharmacy with (b) AxelaCare clinical teams of pharmacists and skilled home infusion nurses who manage the infusion of those medications in patients' homes, as directed by their physicians. AxelaCare nurses and pharmacists in all 17 states are available 24/7 for patient assistance and for consultation with referring physicians -- before, during and after the patient's infusion.

Based on the past experience and demonstrated quality, AxelaCare anticipates no problems in attracting superior staff for this project in urban areas and healthcare centers in this region. Implementation of this project will require development of only a small clinical staff. They will all be employed; none will be employed through a third-party staffing agency.

7. Community Linkage Plan: The applicant should provide a community linkage plan that demonstrates factors such as, but not limited to, referral arrangements with appropriate health care system providers/services (that comply with CMS patient choice protections) and working agreements with other related community services assuring continuity of care focusing on coordinated, integrated systems. A new provider may submit a proposed community linkage plan.

The applicant will be a new provider of nursing services for home infusion of Immune Globulin (IG) pharmaceuticals. For this type of patient, the primary community linkages will be referring specialty physicians, because they will make referral and treatment decisions for these special-needs patients. AxelaCare will regularly call on all area specialty physician groups who serve patients with potential needs for IVIG to keep them currently advised of AxelaCare's resources to optimize their patients' care. AxelaCare will meet monthly with all referring physicians to review and discuss their patient outcome data and to confer on future treatment options.

Secondary community linkages will be to area hospitals' discharge planners and medical staff. AxelaCare representatives will be in regular communication with those groups at most service area hospitals to ensure their awareness of AxelaCare treatment options.

8. TennCare Managed Care Organizations (MCOs) and Financial Viability: Given the time frame required to obtain Medicare certification, an applicant proposing to contract with the Bureau of TennCare's MCOs should provide evidence of financial viability during the time period necessary to receive such certification. Applicants should be aware that MCOs are under no obligation to contract with home care organizations, even if Medicare certification is obtained, and that Private Duty Services are not Medicare certifiable services. Applicants who believe there is a need to serve TennCare patients should contact the TennCare MCOs in the region of the proposed Service Area and inquire whether their panels are open for home health services, as advised in the notice posted on the HSDA website, to determine whether at any given point there is a need for a provider in a particular area of the state; letters from the TennCare MCOs should be provided to document such need. See Note 2 for additional information.

Not applicable. The applicant will not be able to serve TennCare patients because the applicant will not have a Medicare provider number, which is a condition of contracting with the MCO's .

Applicants should also provide information on projected revenue sources, including non-TennCare revenue sources.

As stated in the application, the applicant's gross revenues will be 98% from multiple commercial insurors because the applicant will not be serving Medicare and TennCare patients. s

9. Proposed Charges: The applicant's proposed charges should be reasonable in comparison with those of other similar agencies in the Service Area or in adjoining service areas. The applicant should list:

a. The average charge per visit and/or episode of care by service category, if available in the JAR data.

b. The average charge per patient based upon the projected number of visits and/or episodes of *care* and/or hours per patient, if available in the JAR data.

Table B-1-9 on the next page provides 2015 JAR data on charges per visit and charges per hour for all area agencies that reported those. Reporting is very sketchy in the HHA Joint Annual Reports. The data is for skilled nursing only, which is the only home health service proposed in this application. However, this JAR data does not allow a meaningful comparison to AxelaCare's very different pricing structure.

AxelaCare pays its infusion nurses between $37 and $45 per hour; an average is approximately $40 per hour. However, AxelaCare projects Year One (2018) average expected nursing revenues of $240 per visit, which is much higher than general home health agencies who are not providing infusion care.

The only comparable specialty infusion-specific charge data identified by the applicant in publicly available sources was CN1406-018, approved in 2014 for Coram/CVS Specialty Infusion Services to do specialty home infusion care. In that document, Coram projected average charges for its "specialty infusion patient" at $290-$348 (see page 87 of Coram's CON application). In comparison, the average expected revenue per visit projected by AxelaCare for this project in 2017 is $240 for the nursing component. This is consistent with the Coram projections. The Coram 2015 Joint Annual Report provides no data on average charges. It is Coram's first such report since becoming operational in late 2015.

Table B-1-9: Comparative 2015 Cost and Charge Data Reported by East Tennessee Agencies -- Skilled Nursing Only

Health Statistics ID	Agency County	License Number	Agencies (76)	Cost per Visit Medicare Cert	Avg Chg per Visit Pvt Duty Co	Avg Chg per Hour
01032	Anderson	1	Clinch River Home Health	$166.00		
01042	Anderson	620	Professional Case Management of Tennessee			$60.00
01052	Anderson	148	The Home Option by Hardin Health Care		$1,080.00	
05012	Blount	213	Blount Memorial Hospital Home Health Services	$9.00		
06043	Bradley	13	Family Home Care - Cleveland	$56.00		
06063	Bradley	14	Home Health Care of East Tennessee, Inc.	$115.00		$33.00
07032	Campbell	16	Sunbelt Homecare	$86.00		
10031	Carter	23	Amedisys Home Health Care	$41.00		
13022	Claiborne	25	Amedisys Home Health of Tennessee	$45.00		
13032	Claiborne	93	Suncrest Home Health and Hospice	$75.00		$96.00
14024	Clay	135	Cumberland River Homecare	$75.00		$45.00
15032	Cocke	27	Smoky Mountain Home Health and Hospice	$245.00		
16034	Coffee	29	Suncrest Home Health	$81.00		$73.00
19494	Davidson	42	Elk Valley Health Services		$79.00	$35.00
19544	Davidson	56	Home Care Solutions, Inc.	$90.00		
19654	Davidson	471	Optum Women's and Children's Health, LLC			
19724	Davidson	295	Careall	$98.00		$31.00
19734	Davidson	624	Corum CVS Specialty Infusion Services			
25034	Fentress	80	Quality Private Duty Care			$36.00
25044	Fentress	287	Quality Home Health	$94.00		$50.00
26024	Franklin	83	Encompass Home Health of Tennessee	$104.00		
26054	Franklin	82	Amedisys Home Care	$61.00		
30021	Greene	86	Advanced Home Care, Inc.	$127.00		
30041	Greene	88	Laughlin Home Health Agency	$214.00		
30051	Greene	87	Procare Home Health Services	$163.00		
32102	Hamblen	91	Amedisys Home Health Care	$45.00		
32122	Hamblen	153	Univ. of TN Med Cntr Home Health / Hospice Service	$104.00		
32132	Hamblen	10	Premier Support Services, Inc.	$79.00		$33.00
33033	Hamilton	111	NHC Homecare	$155.00		
33083	Hamilton	115	Guardian Home Care, LLC	$64.00		
33093	Hamilton	100	Gentiva Health Services	$93.00		
33103	Hamilton	113	Amedisys Home Health	$41.00		
33213	Hamilton	98	Continuecare Healthservices, Inc. I	$199.00		
33253	Hamilton	103	CHI Memorial Health at Home	$46.00		
33303	Hamilton	109	Tennessee Home Health	$130.00		
33363	Hamilton	338	Home Care Solutions	$97.00		
33383	Hamilton	108	Continuecare Healthservices, Inc. II	$199.00		
33423	Hamilton	457	Alere Women's and Children's Health, LLC			
33433	Hamilton	613	Maxim Healthcare Services	$30.00	$90.00	$34.00
34011	Hancock	117	Hancock County Home Health and Hospice Agency	$85.00		$32.00
37021	Hawkins	320	Hometown Home Health, Inc.	$117.00		
46031	Johnson	130	Johnson County Home Health.	$145.00		
47012	Knox	143	NHC Homecare	$110.00		
47042	Knox	142	Gentiva Health Services	$42.00		
47062	Knox	144	Camellia Home Health of East Tennessee	$135.00	$160.00	$24.00
47092	Knox	151	Tennova Healthcare Home Health	$142.00		
47132	Knox	156	UTMCK - Home Care Services: Hospice & Home Care	$107.00		
47182	Knox	149	Gentiva Health Services 2 (Girling Health Services)	$86.00		
47202	Knox	150	Amedisys Home Health Care	$45.00		

Table B-1-9: Comparative 2015 Cost and Charge Data Reported by East Tennessee Agencies -- Skilled Nursing Only

Health Statistics ID	Agency County	License Number	Agencies (76)	Cost per Visit Medicare Cert	Avg Chg per Visit Pvt Duty Co	Avg Chg per Hour
47222	Knox	132	East Tennessee Children's Hospital Home Health		$217.00	
47232	Knox	131	Careall Home Care Services			
47402	Knox	133	Covenant Homecare	$125.00		
47432	Knox	2	Maxim Healthcare Services, Inc.	$30.00	$67.00	$38.00
52024	Lincoln	161	Deaconess Homecare	$143.00		
54043	McMinn	166	NHC Homecare	$119.00		
62052	Monroe	190	Intrepid USA Healthcare Services	$165.00		
62062	Monroe	189	Sweetwater Hospital Home Health	$161.00		
67024	Overton	191	Amedisys Home Health	$41.00		
71014	Putnam	197	Highland Rim Home Health Agency	$135.00	$40.00	$40.00
71084	Putnam	198	Intrepid USA Healthcare Services	$165.00		
75024	Rutherford	208	NHC Homecare	$100.00		
75064	Rutherford	5	Amedisys Home Health Care	$51.00		
76032	Scott	211	Deaconess Homecare	$133.00		
82051	Sullivan	249	Advanced Home Care, Inc.	$116.00		
82061	Sullivan	251	Gentiva Health Services	$138.00		
89064	Warren	263	Intrepid USA Healthcare Services	$108.00		
89074	Warren	265	Careall Home Care Services	$110.00		
90081	Washington	269	Medical Center Homecare - Kingsport	$145.00		
90091	Washington	271	Medical Center Homecare Services	$145.00		
90121	Washington	273	Amedisys Home Health	$49.00		
90131	Washington	267	NHC Homecare	$128.00		
95034	Wilson	282	Deaconess Homecare I	$140.00		
96030	London Co, KY	298	Professional Home Health Care Agency	$92.00		
	Knox	633	Implanted Pump Management			
	Washington	629	Maxim Healthcare Services			
	Davidson	632	Pentec Health			
Average of Agencies Reporting Costs & Charges				**$105.94**	**$288.83**	**$44.00**

Note: Hemophilia Preferred Care of West Tennessee Not Yet Licensed and Operating as of -------.
Source: Joint Annual Reports of Home Health Agencies

10. Access: In concert with the factors set forth in HSDA Rule 0720-11-.01(1) (which lists those factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant that is able to show that there is limited access in the proposed Service Area for groups with special medical needs such as, but not limited to, medically fragile children, newborns and their mothers, and HIV/AIDS patients. Pediatrics is a special medical needs population, and therefore any provider applying to provide these services should demonstrate documentation of adequately trained staff specific to this population's needs with a plan to provide ongoing best practice education. For purposes of this Standard, an applicant should document need using population, service, special needs, and/or disease incidence rates. If granted, the Certificate of Need should be restricted on condition, and thus in its licensure, to serving the special group or groups identified in the application. The restricting language should be as follows; CONDITION: Home health agency services are limited to (identified specialty service group); the expansion of service beyond (identified specialty service group) will require the filing of a new Certificate of Need application. Please see Note 3 regarding federal law prohibitions on discrimination in the provision of health care services.

The applicant will serve a very small specialty patient population -- those whose physicians prescribe immune globulin infusions (IVIG). It is not clear that this criterion of the State Health Plan encompasses an IVIG patient. Regardless, the applicant requests that its CON be limited to home infusion of immune globulin pharmaceuticals consistent with the wording in this criterion.

11. Quality Control and Monitoring: The applicant should identify and document its existing or proposed plan for data reporting (including data on patient re-admission to hospitals), quality improvement, and an outcome and process monitoring system (including continuum of care and transitions of care from acute care facilities). If applicable, the applicant should provide documentation that it is, or that it intends to be, fully accredited by the Joint Commission, the Community Health Accreditation Program, Inc., the Accreditation Commission for Health Care, and/or other accrediting body with deeming authority for home health services from CMS.

The applicant has submitted documentation of its accreditation by the Joint Commission, including its Gold Seal award. Examples of AxelaCare's highly articulated Quality Improvement program were submitted as Attachments to the application.

12. Data Requirements: Applicants should agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

The applicant so agrees.

(END OF SERVICE-SPECIFIC STATE HEALTH PLAN CRITERIA)

(NEED Section of the application, continued)

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any, and how it relates to previously approved projects of the applicant.

In 2016, AxelaCare Health Solutions requested CON approval to establish a home health agency to serve 21 West Tennessee counties. Its scope of service was to be limited to the home infusion of specialized immune globulin pharmaceuticals, and nursing services necessary for that specific type of infusion therapy.

The CON Board unanimously approved the application.

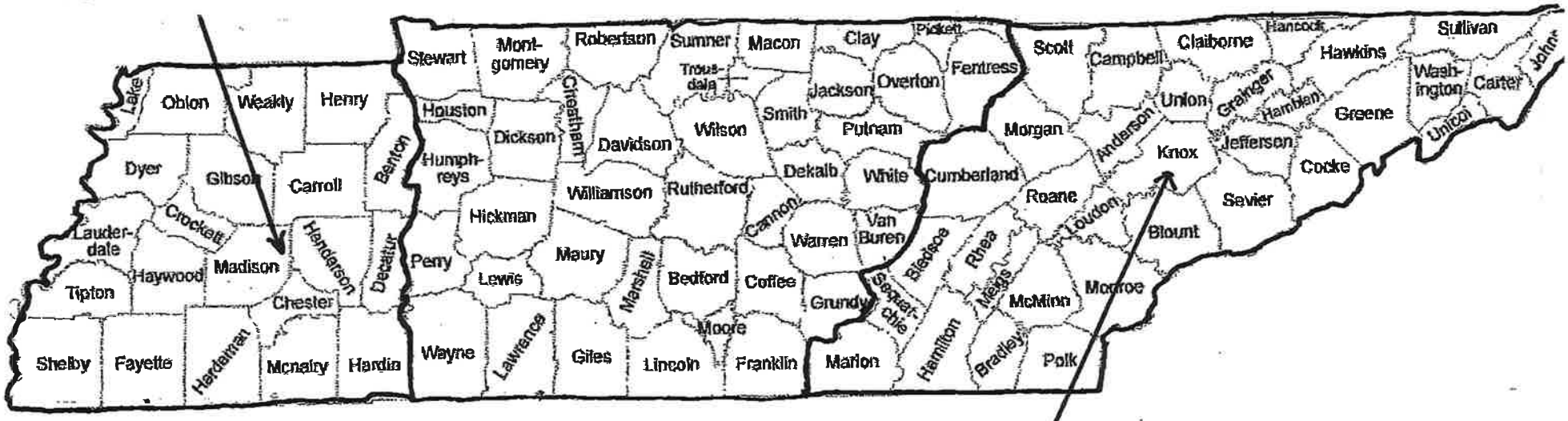
That approved application stated that in two subsequent applications, AxelaCare would propose extending this limited home health service to all other Tennessee counties. This present application is to expand AxelaCare's authorized service area to cover 34 East Tennessee counties; and a companion application has been filed simultaneously, to cover 40 counties of Middle Tennessee. If both are approved, AxelaCare's specialized home health nurses will be able to meet patient needs for immune globulin infusions in all 95 Tennessee counties.

3. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map for the Tennessee portion of the service area, using the map on the following page, clearly marked to reflect the service area as it relates to meeting the requirements for CON criteria and standards that may apply to the project. Please include a discussion of the inclusion of counties in the bordering states, if applicable.

The proposed service area consists of 34 East Tennessee counties. They are Anderson, Bledsoe, Blount, Bradley, Campbell, Carter, Claiborne, Cocke, Cumberland, Grainger, Greene, Hamblen, Hamilton, Hancock, Hawkins, Jefferson, Johnson, Knox, Loudon, McMinn, Marion, Meigs, Monroe, Morgan, Polk, Rhea, Roane, Scott, Sequatchie, Sevier, Sullivan, Unicoi, Union, and Washington Counties.

AXELACARE HEALTH SOLUTIONS

CURRENT SERVICE AREA



Printable Maps From:
terproof Paper.com

PROPOSED EAST TENNESSEE EXPANSION

3. (Continued) Please complete the following tables, if applicable:

Service Area Counties	Historical Utilization by County Residents	% of Total Procedures
Totals		

This data for all service area counties can be found in the Miscellaneous Attachment section of the application, in Department of Health report #6 for 2015. It shows each service area county's use of home health providers during that JAR reporting year.

The following page provides the applicant's patient origin projection by service area county. The projection is based on each county's proportional share of the total service area population. Patient projections are made to one decimal place. When patient numbers this small (25-35 patients) are distributed over such a large 34-county service area, many counties will generate a patient referral only once in a period of years. They will not show as generating any patients in the first two projection years.

It is logical that the most populous counties, in which referring specialists are most numerous and accessible, will be the referral source for most AxelaCare patients initially. As AxelaCare's full-service program becomes more widely known over time, AxelaCare expects to see more referrals from rural counties with smaller populations.

Table B-3: Projected Home Health Patient Origin AxelaCare East Tennessee				
Primary Service Area Counties	**Projected Target* Population Age 0-64 2017**	**Percent of Total Service Area Population 2017**	**Projected AxelaCare Patients Year One (2018)**	**Projected AxelaCare Patients Year Two (2019)**
Knox	399,206	19.99%	5.0	7.0
Hamilton	296,161	14.83%	3.7	5.2
Sullivan	123,719	6.19%	1.5	2.2
Washington	110,439	5.53%	1.4	1.9
Blount	107,558	5.39%	1.3	1.9
Bradley	88,142	4.41%	1.1	1.5
Sevier	82,676	4.14%	1.0	1.4
Anderson	61,965	3.10%	0.8	1.1
Greene	56,925	2.85%	0.7	1.0
Hamblen	53,256	2.67%	0.7	0.9
Hawkins	46,465	2.33%	0.6	0.8
Carter	45,721	2.29%	0.6	0.8
Jefferson	44,532	2.23%	0.6	0.8
McMinn	43,343	2.17%	0.5	0.8
Roane	42,745	2.14%	0.5	0.7
Cumberland	42,156	2.11%	0.5	0.7
Loudon	39,384	1.97%	0.5	0.7
Monroe	37,622	1.88%	0.5	0.7
Campbell	32,657	1.64%	0.4	0.6
Cocke	29,057	1.45%	0.4	0.5
Rhea	27,434	1.37%	0.3	0.5
Claiborne	26,992	1.35%	0.3	0.5
Morgan	19,507	0.98%	0.2	0.3
Scott	19,074	0.95%	0.2	0.3
Grainger	18,941	0.95%	0.2	0.3
Union	16,295	0.82%	0.2	0.3
Johnson	14,712	0.74%	0.2	0.3
Unicoi	14,279	0.71%	0.2	0.3
Polk	13,750	0.69%	0.2	0.2
Sequatchie	12,754	0.64%	0.2	0.2
Bledsoe	10,624	0.53%	0.1	0.2
Meigs	9,489	0.48%	0.1	0.2
Hancock	5,435	0.27%	0.1	0.1
Van Buren	4,280	0.21%	0.1	0.1
Total	**1,997,295**	**100.00%**	**25.0**	**35.0**

Source: TDOH Population Projections, 2016

4A(1). Describe the demographics of the population to be served by the proposal.

This proposed addition covers approximately 36% of the counties in Tennessee, stretching from Middle Tennessee eastward to the State boundaries. It also contains approximately 36% of the State's total population. Between now and CY2018, the service area's total population is projected to increase more slowly than the Statewide population; and its non-elderly (age 0-64) population is projected to increase slowly at half the growth rate of the State population. The target population (adults < 65 years of age) for this project is projected to be approximately 80% of the total population by CY2018.

The service area's median age of 41.8 years is older than the Statewide median age of 38 years. The area has an average median household income approximately 15% below the State's. It has a slightly higher rate of residents living in poverty and a slightly lower percentage of its residents enrolled in TennCare.

A(2). Using current and projected population data from the Department of Health, the most recent enrollee data from the Bureau of TennCare, and demographic information from the U.S. Census Bureau, complete the following table and include data for each county in your proposed service area.

Projected Population Data:

http://www.tn.gov/health/article/statistics-population

TennCare Enrollment Data:

http://www.tn.gov/tenncare/topic/enrollment-data

Census Bureau Fact Finder:

http://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml

Please see the table on the following page.

Table B-Need-4A(2): AxelaCare East Tennessee
Demographic Characteristics of Primary Service Area
2017-2018

	Department of Health / Health Statistics							Bureau of the Census				TennCare	
Primary Service Area Counties	Current Total Population 2017	Projected Total Population 2018	Total Population % Change 2017 - 2018	Current Target* Population Age 0-64 2017	Projected Target* Population Age 0-64 2018	Projected Target* Population 0-64 % Change 2017 - 2018	Projected Target* Population 0-64 As % of Projected Total Population 2018	Median Age	Median Household Income	Persons Below Poverty Level	Persons Below Poverty Level as % of Total Population	Current TennCare Enrollees	TennCare Enrollees as % of Total County or Zip Code Population
Anderson	78,026	78,387	0.5%	61,965	61,854	-0.2%	78.9%	42.6	$42,880	13,967	17.9%	17,328	22.2%
Bledsoe	13,333	13,394	0.5%	10,624	10,595	-0.3%	79.1%	42.3	$37,013	2,893	21.7%	3,460	26.0%
Blount	134,882	136,505	1.2%	107,558	108,041	0.4%	79.1%	41.4	$48,286	19,018	14.1%	24,054	17.8%
Bradley	106,600	107,651	1.0%	88,142	88,578	0.5%	82.3%	38.2	$42,114	20,894	19.6%	23,794	22.3%
Campbell	41,559	41,654	0.2%	32,657	32,487	-0.5%	78.0%	41.7	$32,028	9,642	23.2%	13,795	33.2%
Carter	58,213	58,274	0.1%	45,721	45,444	-0.6%	78.0%	42.2	$33,213	13,738	23.6%	13,382	23.0%
Claiborne	34,038	34,263	0.7%	26,992	26,942	-0.2%	78.6%	41.1	$34,899	7,454	21.9%	9,788	28.8%
Cocke	37,163	37,335	0.5%	29,057	28,967	-0.3%	77.6%	42.9	$31,187	9,700	26.1%	12,057	32.4%
Cumberland	62,847	63,778	1.5%	42,156	42,268	0.3%	66.3%	48.3	$38,576	10,370	16.5%	13,495	21.5%
Grainger	24,073	24,244	0.7%	18,941	18,904	-0.2%	78.0%	42.1	$35,391	4,959	20.6%	6,409	26.6%
Greene	73,075	73,620	0.7%	56,925	56,970	0.1%	77.4%	42.6	$35,196	14,980	20.5%	16,477	22.5%
Hamblen	65,774	66,195	0.6%	53,256	53,340	0.2%	80.6%	39.6	$37,617	14,010	21.3%	17,162	26.1%
Hamilton	359,331	362,471	0.9%	296,161	297,270	0.4%	82.0%	39.3	$48,248	57,493	16.0%	72,087	20.1%
Hancock	6,970	6,981	0.2%	5,435	5,403	-0.6%	77.4%	42.9	$26,898	1,931	27.7%	2,435	34.9%
Hawkins	59,043	59,311	0.5%	46,465	46,308	-0.3%	78.1%	42.1	$36,927	11,277	19.1%	14,511	24.6%
Jefferson	56,406	57,073	1.2%	44,532	44,714	0.4%	78.3%	40.8	$42,417	9,307	16.5%	13,343	23.7%
Johnson	18,876	18,952	0.4%	14,712	14,673	-0.3%	77.4%	43.3	$30,763	4,832	25.6%	4,711	25.0%
Knox	472,075	477,780	1.2%	399,206	402,294	0.8%	84.2%	37.2	$48,701	75,532	16.0%	82,509	17.5%
Loudon	55,192	56,118	1.7%	39,384	39,614	0.6%	70.6%	46.0	$51,107	7,948	14.4%	9,834	17.8%
McMinn	54,783	55,100	0.6%	43,343	43,306	-0.1%	78.6%	41.6	$38,535	10,902	19.9%	13,181	24.1%
Marion	28,610	28,627	0.1%	22,657	22,457	-0.9%	78.4%	42.3	$41,348	5,493	19.2%	7,590	26.5%
Meigs	12,285	12,345	0.5%	9,489	9,438	-0.5%	76.5%	42.9	$34,424	2,555	20.8%	3,360	27.4%
Monroe	48,511	49,048	1.1%	37,622	37,658	0.1%	76.8%	41.6	$35,291	9,363	19.3%	12,430	25.6%
Morgan	23,626	23,848	0.9%	19,507	19,581	0.4%	82.1%	39.8	$39,049	5,363	22.7%	4,994	21.1%
Polk	17,538	17,627	0.5%	13,750	13,745	0.0%	78.0%	42.5	$38,925	3,315	18.9%	4,433	25.3%
Rhea	34,262	34,582	0.9%	27,434	27,523	0.3%	79.6%	39.8	$36,146	8,394	24.5%	9,681	28.3%
Roane	55,813	55,990	0.3%	42,745	42,485	-0.6%	75.9%	44.9	$40,854	10,270	18.4%	12,372	22.2%
Scott	22,976	23,058	0.4%	19,074	19,030	-0.2%	82.5%	38.1	$30,246	6,272	27.3%	8,333	36.3%
Sequatchie	16,125	16,399	1.7%	12,754	12,863	0.9%	78.4%	40.6	$45,408	2,628	16.3%	4,210	26.1%
Sevier	102,998	104,829	1.8%	82,676	83,593	1.1%	79.7%	40.9	$42,258	15,759	15.3%	22,227	21.6%
Sullivan	159,191	159,393	0.1%	123,719	123,103	-0.5%	77.2%	43.6	$40,346	27,858	17.5%	35,922	22.6%
Unicoi	18,921	19,003	0.4%	14,279	14,212	-0.5%	74.8%	44.9	$33,319	4,257	22.5%	4,322	22.8%
Union	20,020	20,124	0.5%	16,295	16,259	-0.2%	80.8%	40. 1	$37,351	4,304	21.5%	5,528	27.6%
Washington	135,611	137,400	1.3%	110,439	111,294	0.8%	81.0%	39.3	$42,817	24,546	18.1%	25,909	19.1%
Service Area Total	2,508,746	2,531,359	0.9%	2,015,672	2,021,213	0.3%	79.8%	41.8	$38,523	505,070	20.1%	545,123	21.7%
State of TN Total	6,887,572	6,962,031	1.1%	5,754,547	5,786,888	0.6%	83.1%	38.0	$45,219	1,212,213	17.6%	1,559,209	22.6%

Sources: TDOH Population Projections, 2016; U.S. Census QuickFacts; TennCare Bureau.
Service area data is either total, or average, as appropriate.

** Target Population is population that the project will primarily serve. For example, nursing home, home health ageny, hospice agency projects typically primarily serve the Age 65+ population; projets for child and adolescent psychiatric services will serve the population Ages 0-19. Projected Year is defined in select service-specific criteria and standards. If Projected Year is not defined, default should be four years from Current Year, e.g., if Current Year is 2016, then default Projected Year is 2020. Here the State Health Plan defines a three year projection for this type of project (Home Health Need Calculation).*

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

The project meets the special needs of a very small, but very compromised, patient population that is well-known to the applicant through its long experience in many other States. The needs of this "niche" patient population have been discussed extensively in other sections of the application. The applicant's experience is that these patients seeking home infusion of immune globulin pharmaceuticals often experience difficulties in obtaining home nursing to administer first and subsequent medication doses in a timely way.

As a consequence, these immune-compromised patients are forced to remain in the hospital for more (expensive) days than necessary to begin infusions pending creation of a competent home nursing team. Or, they must begin traveling back and forth to a freestanding or practice-based infusion center. This second "commuting" option involves burdensome drive times and additional risks of exposure to opportunistic infections.

Rural residents in particular appear to need an additional provider of immune globulin home infusion services.

The project will not serve Medicare or Medicaid/TennCare patients due to restrictive Federal rules. Medicare patients must meet strict Federal guidelines -- "Conditions of Participation" -- to qualify for home infusion nursing. The most difficult of these conditions is meeting the definitions and criteria of "homebound". The few Medicare enrollees who meet that and other Federal criteria can receive home nursing -- but only from a Medicare-certified home health agency. AxelaCare is not such an agency. And, for that same reason, it cannot serve Tennessee Medicaid patients of any age. However, the applicant will serve all other types of insured patients, regardless of their age, gender, race, ethnicity or income. And, based on its national experience, the applicant projects providing charity care of 2% of expected revenue receipts (before bad debt deductions).

These limitations do not prevent Medicare and TennCare enrollees from obtaining needed infusions from other types of providers, however. The applicant believes that most TennCare/Medicare patients needing IVIG therapy are being referred by their physicians to hospital outpatient infusion centers, to freestanding infusion centers or to physician practices that provide infusion suites in the practice office.

5. Describe the existing and approved but unimplemented services of similar healthcare providers in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. List each provider and its utilization and/or occupancy individually. Inpatient bed projects must provide the following data: admissions or discharges, patient days, average length of stay, and occupancy. Other projects should use the appropriate measures, e.g., cases, procedures, visits, admissions, etc. This does not apply to projects that are solely relocating a service.

Attachment Need-B-5 contains a series of tables that identify all the home health agencies currently authorized to serve this area, and provide utilization data from their final 2013-2015 Joint Annual Reports. *(Note: these are the same categories of statistics that were accepted for AxelaCare's approved West Tennessee CN#1606-022.)*

Tables

- Tables B.5-1A & 1B: Service area counties that are authorized for each approved agency.

- Tables B.5-2A & 2B: Patients served during 2015, in each agency's authorized counties within the project service area.

- Tables B.5-3A & 3B & 3C: Area agencies' patient utilization 2013-2015, with agencies' dependence on patients from the project service area.

- Tables B.5-4A &4B & 4C: Agencies' TennCare gross revenues (charges) as a percent of their total gross revenues, and a ranking by level of TennCare participation.

These tables show the following:

1. There are 76 agencies licensed to serve one or more counties in this project's 40-county service area--ranging from 15 agencies for Johnson County to 31 agencies for Roane County.

2. Only 5 of 74 surveyed providers (one of whom consists of 3 separately licensed agencies under common ownership) indicated an ability to infuse IG patients. Of the 5, only 1 is licensed to serve all 34 service area counties. But it has only 1 IVIG nurse for all of that territory. The remaining five agencies do not have complete geographic coverage of the service area. Their gaps in licensure coverage vary from 82% to 90% of the service area counties. This demonstrates a shortage of home care providers for a small subset of IG patients with serious needs.

3. The agencies served 68,979 home care patients in the project service area in 2015.

4. The applicant's projected 35 patients in CY2019 equates to only .05% (five-hundredths of one percent) of the patients served by all agencies in 2015. Therefore the project will have almost no measurable impact on existing agencies collectively.

5. The 76 agencies' 23.3% *average* TennCare utilization is misleading. Only 17 of the 76 agencies had a TennCare mix that high; while 36 agencies (47% of the total) served no TennCare patients at all.

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three years and the projected annual utilization for each of the two years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

The applicant has no historical utilization because it was approved in late 2016 for its first Tennessee service area (West Tennessee) and will not be licensed until February 2017.

At an average of 24 visits per patient, the applicant projects the following utilization in the East Tennessee operation and Statewide:

Table Need-B.6-A: Projected Patients and Visits for AxelaCare East Tennessee CY2018 - CY2019		
	Year One--CY2018	Year Two--CY2019
Patients	25	35
Visits	600	840

Table Need-B.6-B Projected Patients for AxelaCare Home Infusions By Region				
Projection Year	AxelaCare West Tennessee	AxelaCare Middle Tennessee	AxelaCare East Tennessee	AxelaCare Statewide
CY2018	20* patients 480 visits	25 patients 600 visits	25 patients 600 visits	70 patients 1,680 visits
CY2019	30 patients 720 visits	35 patients 840 visits	35 patients 840 visits	100 patients 2,400 visits

** Projection reduced from 45 patients in CN 1606-022.*

Patient Projection Methodology

New uses of immune globulin currently being explored and demonstrated (see articles included in the Attachments) make it reasonable to assume a steady increase in demand for these medications, from allergists, immunologists and neurologists.

As one of the country's leading provider of these medications, and a home health provider for their products' infusion in many States, AxelaCare anticipates rapid increases in its referrals once it can offer physicians its own quality-controlled home infusion services as well as AxelaCare pharmaceuticals and serve their patients no matter where in Tennessee they live. Comprehensive availability combined with demonstrated quality of service and product will drive increased patient referrals.

In 2016, AxelaCare records show that 37 Tennessee patients who were referred to AxelaCare were successfully placed with existing home health agencies to infuse AxelaCare immune globulin (IG) pharmaceuticals (Statewide). (There were a larger number of additional IG referrals that could not be accepted or placed).

In 2017, with a West Tennessee home health license for IG infusion, AxelaCare expects to serve at least 20 referrals through its West Tennessee nursing staff, with additional referrals being placed with contracted agencies in other regions.

In 2018, if both AxelaCare's companion CON applications for Middle and East Tennessee are approved and operational, AxelaCare anticipates a major increase in Statewide referrals due to reasons stated in the first two paragraphs of this subsection.

In 2018, AxelCare projects that at least 70 referrals will be accepted Statewide, almost twice the number accepted in 2016. In 2019, the projected Statewide number of accepted referrals is 100 patients, a 43% increase over 2018.

These percentages are realistic because they represent increases of a very small patient population. They assume Statewide incremental gains of only 2.5 to 3 patients per month -- in a State with a population of more than five million persons under the age of 65 (the AxelaCare target population).

In distributing the Statewide projection among the three proposed regions, AxelaCare is lowering the projection made in CN1606-022 for West Tennessee. The remainder of each year's Statewide projection is distributed equally between the proposed Middle Tennessee and East Tennessee service areas. Those two areas have similar target populations (<65 years of age). The applicant will devote equal marketing resources to the two regions, and will have equal development objectives. The applicant therefore did not differentiate between them in making utilization projections. They are larger than the West Tennessee projection because Middle and East Tennessee have a slightly larger target population.

Visit Projection Methodology

Visits were projected at an average of 24 per patient. The numbers of visits required to serve immune globulin infusion patients vary widely, depending on the medical direction as to dosage amount, rate of infusion, spacing of infusions (daily, alternating days, weekly, etc.) and duration of treatment.

ECONOMIC FEASIBILITY

1. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.

A. All projects should have a project cost of at least $15,000 (the minimum CON Filing Fee), (See application instructions for Filing Fee.)

B. The cost of any lease, The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.

C. The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.

D. Complete the Square Footage Chart on page 8 and provide the documentation. Please note the Total Construction Cost reported on line 5 of the Project Cost Chart should equal the Total Construction Cost reported on the Square Footage Chart.

Not applicable. The project will not require AxelaCare to establish another principal or branch office in the proposed service area. The project's principal office is already established pursuant to CN1606-022. It is in Suite 2700 on the 27th floor of the "Clark Tower" building at 5100 Poplar Avenue, Memphis, Shelby County, Tennessee 38137. The leased space consists of one 149-SF office in an Executive Suite on that floor. It requires no renovation or installation of patient care equipment. The pharmaceuticals, supplies and equipment needed for home infusion of immune globulin medications will be direct-shipped to the patients' homes, where AxelaCare registered nurses will administer and manage the infusion process under the direction of the patient's physician and the AxelaCare pharmacist at other locations.

E. For projects that include new construction, modification, and/or renovation documentation must be provided from a licensed architect or construction professional that support the estimated construction costs. Provide a letter that includes the following:

Not applicable. See response 1.D. immediately above.

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PROJECT COST CHART-- AXELACARE EAST TENNESSEE

A. Construction and equipment acquired by purchase:

1.	Architectural and Engineering Fees	$ 0
2.	Legal, Administrative, Consultant Fees (Excl CON Filing Fee)	50,000
3.	Acquisition of Site	0
4.	Preparation of Site	0
5.	Total Construction Cost	0
6.	Contingency Fund	0
7.	Fixed Equipment (Not included in Construction Contract)	0
8.	Moveable Equipment (List all equipment over $50,000 as separate attachment)	5,000
9.	Other (Specify) _____	0

B. Acquisition by gift, donation, or lease:

1.	Facility (inclusive of building and land)	0
2.	Building only	0
3.	Land only	0
4.	Equipment (Specify) _____	0
5.	Other (Specify) _____	0

C. Financing Costs and Fees:

1.	Interim Financing	0
2.	Underwriting Costs	0
3.	Reserve for One Year's Debt Service	0
4.	Other (Specify) _____	0

D. Estimated Project Cost (A+B+C) 55,000

E. CON Filing Fee 15,000

F. Total Estimated Project Cost (D+E) **TOTAL $** 70,000

Actual Capital Cost 70,000

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2. Identify the funding sources for this project.

Check the applicable item(s) below and briefly summarize how the project will be financed. (Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)

_____A. Commercial Loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;

_____B. Tax-Exempt Bonds--copy of preliminary resolution or a letter from the issuing authority, stating favorable contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;

_____C. General Obligation Bonds--Copy of resolution from issuing authority or minutes from the appropriate meeting;

_____D. Grants--Notification of Intent form for grant application or notice of grant award;

__x___E. Cash Reserves--Appropriate documentation from Chief Financial Officer; or

_____F. Other--Identify and document funding from all sources.

The project will be fully funded by a cash grant from the applicant's ultimate parent company, UnitedHealth Group. That funding will be transferred to the applicant's immediate parent company (BriovaRx Infusion Services) through the chain of wholly owned subsidiaries described in other parts of the application.

Documentation of the availability of the funding from Briova Rx is provided in Attachment B-Economic Feasibility-2. The funding assurance letter is from the Controller of Briova Rx (which was formerly named AxelaCare Holdings, Inc. at the time of Alexa's West Tennessee application approved last year). The Controller is authorized to make this commitment. The income statement and balance sheet for the Briova subsidiary, and also for the UnitedHealth Group Incorporated, are provided in the same Attachment.

3. Complete Historical Data Charts on the following pages—Do not modify the Charts provided or submit Chart substitutions!

Historical Data Chart represents revenue and expense information for the last three (3) years for which complete data is available. Provide a Chart for the total facility and Chart just for the services being presented in the proposed project, if applicable. Only complete one chart if it suffices.

Note that "Management Fees to Affiliates" should include management fees paid by agreement to the parent company, another subsidiary of the parent company, or a third party with common ownership as the applicant entity. "Management Fees to Non-Affiliates" should include any management fees paid by agreement to third party entities not having common ownership with the applicant.

Not applicable. The applicant has no historical operations in Tennessee. Its initial licensure has been requested. Receipt of licensure is expected in February 2017.

4. Complete Projected Data Charts on the following pages – *Do not modify the Charts provided or submit Chart substitutions!*

The Projected Data Chart requests information for the two years following the completion of the proposed services that apply to the project. Please complete two Projected Data Charts. One Projected Data Chart should reflect revenue and expense projections for the *Proposal Only* (*i.e.*, if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility). The second Chart should reflect information for the total facility. Only complete one chart if it suffices.

Note that "Management Fees to Affiliates" should include management fees paid by agreement to the parent company, another subsidiary of the parent company, or a third party with common ownership as the applicant entity. "Management Fees to Non-Affiliates" should include any management fees paid by agreement to third party entities not having common ownership with the applicant.

Following this page are four Projected Data Charts. Year One for the projections is CY2018.

The first three Charts pertain only to the proposed East Tennessee project: its nursing component only; its pharmaceutical component only; and its nursing and pharmaceutical components combined. These parallel what the HSDA reviewed in the approved West Tennessee application.

The fourth Chart covers the entire home health agency when it combines both its West and East Tennessee operations. This is needed because the application is an expansion of an existing (recently approved) home health agency.

O TOTAL FACILITY
X PROJECT ONLY

PROJECTED DATA CHART --AXELACARE EAST TENNESSEE (NURSING ONLY)

Give information for the last three (3) years for which complete data are available for the facility or agency. The fiscal year begins in January.

			Year 2018 (Year One)	Year 2019 (Year Two)
A.	Utilization Data	Patients	25	35
	(Specify unit or measure)	Visits	600	840
B.	Revenue from Services to Patients			
	1. Inpatient Services		$	$
	2. Outpatient Services		144,000	201,600
	3. Emergency Services			
	4. Other Operating Revenue			
	(Specify) See notes page			
		Gross Operating Revenue	$ 144,000	$ 201,600
C.	Deductions from Gross Operating Revenue			
	1. Contractual Adjustments		$	$
	2. Provision for Charity Care		2,880	4,032
	3. Provisions for Bad Debt		1,440	2,016
		Total Deductions	$ 4,320	$ 6,048
NET OPERATING REVENUE			$ 139,680	$ 195,552
D.	Operating Expenses			
	1. Salaries and Wages			
	a. Clinical		$ 369,840	$ 483,605
	b. Non-Clinical			
	2. Physicians Salaries and Wages			
	3. Supplies		6,984	9,778
	4. Rent			
	c. Paid to Affiliates			
	d. Paid to Non-Affiliates		12,000	12,000
	5. Management Fees			
	a. Paid to Affiliates			
	b. Paid to Non-Affiliates			
	6. Other Operating Expenses	See notes page	9,798	12,983
		Total Operating Expenses	$ 398,622	$ 518,365
E.	**Earnings Before Interest, Taxes, and Depreciation**		$ (258,942)	$ (322,813)
F.	Non-Operating Expenses			
	1. Taxes		$	$
	2. Depreciation			
	3. Interest			
	4. Other Non-Operating Expenses			
		Total Non-Operating Expenses	$ 0	$ 0
NET INCOME (LOSS)			$ (258,942)	$ (322,813)

Chart Continues Onto Next Page

	Year 2018	Year 2019
NET INCOME (LOSS)	$ (258,942)	$ (322,813)
G. Other Deductions		
1. Annual Principal Debt Repayment	$	$
2. Annual Capital Expenditure		
Total Other Deductions	$ 0	$ 0
NET BALANCE	$ (258,942)	$ (322,813)
DEPRECIATION	$	$
FREE CASH FLOW (Net Balance + Depreciation)	$ (258,942)	$ (322,813)

0 TOTAL FACILITY
X PROJECT ONLY

PROJECTED DATA CHART -- OTHER EXPENSES

OTHER EXPENSES CATEGORIES	Year 2018	Year 2019
1. Postage	$ 300	$ 300
2. RN Mileage	5,638	8,143
3. Phone	900	900
4. i-pad	960	1,440
5. Training	1,500	1,500
6. Nursing Supplies	500	700
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14		
15.		
Total Other Expenses	$ 9,798	$ 12,983

O TOTAL FACILITY
X PROJECT ONLY

PROJECTED DATA CHART --AXELACARE MIDDLE TENNESSEE (PHARMACEUTICALS ONLY)

information for the last three (3) years for which complete data are available for the facility or agency.
iscal year begins in January.

		Year 2018 (Year One)	Year 2019 (Year Two)
Utilization Data	Patients	25	35
(Specify unit or measure)	Visits	600	840
Revenue from Services to Patients			
1. Inpatient Services		$	$
2. Outpatient Services		2,400,000	3,360,000
3. Emergency Services			
4. Other Operating Revenue			
(Specify) See notes page			
	Gross Operating Revenue	$ 2,400,000	$ 3,360,000
Deductions from Gross Operating Revenue			
1. Contractual Adjustments		$	$
2. Provision for Charity Care		48,000	67,200
3. Provisions for Bad Debt		24,000	33,600
	Total Deductions	$ 72,000	$ 100,800
OPERATING REVENUE		$ 2,328,000	$ 3,259,200
Operating Expenses			
1. Salaries and Wages			
a. Clinical		$ 287,500	$ 296,125
b. Non-Clinical			
2. Physicians Salaries and Wages			
3. Supplies		1,396,800	1,955,520
4. Rent			
c. Paid to Affiliates			
d. Paid to Non-Affiliates			
5. Management Fees			
a. Paid to Affiliates			
b. Paid to Non-Affiliates			
6. Other Operating Expenses	See notes page	19,200	26,400
	Total Operating Expenses	$ 1,703,500	$ 2,278,045
Earnings Before Interest, Taxes, and Depreciation		$ 624,500	$ 981,155
Non-Operating Expenses			
1. Taxes		$ 120,000	$ 240,000
2. Depreciation		15,000	25,000
3. Interest			
4. Other Non-Operating Expenses			
	Total Non-Operating Expenses	$ 135,000	$ 265,000
NCOME (LOSS)		$ 489,500	$ 716,155

: *Continues Onto Next Page*

	Year 2018	Year 2019
NET INCOME (LOSS)	$ 489,500	$ 716,155
G. Other Deductions		
1. Annual Principal Debt Repayment	$	$
2. Annual Capital Expenditure	75,000	50,000
Total Other Deductions	$ 75,000	$ 50,000
NET BALANCE	$ 414,500	$ 666,155
DEPRECIATION	$ 15,000	$ 25,000
FREE CASH FLOW (Net Balance + Depreciation)	$ 429,500	$ 691,155

0 **TOTAL FACILITY**
X **PROJECT ONLY**

PROJECTED DATA CHART -- OTHER EXPENSES

OTHER EXPENSES CATEGORIES	Year 2018	Year 2019
1. Postage	$ 300	$ 300
2. Phone	900	$ 900
3. Pharma/Shipping	18,000	$ 25,200
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14		
15.		
Total Other Expenses	$ 19,200	$ 26,400

X TOTAL FACILITY
O PROJECT ONLY

PROJECTED DATA CHART --AXELACARE WEST AND EAST TENNESSEE (NURSING AND PHARMACEUTICALS COMBINED)

Give information for the last three (3) years for which complete data are available for the facility or agency. The fiscal year begins in January.

			Year 2018 (Year One)	Year 2019 (Year Two)
A.	Utilization Data	Patients	45	65
	(Specify unit or measure)	Visits	1,320	1,320
B.	Revenue from Services to Patients			
	1. Inpatient Services		$ 0	$ 0
	2. Outpatient Services		4,579,200	6,614,400
	3. Emergency Services		0	0
	4. Other Operating Revenue		0	0
	(Specify) See notes page			
		Gross Operating Revenue	$ 4,579,200	$ 6,614,400
C.	Deductions from Gross Operating Revenue			
	1. Contractual Adjustments		$ 0	$ 0
	2. Provision for Charity Care		91,584	132,288
	3. Provisions for Bad Debt		45,792	66,144
		Total Deductions	$ 137,376	$ 198,432
NET OPERATING REVENUE			$ 4,441,824	$ 6,415,968
D.	Operating Expenses			
	1. Salaries and Wages			
	a. Clinical		$ 1,375,004	$ 1,518,923
	b. Non-Clinical		0	$ 0
	2. Physicians Salaries and Wages		0	0
	3. Supplies		2,526,811	3,649,838
	4. Rent			
	c. Paid to Affiliates			
	d. Paid to Non-Affiliates		48,209	48,209
	5. Management Fees			
	a. Paid to Affiliates		0	0
	b. Paid to Non-Affiliates		0	0
	6. Other Operating Expenses	See notes page	87,781	98,166
		Total Operating Expenses	$ 4,037,805	$ 5,315,137
E.	**Earnings Before Interest, Taxes, and Depreciation**		$ 404,019	$ 1,100,831
F.	Non-Operating Expenses			
	1. Taxes		$ 132,000	$ 412,000
	2. Depreciation		22,500	30,000
	3. Interest		0	0
	4. Other Non-Operating Expenses		0	0
		Total Non-Operating Expenses	$ 154,500	$ 442,000
NET INCOME (LOSS)			$ 249,519	$ 658,831

Chart Continues Onto Next Page

	Year 2018	Year 2019
NET INCOME (LOSS)	$ 249,519	$ 658,831
G. Other Deductions		
1. Annual Principal Debt Repayment	$	$
2. Annual Capital Expenditure	325,000	75,000
Total Other Deductions	$ 325,000	$ 75,000
NET BALANCE	$ (75,481)	$ 583,831
DEPRECIATION	$ 22,500	$ 30,000
FREE CASH FLOW (Net Balance + Depreciation)	$ (52,981)	$ 613,831

X **TOTAL FACILITY**
O **PROJECT ONLY**

PROJECTED DATA CHART -- OTHER EXPENSES

OTHER EXPENSES CATEGORIES (examples below)	Year 2018	Year 2019
1. Postage	$ 600	$ 600
2. RN Mileage	13,781	16,286
3. Phone	1,800	1,800
4. i-pad	2,400	2,880
5. Training	1,500	1,500
6. Nursing Supplies	500	700
7.		
8. Postage	600	600
9. Phone	1,800	1,800
10. Pharma/Shipping	64,800	72,000
11.		
12.		
13.		
14		
15.		
Total Other Expenses	$ 87,781	$ 98,166

X TOTAL FACILITY
O PROJECT ONLY

PROJECTED DATA CHART --AXELACARE WEST AND EAST TENNESSEE (NURSING AND PHARMACEUTICALS COMBINED)

Give information for the last three (3) years for which complete data are available for the facility or agency. The fiscal year begins in January.

			Year 2018 (Year One)	Year 2019 (Year Two)
A.	Utilization Data	Patients	45	65
	(Specify unit or measure)	Visits	1,320	1,320
B.	Revenue from Services to Patients			
	1. Inpatient Services		$ 0	$ 0
	2. Outpatient Services		4,579,200	6,614,400
	3. Emergency Services		0	0
	4. Other Operating Revenue		0	0
	(Specify) See notes page			
		Gross Operating Revenue	$ 4,579,200	$ 6,614,400
C.	Deductions from Gross Operating Revenue			
	1. Contractual Adjustments		$ 0	$ 0
	2. Provision for Charity Care		91,584	132,288
	3. Provisions for Bad Debt		45,792	66,144
		Total Deductions	$ 137,376	$ 198,432
NET OPERATING REVENUE			$ 4,441,824	$ 6,415,968
D.	Operating Expenses			
	1. Salaries and Wages			
	a. Clinical		$ 1,375,004	$ 1,518,923
	b. Non-Clinical		0	$ 0
	2. Physicians Salaries and Wages		0	0
	3. Supplies		2,526,811	3,649,838
	4. Rent			
	c. Paid to Affiliates			
	d. Paid to Non-Affiliates		48,209	48,209
	5. Management Fees			
	a. Paid to Affiliates		0	0
	b. Paid to Non-Affiliates		0	0
	6. Other Operating Expenses	See notes page	87,781	98,166
		Total Operating Expenses	$ 4,037,805	$ 5,315,137
E.	**Earnings Before Interest, Taxes, and Depreciation**		$ 404,019	$ 1,100,831
F.	Non-Operating Expenses			
	1. Taxes		$ 132,000	$ 412,000
	2. Depreciation		22,500	30,000
	3. Interest		0	0
	4. Other Non-Operating Expenses		0	0
		Total Non-Operating Expenses	$ 154,500	$ 442,000
NET INCOME (LOSS)			$ 249,519	$ 658,831

Chart Continues Onto Next Page

	Year 2018	Year 2019
NET INCOME (LOSS)	$ 249,519	$ 658,831
G. Other Deductions		
1. Annual Principal Debt Repayment	$	$
2. Annual Capital Expenditure	325,000	75,000
Total Other Deductions	$ 325,000	$ 75,000
NET BALANCE	$ (75,481)	$ 583,831
DEPRECIATION	$ 22,500	$ 30,000
FREE CASH FLOW (Net Balance + Depreciation)	$ (52,981)	$ 613,831

X **TOTAL FACILITY**
0 **PROJECT ONLY**

PROJECTED DATA CHART -- OTHER EXPENSES

OTHER EXPENSES CATEGORIES (examples below)	Year 2018	Year 2019
1. Postage	$ 600	$ 600
2. RN Mileage	13,781	16,286
3. Phone	1,800	1,800
4. i-pad	2,400	2,880
5. Training	1,500	1,500
6. Nursing Supplies	500	700
7.		
8. Postage	600	600
9. Phone	1,800	1,800
10. Pharma/Shipping	64,800	72,000
11.		
12.		
13.		
14		
15.		
Total Other Expenses	$ 87,781	$ 98,166

5.A. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge using information from the Projected Data Chart for Year 1 and Year 2 of the proposed project. Please complete the following table.

West and East Tennessee Nursing Only (both alike)	Project Previous Year	Project Current Year	Project Year One	Project Year Two	% Change (Current Yr to Yr2)
Gross Charge -- Gross Operating Revenue / PATIENT	NA	NA	$5,760	$5,760	0%
Revenue / VISIT	NA	NA	$240	$240	0%
Deduction from Revenue --Total Deductions / PATIENT	NA	NA	$173	$173	0%
Deductions / VISIT	NA	NA	$7	$7	0%
Average Net Charge -- Net Operating Revenue / PATIENT	NA	NA	$5,587	$5,587	0%
Revenue / VISIT	NA	NA	$233	$233	0%

West & East Tennessee Nursing and Pharma Combined	Project Previous Year	Project Current Year	Project Year One	Project Year Two	% Change (Current Yr to Yr2)
Gross Charge -- Gross Operating Revenue / PATIENT	NA	NA	$101,760	$101,760	0%
Revenue / VISIT			$3,469	$3,469	0%
Deduction from Revenue --Total Deductions / PATIENT	NA	NA	$3,053	$3,053	0%
Deductions / VISIT			$104	$104	0%
Average Net Charge -- Net Operating Revenue / PATIENT	NA	NA	$98,707	$98,707	0%
Revenue / VISIT			$150	$150	0%

B. Provide the proposed charges for the project and discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the project and the impact on existing patient charges.

AxelaCare negotiates a separate pricing structure with every insurer. Negotiated rates vary. They are proprietary and confidential. The insurers are billed only the negotiated amount. AxelaCare does not record or bill a "gross charge" that is discounted by "contractual adjustments" to yield "net revenue". The revenue figures shown in Section B of the Projected Data Charts are the billed or "expected" revenues -- i.e., the projected receipts based on pre-negotiated reimbursement contracts, before deductions for charity and bad debt.

The table below (repeated from a prior section of the application) shows the average expected (comparable to gross) charge/revenue data per patient and per visit for AxelaCare's nursing services (home office and field staff) in West Tennessee.

Table Three (Repeated): AxelaCare Healthcare Solutions, Middle Tennessee Nursing and Home Office Staff (Excluding Pharmaceuticals)

	Year One CY2018	Year Two CY2019
Expected (Gross) Nursing Revenue	$144,000	$201,600
Visits	600	840
Expected (Gross) Average Revenue/Visit	$240	$240
Patients	25	35
Expected (Gross) Average Revenue/Patient	$5,760	$5,760

C. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Although the applicant will not participate in Medicare for nursing services, Medicare pays for a 60-day episode of care at rates that vary by region and State. The approximate reimbursement for more than four visits is estimated by AxelaCare at $2400.

The only specialty infusion-specific charge data identified by the applicant in recently approved CON projects are in CN1406-018, approved for Coram/CVS Specialty Infusion Services two years ago, in June 2014. Coram projected average charges for its Middle Tennessee "specialty infusion patient" at $290-$348 (see page 87 of Coram CON application). In comparison, the average expected revenue per visit projected by AxelaCare for this project in 2017 is $240 for the nursing component. This is consistent with the Coram projections.

6.A. Discuss how projected utilization rates will be sufficient to support the financial performance. Indicate when the project's financial breakeven is expected and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Cost-effectiveness is demonstrated by the positive operating margin of the Projected Data Chart for the consolidated Nursing and Pharmaceutical components of the project. The Pharmaceutical operations attributable to the project will absorb losses projected by the Nursing operations of the project. The project will attain break-even during its first operational year.

Please see the Projected Data Chart for documentation of positive cash flow in the first and second years of operation.

Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For all projects, provide financial information for the corporation, partnership, or principal parties that will be a source of funding for the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility. NOTE: Publicly held entities only need to reference their SEC filings.

See Attachment Section B-Economic Feasibility-6A.

B. Net Operating Margin Ratio – Demonstrates how much revenue is left over after all the variable or operating costs have been paid. The formula for this ratio is: (Earnings before interest, Taxes, and Depreciation/Net Operating Revenue).

Utilizing information from the Historical and Projected Data Charts please report the net operating margin ratio trends in the following table:

AxelaCare East Tennessee Only (Nursing + Pharmacy)					
	2nd Yr Previous to Current Yr	1st Yr Previous to Current Yr	Current Yr	Projected Yr 1	Projected Yr 2
Net Operating Margin Ratio	NA	NA	NA	14.1%	19.1%

AxelaCare West and East Tennessee Combined (Nursing + Pharmacy)					
	2nd Yr Previous to Current Yr	1st Yr Previous to Current Yr	Current Yr	Projected Yr 1	Projected Yr 2
Net Operating Margin Ratio	NA	NA	NA	9.1%	10.2%

C. Capitalization Ratio (Long-term debt to capitalization) – Measures the proportion of debt financing in a business's permanent (Long-term) financing mix. This ratio best measures a business's true capital structure because it is not affected by short-term financing decisions. The formula for this ratio is: (Long-term debt/(Long-term debt/Total Equity (Net assets)) x 100).

For the entity (applicant and/or parent company) that is funding the proposed project please provide the capitalization ratio using the most recent year available from the funding entity's audited balance sheet, if applicable. The Capitalization Ratios are not expected from outside the company lenders that provide funding.

The most current published capitalization ratio for United HealthGroup Incorporated, which is funding the project, is 40.96. The calculation, made from its Q3 2016 quarterly 10Q report, is:

Long term debt = 26,022 (in millions)

Equity = 37,544 (in millions)

Capitalization Ratio is (26,022 MM / 63,516 MM) X 100 = 40.96

7. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid and medically indigent patients will be served by the project. Additionally, report the estimated gross operating revenue dollar amount and percentage of projected gross operating revenue anticipated by payor classification for the first year of the project by completing the table below.

Applicant's Projected Payor Mix, Year 1		
Payor Source	**Projected Gross (Expected) Operating Revenue**	**As a Percent of Total Revenue**
Medicare/Medicare Managed Care	0	0%
TennCare/Medicaid	0	0%
Commercial/Other Managed Care	$2,493,120	98%
Self-Pay	0	0%
Charity Care	$50,880	2%
Other	0	0%
Total	$2,544,000	100%

The anticipated payor mix for home care nursing services is 98% commercial (including Blue Cross and Medicare replacement plans), and 2% charity.

Year One expected revenue will be $. Commercial payor expected revenue, at 98%, will be $2,493,120. Charity care at 2% will be $50,880.

8. Provide the projected staffing for the project in Year 1 and compare to the current staffing for the most recent 12-month period, as appropriate. This can be reported using full-time equivalent (FTE) positions for these positions. Additionally, please identify projected salary amounts by position classifications and compare the clinical staff salaries to prevailing wage patterns in the proposed service area as published by the Department of Labor & Workforce Development and/or other documented sources.

See the staffing table on the following page. There is no current skilled nursing salary information available to the applicant for this service area.

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Table B-Need-12: AxelaCare East Tennessee Projected Staffing--Incremental FTE's for Tennessee Principal Office and Field Nurses				
Position Classification	**Existing FTEs (Yr 2017)**	**Projected FTEs (Yr 1-2018)**	**Average Wage (Contractual Rate)**	**Areawide / Statewide Average Wage**
A. Direct Patient Care Positions				
RN Home Care Director		0.50	$85,000	
Infusion Field RN		2.00	$77,000	
Total Direct Patient Care Positions		2.50		
B. Non-Patient Care Positions				
RN Home Care Director		0.50	$85,000	
Account Executive		1.00	$65,000	
Administrative Assistant (corp-remote)		0.50	$35,000	
Total Non-Patient Care Positions		2.00		
Total Employees (A + B)		4.50		
C. Contractual Staff				
Total Staff (A+B+C)		4.50		

Source: Applicant's management.

Existing FTE's will be an allocation of Memphis Office FTE's (can be fractional) needed to support operations of the new counties

Table B-Need-12: AxelaCare East Tennessee Projected Staffing--Incremental Staffing for KS Central Pharmacy and Delivery				
Position Classification	**Existing FTEs (Yr 2017)**	**Projected FTEs (Yr -2018)**	**Average Wage (Contractual Rate)**	**Areawide / Statewide Average Wage**
A. Direct Patient Care Positions				
Pharmacist		1.00	$145,000	
Techs		1.00	$40,000	
Delivery		1.00	$25,000	
Total Direct Patient Care Positions		3.00		
B. Non-Patient Care Positions				
BackOffice		1.00	$40,000	
Total Non-Patient Care Positions		1.00		
Total Employees (A + B)		4.00		
C. Contractual Staff				
Total Staff (A+B+C)		4.00		

Source: Applicant's management.

9. Describe all alternatives to this project that were considered and discuss the advantages and disadvantages of each alternative, including but not limited to:

A. Discuss the availability of less costly, more effective and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, justify why

Continuation of the status quo was rejected for reasons discussed at length throughout the application. Current patient care problems that need to be resolved include:

(1) Physician difficulties in finding agencies that are immediately staffed and ready to start patient infusions at home and are willing to provide care for sessions longer than 2 hours;

(2) Less than desirable results in training other agency's staff in the consistent and effective use of AxelaCare's handheld CareExchange technology, which is an optimal tool for ensuring complete, accurate, usable and real-time availability of patient clinical data to the team pharmacist and referring physician.

B. Document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements.

Not applicable. No new construction is proposed.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (i.e., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, that may directly or indirectly apply to the project, such as transfer agreements or contractual agreements for health services.

AxelaCare has, and expects to develop, referral and working relationships with several hospitals, specialty medical practices and home health agencies in East Tennessee.

2. Describe the effects of competition and/or duplication of the proposal on the health care system, including the impact to consumers and existing providers in the service area. Discuss any instances of competition or duplication arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

The applicant believes that the benefits of this project far outweigh the minuscule negative impact that 35 AxelaCare home nursing patients would have on the overall array of 87 agencies serving almost 69,000 patients a year in East Tennessee and more than 89,000 patients Statewide. The AxelaCare patient volume will be only five-hundredths of one percent (.05%) of the 68,979 patients served by these agencies in this area in the last JAR reporting year (2015).

On the positive side, the project has clear patient benefits for the health system. The project will encourage movement of IVIG infusion patients out of costlier and less convenient settings, where they now have to go in order to obtain this specialized medication dosing for their immune disorders. AxelaCare will manage their conditions with specialty-trained infusion nurses, using state-of-the-art information technology that enhances real-time communication between the care team and the patient's physician. AxelaCare's unique CareExchange technology also helps compile ever-larger databases that are usable for ongoing research to improve the effectiveness of these complex and evolving medications and their administration.

3.A Discuss the availability of an accessibility to human resources required by the proposal, including clinical leadership and adequate professional staff, as per the State of Tennessee licensing requirements and/or requirements of accrediting agencies such as the Joint Commission and the Commission on Accreditation of Rehabilitation Facilities.

AxelaCare Health Solutions, LLC is familiar with State requirements for staffing a licensed home health agency. The small number of additional skilled R.N.'s (3.0 FTE's) that are needed to operate the project are readily available through AxelaCare's corporate recruiting resources.

B. Verify that the applicant has reviewed and understands all licensing and/or certification as required by the State of Tennessee and/or accrediting agencies such as the Joint Commission for medical/clinical staff. These include, without limitation, regulations concerning clinical leadership, icies and programs, record keeping, clinical staffing requirements, and staff education.

The applicant so verifies.

C. Discuss the applicant's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

The applicant has no plans at this time to participate in training programs.

4. Identify the type of licensure and certification requirements applicable and verify that the applicant has reviewed and understands them. Discuss any additional requirements, if applicable. Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

LICENSURE: The applicant will soon receive a limited home health agency license from the Board for Licensure of Healthcare Facilities, Tennessee Department of Health (TDH). The applicant's Specialty Pharmacy already holds a Tennessee non-resident pharmacy license and its associated Sterile Compounding License (granted by TDH). If this application is approved, the facility license will be amended to include the proposed additional counties of East Tennessee.

CERTIFICATION: The applicant does not qualify for Medicare or TennCare certification because of the non-homebound patient population that it serves.

ACCREDITATION: AxelaCare is Joint Commission accredited nationally and holds the Joint Commission's Gold Seal of Approval. AxelaCare's Specialty Pharmacy Program is also accredited by URAC (originally named the "Utilization Review Accreditation Program").

A. If an existing institution, describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility and accreditation designation.

The applicant is an approved home health agency that is anticipating initial licensure in February 2017 as a Home Health Agency restricted to infusion of immune globulin pharmaceuticals and related nursing services.

AxelaCare's Lexena, Kansas Specialty Pharmacy and Sterile Compounding Licenses are in good standing.

B. For existing providers, please provide a copy of the most recent statement of deficiencies/plan of correction and document that all deficiencies/findings have been corrected, by providing a letter from the appropriate agency.

Not applicable.

C. Document and explain inspections within the past three survey cycles which have resulted in any of the following state, federal, or accrediting body actions: suspension of admissions, civil monetary penalties, notice of 23- ore 90-day termination proceedings from Medicare or Medicaid/TennCare, revocation/denial of accreditation, or other similar actions.
(1) Discuss what measures the applicant has or will put in place to avoid similar findings in the future.

Not applicable to a new agency not yet licensed or in operation.

5. Respond to all of the following and for such occurrences, identify, explain, and provide documentation:

A. Has any of the following:
(1) Any person(s) or entity with more than 5% ownership (direct or indirect) in the applicant (to include any entity in the chain of ownership for applicant);
(2) Any entity in which any person(s) or entity with more than 5% ownership (direct of indirect) in the applicant (to include any entity in the chain of ownership for applicant) has an ownership interest of more than 5%; and/or
(3) Any physician or other provider of health care, or administrator employed by any entity in which any person(s) or entity with more than 5% ownership in the applicant (to include any entity in the chain of ownership for applicant) has an ownership interest of more than5%...

B. Been subjected to any of the following:
(1) Final Order or Judgment in a State licensure action;
(2) Criminal fines in cases involving a Federal or State health care offense;
(3) Civil monetary penalties in cases involving a Federal or State health care offense;
(4) Administrative monetary penalties in cases involving a Federal or State health care offense;
(5) Agreement to pay civil or monetary penalties to the Federal government or any State in cases involving claims related to the provision of health care items and services; and/or
(6) Suspension or termination of participation in Medicare or Medicaid/TennCare programs;
(7) Is presently subject of/to an investigation, regulatory action, or party in any civil or criminal action of which you are aware;
(8) Is presently subject to a corporate integrity agreement.

None of the persons or entities in question 5A above has been subjected to any of the sanctions listed in question 5B above.

6. Outstanding Projects:

a. Complete the following chart by entering information for each applicable outstanding CON by applicant or share common ownership; and
b. Provide a brief description of the current progress, and status of each applicable outstanding CON.

None. The applicant is awaiting licensing inspection and licensure as a restricted Home Health Agency, pursuant to CN1606-022.

*** Annual Progress Reports – HSDA Rules require that an Annual Progress Report (APR) be submitted each year. The APR is due annually until the Final Project Report (FPR) is submitted (FPR is due within 90 ninety days of the completion and/or implementation of the project). Brief progress status updates are requested as needed. The project remains outstanding until the FPR is received.**

7. Equipment Registry -- For the applicant and all entities in common ownership with the applicant.

a. Do you own, lease, operate, and/or contract with a mobile vendor for a Computed Tomography Scanner (CT), Linear Accelerator, Magnetic Resonance Imaging (MRI), and/or Positron Emission Tomographer (PET)?

No.

b. If yes, have you submitted their registration to HSDA? If you have, what was the date of the submission?

Not applicable.

c. If yes, have you submitted their utilization to HSDA? If you have, what was the date of the submission?

Not applicable.

Facility	Date of HSDA Registration	Date of Last Utilization Submittal

QUALITY MEASURES

Please verify that the applicant will report annually using forms prescribed by the Agency, concerning continued need and appropriate quality measures as determined by the Agency pertaining to the Certificate of Need, if approved.

The applicant so verifies.

SECTION C: STATE HEALTH PLAN QUESTIONS

T.C.A. §68-11-1625 requires the Tennessee Department of Health's Division of Health Planning to develop and annually update the State Health Plan (found at http://www.tn.gov/health/topic/health-planning). The State Health Plan guides the State in the development of health care programs and policies and in the allocation of health care resources in the State, including the Certificate of Need program. The 5 Principles for Achieving Better Health are from the State Health Plan's framework and inform the Certificate of Need program and its standards and criteria.

Discuss how the proposed project will relate to the 5 Principles for Achieving Better Health found in the State Health Plan.

1. The purpose of the State Health Plan is to improve the health of the people of Tennessee.

Authorization of AxelaCare to provide home infusion nursing will address the needs of immune-compromised IVIG recipients to obtain AxelaCare medications in the most economical setting, without incurring needless extra time in the hospital for first dosages. Approval will eliminate burdensome commuting to remote infusion facilities. It also will eliminate the added risks of infections through exposure to other persons when they go to those infusion facilities.

2. People in Tennessee should have access to health care and the conditions to achieve optimal health.

Provision of the proposed service to all of the region's counties will improve access to this type of care for rural residents of the region, whose counties are not served by a choice of home IVIG infusion providers. Those using AxelaCare home nursing teams will be spared multiple long drives to remote infusion centers.

3. Health resources in Tennessee, including health care, should be developed to address the health of people in Tennessee while encouraging economic efficiencies.

This type of patient, in this region of Tennessee, deserves expansion of choice among specialty providers of IVIG home infusion care. Only a handful of agencies licensed for this service area are staffed and prepared to provide immune globulin infusion at all. And only 1 of them is authorized to serve every East Tennessee county. The others serve only a few. This compares poorly to the many agencies serving all counties' routine home health needs. This project encourages reasonable levels of provider competition, and allows into the market an innovative national home care provider whose infusion management technology is valuable to the entire caregiver team as well as to academic research.

4. People in Tennessee should have confidence that the quality of health care is continually monitored and standards are adhered to by providers.

The applicant has a robust quality assurance program, in which regional and corporate clinical staff continuously review patient data to ensure that AxelaCare nurses maintain the

highest standard of competence and provide the best possible patient outcomes for every infusion session. The CareExchange technology used by AxelaCare nurses facilitates achieving optimal care during the infusion itself, allowing pharmacist and physician team members to participate in treatment decisions real-time as infusion proceeds, reflecting changing patient needs for changes in dosage amounts, infusion rates and other services. The AxelaCare program ensures the highest possible quality of treatment outcomes in this difficult and complex area of care.

5. The state should support the development, recruitment, and retention of a sufficient and quality health workforce.

The project provides additional assurances to physicians and patients that their home infusion provider will be of the highest level of competence. Staffing the project will create an experienced and highly qualified specialty nursing staff for expanded service to rural counties as well as the urbanized counties in East Tennessee.

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper that includes a copy of the publication as proof of the publication of the letter of intent.

See Attachment "Proof of Publication", which will be completed prior to the end of the filing month, by submissions under separate cover.

NOTIFICATION REQUIREMENTS

(Applies only to Nonresidential Substitution-Based Treatment Centers for Opiate Addiction)
Note that T.C.A. §68-11-1607(c)(3) states that "...Within ten (10) days of filing an application for a nonresidential substitution-based treatment center for opiate addiction with the agency, the applicant shall send a notice to the county mayor of the county in which the facility is proposed to be located, the member(s) of the House of Representatives and the Senator of the General Assembly representing the district in which the facility is proposed to be located, and to the mayor of the municipality, if the facility is proposed to be located within the corporate boundaries of a municipality, by certified mail, return receipt requested, informing such officials that an application for a nonresidential substitution based treatment center for opiate addiction has been filed with the agency by the applicant." ....

Not applicable.

DEVELOPMENT SCHEDULE

T.C.A. §68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

1. **Complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.**
2. **If the response to the preceding question *indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph,* please state below any request for an extended schedule and document the "good cause" for such an extension.**

The applicant does not request an extended implementation schedule.

PROJECT COMPLETION FORECAST CHART

Assuming the Certificate of Need (CON) approval becomes the final HSDA action on the date listed in Item 1. below, indicate the number of days from the HSDA decision date to each phase of the completion forecast.

June 28, 2017

PHASE	DAYS REQUIRED	Anticipated Date (MONTH /YEAR)
1. Initial HSDA Decision Date	0	
1. Architectural & engineering contract signed		
2. Construction documents approved by TDH		
3. Construction contract signed		
4. Building permit secured		
5. Site preparation completed		
6. Building construction commenced		
7. Construction 40% complete		
8. Construction 80% complete		
9. Construction 100% complete		
10. * Issuance of license		
11. *Initiation of service	187	1-1-18
12. Final architectural certification of payment	NA	NA
13. Final Project Report Form (HF0055)	277	4-1-18

*** For projects that DO NOT involve construction or renovation: please complete items 11 & 13 only.**

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

INDEX OF ATTACHMENTS

Section A

A-3A(1)	Additional Project Description
A-4A	Legal Status and Ownership Structure of Applicant

Section B

B-Need-3	Service Area Map
B-Need-5	Historic Utilization of Existing Agencies in Service Area
B-Economic Feasibility-2	Documentation of Funding/Financing Availability
B-Economic Feasibility-6A	Applicant's Financial Statements
C, Need--1	Documentation of Project-Specific Review Criteria 1. Performance Improvement Plan 2. Patient Satisfaction Survey 3. Emergency Response Protocols 4. Financial Assistance Program 5. R.N. Job Description 6. Resume--Regional and National Nurse Manager

Other Attachments

Proof of Publication

Miscellaneous Information

1. TennCare Enrollment
2. Publications Concerning Immune Globulin Infusion
3. TDH Report of HHA's Currently Serving Area Residents
4. URAC--Specialty Pharmacy

Support Letters

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A-3A(1)
Additional Project Description

A-3A(1): Additional Project Description

1. Limited Scope of Services

Specialty home infusion is the process of providing very specialized medicines intravenously in a patient's home, with the presence and support of a skilled registered nurse (R.N.) who works under the direction of the patient's referring physician.

AxelaCare is requesting approval to provide East Tennessee patients direct services and product for specialty home infusion of ***immune globulin medications only***. These services would be limited to adult and pediatric patients in 40 contiguous East Tennessee counties, using AxelaCare-employed and skilled RN staff. The service will provide infusion of immune globulin either directly into the vein or through a subcutaneous (i.e., under the skin) site. It is a type of home health care that few Tennessee home health agencies are staffed for or willing to provide.

The applicant is not requesting authorization for infusion of other medications. This limitation to only one narrow type of specialty infusion (AxelaCare's immune globulin products) will differentiate this agency from all other home health agencies in the service area. In this application, the service is abbreviated as "IVIG" (intravenous immune globulin).

This service can be delivered in every county in the proposed service area. The AxelaCare regional pharmacy in Kansas has a Tennessee non-resident pharmacy license that allows it to ship immune globulin product to patient homes in every Tennessee county when prescribed by those patients' physicians.

2. Staffing and Staff Support

In Year Two, this project will require 10 FTE's of new personnel. This includes 3.0 skilled care field R.N. FTE's in East Tennessee, and 0.5 of a RN Nurse Director FTE based at the principal office in Memphis but also doing patient care in East Tennessee. Other staff include non-clinical staff in Memphis and at the Regional Pharmacy in Kansas.

The R.N.'s will be specially trained in starting and managing home infusions. They will be trained thoroughly in the AxelaCare infusion program and in the use of Axela's CareExchange technology--which is an iPad-based platform for documenting patient dosages and responses. CareExchange enables real-time communication with the team pharmacist and the referring physician, while the infusion is performed. Nurses employed by AxelaCare for this service will be encouraged to have, or to obtain within one year of employment, the Certified Registered Nurse Infusion (CRNI) designation that denotes special competence in managing infusions. AxelaCare employs only nurses who are already skilled in this service, as validated by an internal assessment program prior to employment. Many qualified nurses have never sought CNRI designation because it is very expensive and time-consuming to complete the required coursework and testing. AxelaCare will provide those nurse employees with financial support to seek and obtain the designation.

The AxelaCare staff's specialization in home infusion care of the immune globulin recipient, and the CRNI designation that AxelaCare nurses will attain in Tennessee are another

difference between this service and virtually all other home health organizations operating in the area.

To make care accessible to both patients and nurses, AxelaCare will employ nurses who have a reasonable drive time from their homes to patients' homes in each nurse's own judgment. The drive time from the principal office in Memphis to East Tennessee patients is not relevant, because AxelaCare patients in East Tennessee will be cared for by R.N.'s who live much closer to them, in counties within a reasonable drive time.

Once deployed in the field, nurses do not need to come to the home office in Memphis. Nurses come to the patient's home with simply a nursing bag, a cell phone and a company-leased iPad with AxelaCare software loaded.

The supplies needed for each infusion patient (medication and equipment) are shipped monthly by FedEx directly to the patient, and are waiting at the patient's home for the arrival and administration by the RN. IG shelf life is between two and three years. AxelaCare requires proof of delivery by signature, either by the patient or the patient's designee. AxelaCare strongly discourages patient authorization of medication deliveries without a recipient signature and it is rarely allowed as a matter of company policy.

At the physician's direction, the patient is scheduled by AxelaCare to receive infusions at a set interval. When the nurse completes a visit, an approximate date is determined for the next infusion. Several (4-7) days prior to that date, the pharmacy in Kansas phones the patient and confirms or modifies the visit date and the medication delivery date with the patient. The complete delivery is targeted to occur one, or two days prior to the day of infusion. Once the delivery date is confirmed, it is communicated to the nurse and the nurse is scheduled to deliver care (i.e., to administer the IVIG medication) to the patient in the patient's home. The day before the infusion, the nurse verifies with the patient that the delivery has occurred.

Group training, CME and other sessions are periodically provided by AxelaCare regional nurse managers at facilities in the field. They also travel to support field nurses on-site as needed, working with difficult patients and assisting the nurse with performing a new procedure, using a new medication or using new equipment as technology changes. As described in section 5f below, the clinical information gathered by the nurse at the bedside is sent over a secure internet connection to AxelaCare's regional and central offices and to the patient's physician and supervising pharmacist. Data is transferred during the infusion. The nurse does not need to return to an AxelaCare office to complete paperwork or to obtain supplies. AxelaCare then reviews and compiles patient data into a central database for use by the company and by research teams across the United States.

3. Schedule for Implementing the Services

If granted final CON approval on or before July 1, 2017, AxelaCare projects amendment of its State licensure and initiation of patient care in East Tennessee by the end of CY2017. The first full year of operation is projected to be CY2018.

4. Clinical Needs Addressed By the Project

Immune Globulin is a medicine that contains antibodies, which are tiny proteins that patrol the blood stream to alert the body to germs, which the body then can destroy through complex "immune system" responses.

Specialists in many areas of medicine use immune globulin infusions (IVIG) when other therapies have failed. Referring medical specialties most likely to utilize this AxelaCare program will include neurologists, immunologists, oncologists and dermatologists. They prescribe immune globulin therapy to treat patients with challenging immune system disorders of many kinds, including the following (several of which are briefly described near the end of this response).

- Peripheral Neuropathy (PN)
- Small Fiber Neuropathy (SFN)
- Primary Immunodeficiency Disease (PIDD)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Guillain-Barre Syndrome (GBS)
- Multifocal Motor Neuropathy (MMN)
- Myasthenia Gravis (MG)
- Multiple Sclerosis (MS)
- Pemphigoid / Pemphigus
- Common Variable Immunodeficiency Disease (CVID)
- Chronic Granulomatous Disease (CGD)
- Hyper IgM Syndrome
- Selective IgA Deficiency (SIgAD)
- Severe Combined Immunodeficiency Disease (SCID)
- Wiskott-Aldrich Syndrome
- X-linked Agammaglobulinemia
- Auto-immune Encephalopathy (AE)
- Dermatomyositis
- Idiopathic Thrombocytopenia Purpura (ITP)
- Lambert-Eaton Myasthenic Syndrome (LEMS)
- Mononeuritis Multiplex
- Polymyositis
- Transplant-related Conditions
- Stiff-person Syndrome (SPS)

The patients who will be served by this project are often among the most challenged of home health patients. Their care requires very sophisticated management by their physicians and the skilled care nurses who carry out prescribed home infusions.

Very few home health agencies are willing and able to offer ready availability of the specialized skilled nursing staff that is needed when providing IVIG infusions at home. Optimal nursing care for IVIG infusion requires significant nursing experience and training. It requires the nurse to spend long hours with the patient over a prolonged treatment period, during which significant monitoring of patient responses takes place. In the AxelaCare service model, nurses also record patient data continuously for the referring physician to review during and after the course of the dosing -- and for post-care research, as explained below.

5. *AxelaCare's Program for Delivery of Home Infusion Care for IVIG Patients*

AxelaCare is dedicated solely to comprehensive excellence in specialty home infusion care. Its highly trained and experienced clinical staff are its own employees. Its internal Quality Improvement program is among the most robust in the industry. And, most notably, the CareExchange technology it uses in the patient's home during the infusion treatment is continuously gathering clinical data that is made available not only to the patient's physician, but also to medical researchers (with properly obtained consent) -- thus advancing medical knowledge in a complex and evolving area of medicine. AxelaCare's sequence of services to its Tennessee IVIG patients will be as follows:

a. Patient and Physician Contacts

AxelaCare has relationships with medical specialists in the service area and will work with them to ensure that patient referral processes are straightforward and efficient. When a referral is made, the AxelaCare staff will secure required information and paperwork from the physician's office and will send it to an AxelaCare Pharmacy. The Pharmacy will (a) assign a Pharmacist with 24/7 availability to the patient; (b) prepare the prescribed pharmaceuticals; and (c) direct-ship them in the correct dosages to the patient's home via FedEx for infusion. An AxelaCare specialty home infusion nurse will be assigned to provide care to the East Tennessee patient. AxelaCare will not subcontract this type of care to any other agency. A pre-dose screening will be performed to determine if each patient is clinically appropriate to receive a first dose at home. AxelaCare's experience is that the majority of patients qualify as low-risk, appropriate for care at home. (Patients who do not qualify as low-risk for first dosage always receive a first dose in a monitored setting and subsequent doses at home.)

b. Comprehensive Assistance to the Patient Prior to Infusion

After contacting the referred patient, AxelaCare's Care Team will simplify arrangements for the patient's insurance coverage, evaluating all benefit sources and potential coverage, obtaining letters of medical necessity, securing coverage for patients previously denied, educating the patient on available benefits and the patient's projected costs, coordinating with the physician's office for timely approvals and prior authorizations and coordinating direct billing to insurance and other payment sources.

c. The Initial Home Visit

An initial home visit is scheduled so that the skilled care infusion nurse can become personally acquainted with the patient and his/her home environment, discuss the infusion process, answer patient questions, establish a schedule of visits, and obtain required patient consent to share with the patient's physician and with AxelaCare's research center a set of clinical data and information to be obtained during infusion sessions.

d. Preparation for Infusion or "Dosing"

Before home infusion begins, many patients need oral or venous hydration and/or premedication to lower the risks associated with infusion, which can include headaches and blood pressure changes. These risks are the same, whether infusion is provided in the home or in another setting like a physician office or freestanding infusion center. In infusion medicine, a "dose" is not a "visit" or "hours" as in most home health care. A dose is a prescribed amount of medication to be administered in a single "dosing cycle". A dosing cycle can take from ***one to***

five consecutive days, depending on the amount to be infused and on the infusion rate that the patient can tolerate without having negative reactions. Dosing cycles may be required at weekly intervals.

It should be noted that this agency will not serve diagnosed chronic pain patients. They are not IVIG cases. Minor pain management pharmaceuticals such as Tordol (a non-steroidal anti-inflammatory or "NSAID") may on occasion be administered prior to administering IVIG, if the referring physician deems it to be needed; but this would be incidental to the IVIG therapy for which the patient was referred. AxelaCare is not a pain management provider and does not administer opioids.

e. Care During the Infusion Sessions

A nursing visit in a dosing cycle can be from 2-10 hours daily in duration, depending on the prescription, the dose amount, dose rate and patient reactions to the infusion. Before, during and after infusion, the AxelaCare nurse follows detailed protocols that include periodically taking vital signs, taking spirometry readings, discussing the patient's bodily responses to the infusion, requesting patient performance of simple physical tests such as grip strength measurement and rising from a chair to walk across the room.

Nursing visits are timed to coincide with the infusion dose delivery. Patients are ordered to receive the infusion at a set interval. When the nurse completes the current visit an approximate date is determined for the next infusion. Several days (4-7 days) prior to the tentative date, the pharmacy calls the patient and confirms/modifies the visit date and medication delivery date with the patient. The complete delivery should occur 1-2 days before the infusion. Once the delivery date is confirmed it is communicated to the nurse. The nurse verifies with the patient the day before the infusion that the delivery has occurred.

f. *CareExchange Technology*

One of the distinguishing advantages of AxelaCare "bedside" services is CareExchange -- a unique and proprietary technology tool developed by AxelaCare in 2012. Continuously during every dosing day, the nurse gathers and enters all clinical data and patient descriptions of pain, fatigue, etc. into an iPad fitted with CareExchange software. CareExchange organizes this information into clear and usable reports that are then transmitted over secure electronic channels to the patient's AxelaCare pharmacist and to the patient's physician. These iPads are leased by AxelaCare and kept up to date.

With this "real-time" data, both the pharmacist and the referring physician specialist can more quickly evaluate patient reactions to the medication and can direct appropriate adjustments such as variations in the dosing rate or dosing amount, as indicated by digitally documented patient reactions. In addition, the infusion nurse can identify and discuss issues with the AxelaCare pharmacist during, as well as after, infusion (the pharmacist is available 24/7), and the pharmacist and nurse can telephonically alert the physician to patient response issues and can discuss modifications of the treatment.

CareExchange's capturing and analysis of patient response data during the dosing cycle, and its rapid communication to the treatment team, helps both the patient and the referring physician. From the ***patient's*** perspective, it ensures that patients are receiving optimal therapy for maximum effectiveness of the infusion medication. The technology tracks patient progress and changes in the patient's condition. It establishes baseline and trending information to

compare those changes. From the ***physician's*** perspective, it provides real-time data between patient office visits, to help manage the patient's condition; it allows rapid adjustment of the prescribed therapy to find the most effective dose; and it gives a better understanding of how the therapy is working and how it might work for other patients with similar conditions.

After treatments, CareExchange uploads its clinical data to a national AxelaCare database that is made available for medical research, with the appropriate protections put in place from a privacy perspective. So from a ***research*** perspective, the steadily growing AxelaCare central database of patient responses to these new pharmaceuticals provides academic and other researchers with a unique source of clinical information that is very valuable.

In rare instances, some rural patients may live in areas without internet coverage, which would prevent real-time communication between the nurse and the physician unless a telephone line is available. To compensate for this, the CareExchange technology allows the R.N. to plan for it in advance. The forms and response sheets that would ordinarily be downloaded onsite at the patient's home will be downloaded to the nurse's iPad before the home visit. They will then be completed manually during treatment, and will reside on the iPad until the nurse enters a covered zone on the return trip. Then the program would automatically detect coverage and upload all data to where it will be accessible to the patient's physician 24/7.

For additional details, the applicant is attaching after this page an additional description of this technology, including its advantages over other provider software.

CareExchange--The AxelaCare Advantage

After extended research, AxelaCare introduced its nurse-managed, iPad-based CareExchange technology in 2012. It was the first such system developed for physicians and their patients, and for the research community. As described in the CON application (pgs 14-15), this is an iPad-based software tool that the infusion nurse uses to:

(a) record critically important patient treatment and response data, including patient input, during the dosing session, and to

(b) make that data available via internet connection to the patient's physician in graphics, tables, and text formats both during and after the treatment session, and to

(c) create a growing database of significant importance to research studies.

The system is superior to that of other agencies known to the applicant; and the differences are significant.

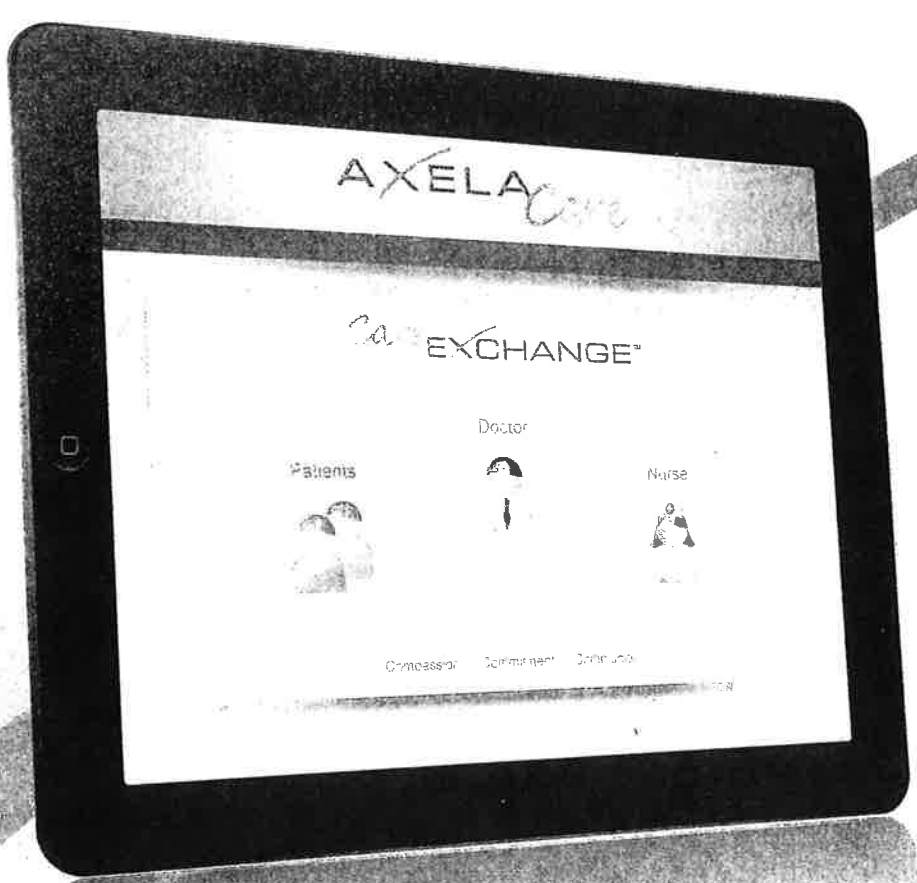
First, the CareExchange software's data-gathering instruments were developed and are maintained using "best data" recommendations and requests from nationally recognized physician leaders and researchers in this complex field. AxelaCare believes that no other home health infusion company is as deeply involved with those clinical experts on an ongoing basis.

Second, the iPad-based information-gathering process is managed by a trained nurse working on-site at the time of treatment to gather important patient response data directly from the patient as well as from nursing observations. This real-time approach that incorporates both nurse and patient input about measurable and felt responses to infusion is more accurate, informative and comprehensive than the old way -- which consisted of the team pharmacist interviewing the patient by telephone some time after the infusion visit, and the infusion nurse writing nursing reports from notes at some time after leaving the patient. This real-time, on-site, comprehensive information gathering and communication system is unique to AxelaCare. The referring physician can access relevant data--both quantitative and "soft" information--in highly usable formats, at any time day or night, including during the infusion session itself.

Third, CareExchange captures data from a set of physical assessments of the patient at the time of the infusion session. The patient is asked to perform a set of simple physical tasks that have clinical meaning to reviewing physicians; and their performance of those tasks is quantified, recorded and put into the physician's hands immediately to help inform treatment decisions. To AxelaCare's knowledge, only CareExchange has this important capability. It provides much-needed information for the physician.

EXCHANGE®

Outcome Assessment Technology

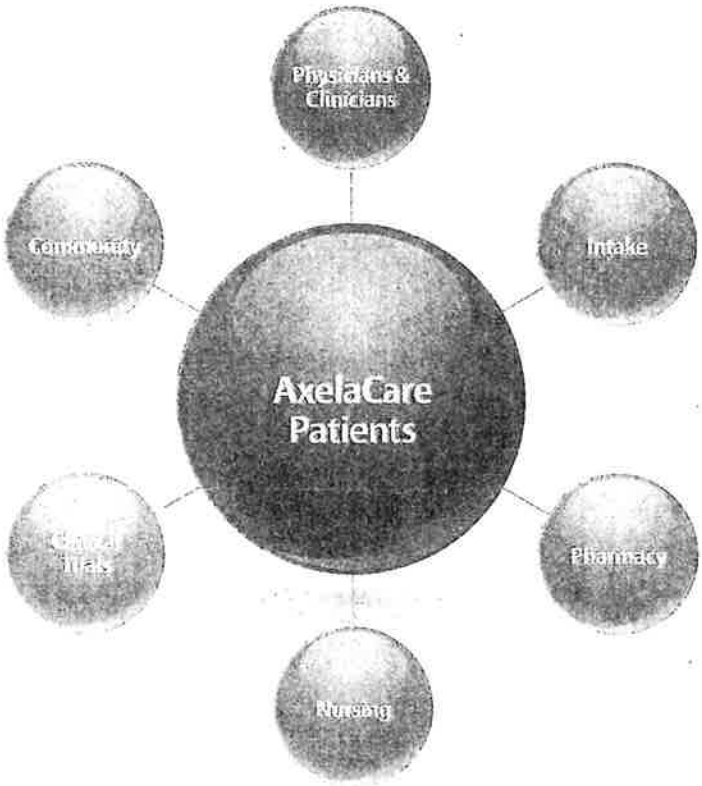


Introducing CareExchange®: Innovation in Patient-Centered Care

The new technology-driven solution from AxelaCare®, called CareExchange®, allows physicians and nurses to easily capture information about the treatments of rare and complex diseases and patients' responses to them – ultimately improving patient outcomes and reducing costs. CareExchange gives physicians the ability to optimize dosing, determine the best therapy strategies and identify natural and non-responders.

The features of CareExchange® innovation include:

- Infusion nurse data collection
- iPad data entry tool
- Validated outcomes assessments
- Web-based physician data access
- Dose vs. outcomes analysis and graphs



CareExchange® Database Architecture

CareExchange is a SQL database that ties all collected outcomes data to AxelaCare's foundational CareLink database. CareLink integrates pharmacy, prescriptions and operations with all patient, history, diagnostics and insurance information, providing an unparalleled ability to correlate and data mine across care elements.

CareExchange® Database Design

AxelaCare built and designed CareExchange with expert input from thought leaders in CIDP, Immuno Globulin, pharmacy and nursing, peripheral neuropathy, neurology, immunology and many others. AxelaCare sought guidance from these experts on outcomes measurements and their applicability from a research and clinical trial setting into an infusion nurse driven scenario. The data collection and validation process is intended to give the most practical and insightful data to practicing clinicians as well as build data sets with specific research objectives in mind. AxelaCare welcomes feedback and collaboration on the design, implementation and research objectives of CareExchange. If you are interested in being a part of the process, please don't hesitate to contact us.

How CareExchange® Works

Employing the latest technology including wireless internet access and iPads, CareExchange tracks data collected through standard studies and practices. The iPad outcomes assessment is nurse-administered during home infusions, and is a patient management tool that optimizes data collection. The resulting data reports are simple to view and easily available to physicians who are creating treatment plans for patients.

Features include:

- Web-based, wireless connectivity for immediate data upload
- Simple touch pad for nurse and patient ease-of-use
- Outcome measures, including:

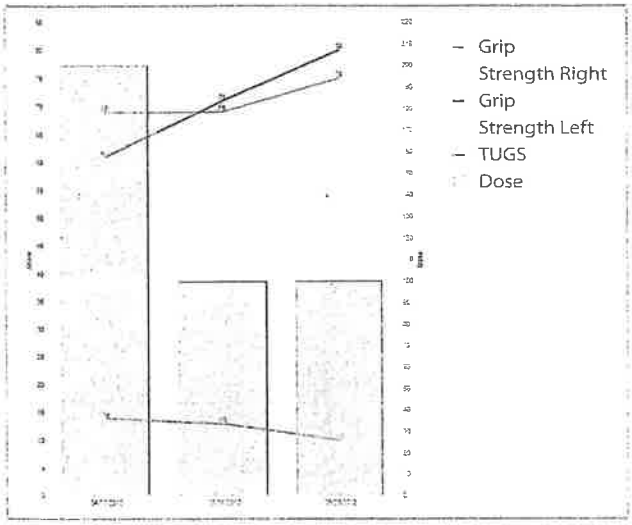
  Physical Assessments
  - Timed Up and Go (TUGS), Grip Strength (Jamar)

  Disability Scores
  - RODS, ONLS, mFSS (Fatigue), VAS (Pain)

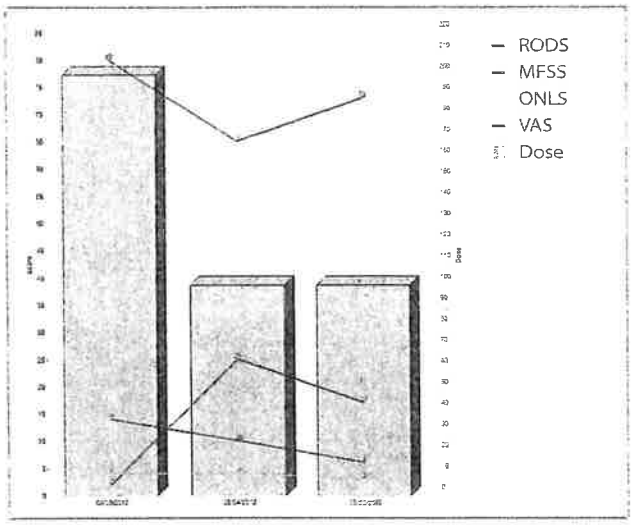
  Quality of Life Measures
  - SF-36

Patient Test

Physical Assessments



Disability Scores



Quality of Life Measures

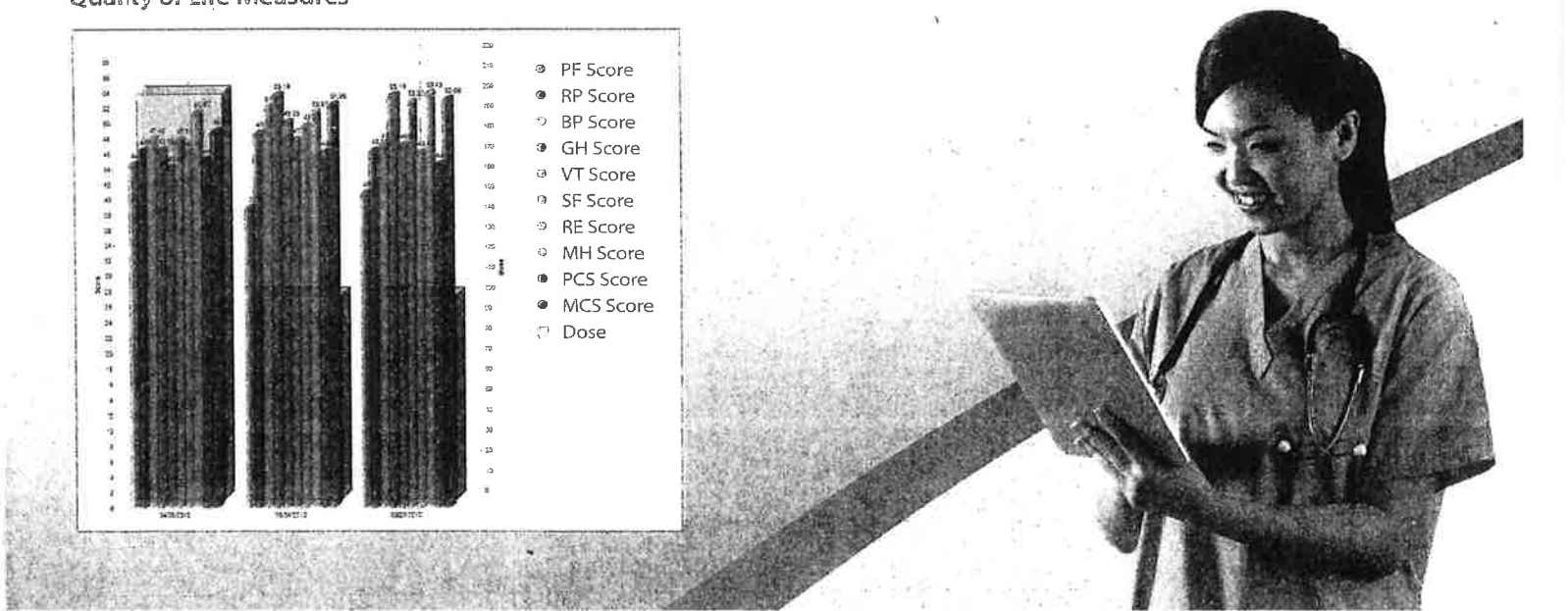
What is the CareExchange® Outcome?

CareExchange allows physicians and nurses to track patients' progress and optimize therapy. This type of data tracking and management improves:

- Physician access to data and communications
- Physician's understanding of how a therapy is working, and how it might work for other patients with similar conditions
- Physician's ability to adjust therapy to find the most effective dose
- Access to real-time information between office visits to help manage a patient's condition
- Quality and continuity of care
- Nurse productivity
- Research data collection
- Identifying natural responders and non-responders
- Patient care outcomes for those suffering from many rare diseases such as:
  - CIDP
  - Peripheral Neuropathy
  - MGUSP

Future tests may include:

- MMN
- Small Fiber Neuropathy
- MG
- MS
- PIDD
- Stiff-Person Syndrome



How can I enroll my patients in CareExchange®?

Simply complete the CareExchange Enrollment Form and provide any of the appropriate items listed below:

- Copy of patient's insurance card
- H & P (History & Physical) or letter to referring MD
- EMG/NCS results
- Nerve biopsy (if done)
- CSF – Cerebral Spinal Fluid (if done)
- Tried and failed therapies

Is the patient data safe?

Yes. The system is a HIPPA compliant electronic medical record database with HTTPS encryption. Patient data is only shared with their physicians and caregivers. Research information is not connected in any way to any Personal Health Information (PHI).

Will patients sign an Informed Consent?

Yes, all patients will get an Informed Consent Form. The AxelaCare team will guide them through everything that CareExchange entails.

How do I learn more?

For additional information regarding CareExchange and AxelaCare, please contact your AxelaCare representative at 877.342.9352 or visit us at www.axelacare.com.

Clinical Care Research Overview

Many rare and complex diseases, and the medicines that treat them, lack robust bodies of research to support physicians in designing the most effective care plans. By better understanding these conditions and the way they are treated, we can offer new hope to people facing serious long-term medical challenges.

AxelaCare's clinical care research programs monitor numerous aspects of a patient's treatment and track outcomes on a large scale, helping us to understand the applications of infusion medicine in greater depth and breadth more than ever before and providing new tools for physicians and nurses in managing care.

Clinical care research initiatives include:

- Dose optimization
- Patient outcomes measurement and reporting
- Quality of Life (QOL) measures
- Biomarker development
- Digital recordkeeping and physician collaboration tools
- New therapeutic and patient management strategies
- Supporting clinical research protocols and investigator-initiated studies
- Treatment algorithms
- Natural responders
- Patient education

If you are a physician or research organization interested in participating in AxelaCare's clinical care research initiatives, please contact us at **research@axelacare.com**.

CareEXCHANGE™

for Primary Immune (PIDD) IVIg and SCIg

Test Menu

Physical Assessments (Physical Testing)

- Spirometry FEV1/PEF

Disability Scores (Questionnaires)

- AxelaCare Touch™ Patient Self Assessment
- Energy Level/mFSS (modifed Fatigue Severity Score)
- Breathing Ability
- Infections
- Work/School/Activities
- Pain

Quality of Life Measures (Assessment)

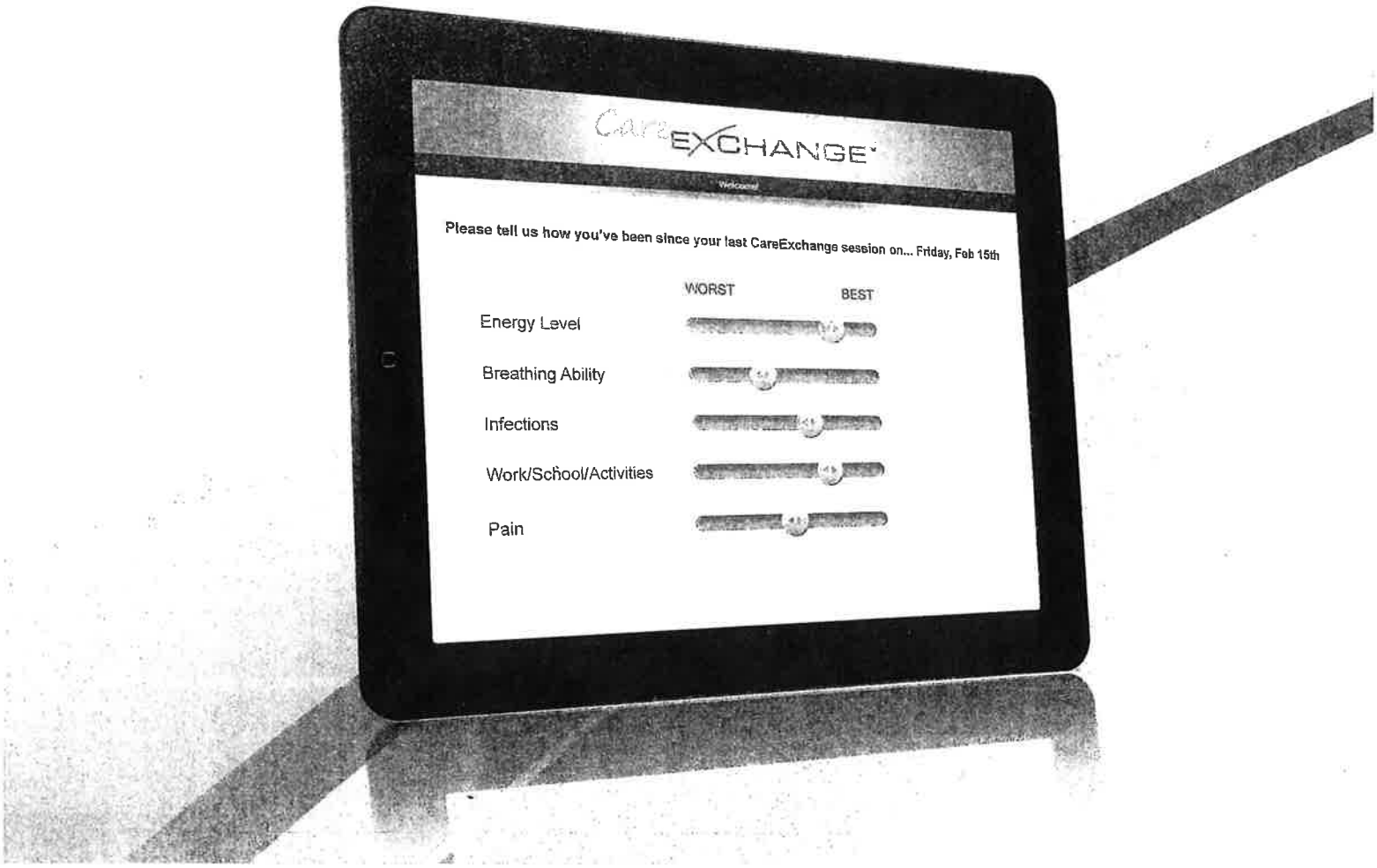
- SF-36 (Adult)
- CHQ-28 (Pediatric)

References

van Nes, Sonja I, et al. (2009). Improving fatigue assessment in immune-mediated neuropathies: the modified Rasch-built fatigue severity scale. *Journal of the Peripheral Nervous System*. 14, 268-278.

Ware Jr., John E. (2000). SF-36® Health Survey Update. *SPINE*. 25 (24), 3130-3139.

Landgraf, J.M., Abetz, L., & Ware Jr., J.E. (1996). Child Health Questionnaire (CHQ): *A User's Manual. First Edition*. Boston, MA: The Health Institute, New England Medical Center.



Patient Assessments

Energy Level

Tap for instructions...

Modified Fatigue Severity Scale

Rasch-built 7-item modified fatigue survey scale: "The higher the score you choose, the more you agree with the question (the lower the score the less you agree)"

Exercise brings on my fatigue

0 DISAGREE

1

2

3 AGREE

I am easily fatigued

0 DISAGREE

1

2

3 AGREE

0 DISAGREE

Infections

Tap for instructions...

1) Since your last infusion...

a. Do you think you have an infection in the?

i) Head

Yes

No

ii) Sinus

Yes

No

iii) Lung

Yes

No

Breathing

Tap for instructions...

Since your last infusion...

Has difficulty in breathing prevented you from performing any activities?

Yes

No

Have you experienced any shortness of breath, coughing or wheezing?

Yes

No

Have you used any rescue inhalers or nebulizers in addition to any regularly prescribed medications you take for your breathing?

Yes

No

Yes

Activities

Tap for instructions...

1) Since your last infusion, due to your condition...

a. Have you missed any work(days)?

1/2

1

2

3

4

5

>5

None

NA

b. Have you missed any school/daycare/activities(days)?

1/2

N

Spirometry

FEV1 and PEF

Spirometry

Forced Expiratory Volume at 1 Second

FEV1 1: FEV1 2: FEV1 3:

Peak Expiratory Flow

PEF 1: PEF 2: PEF 3:

Finalize Spirometry on Save | Save Spirometry

Infusion

Medication Administration and Reactions

Immunoglobulin Liquid | Route: IV

Start Time End Time Lot # / Expiration Date

Dose Dose UOM

gm

Selected Lot(s)

No lots selected

Adverse Reaction(s)

Amount Infused Amount Infused UOM

ml

Chills

Headache

Migraine

Diarrhea

Selected Adverse Reaction(s)

No adverse reactions selected

Comments

To Learn More

www.axelacare.com

CETMPIDi

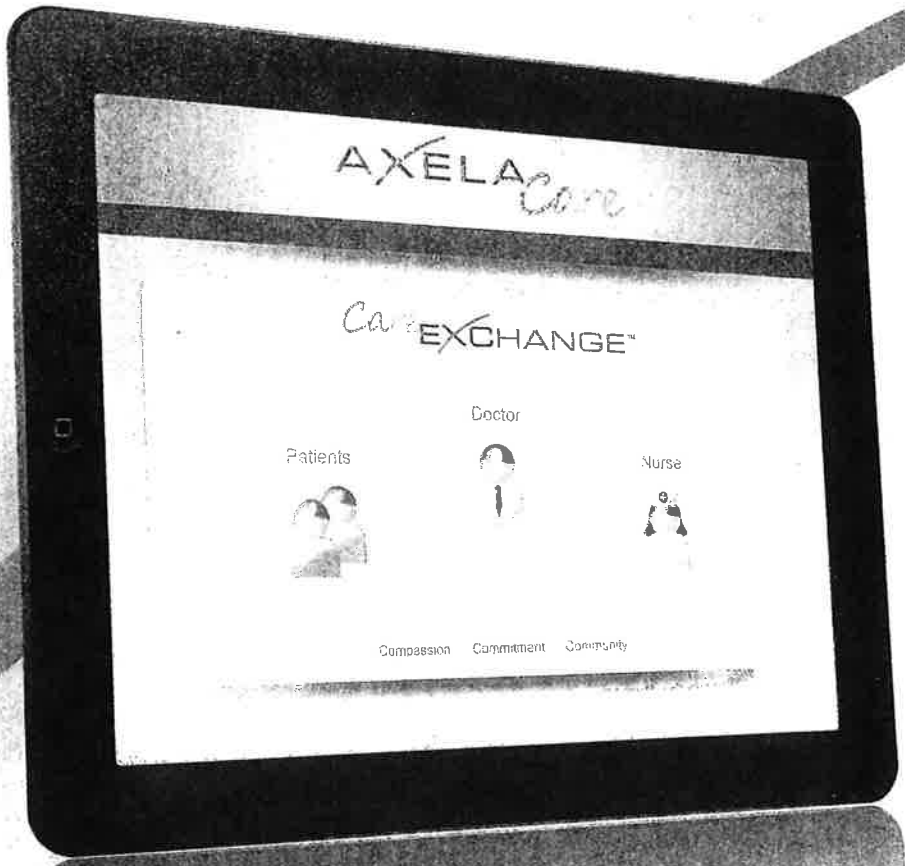
AXELA Care

Home Infusion Specialists

CareExchange™ for Managed Care

Better...

- Patient Outcomes
- Drug Optimization
- Cost Savings



Experience. The Difference.

Who We Are

AxelaCare is a patient-focused, in-home provider of Immune Globulin (IgG) and other specialized intravenous infusion medicines. We provide comprehensive service and support for people with complex and chronic medical needs including medications, pharmacy services, treatment management, insurance support, home infusion nursing and patient advocacy. Our team strives to make the treatment process as affordable, comfortable, convenient and personal as possible, with the ultimate goal of improving our patients overall quality of life.

AxelaCare Home Infusion Service and Support includes:

- Specialized Home Infusion
- Pharmacy and Nursing
- Patient Advocacy and Reimbursement Support
- Home Infusion - Antibiotics, Etc.
- Total Parenteral Nutrition
- Immune Globulin (IgG) Therapy
- Administrative Services
- Treatment Management
- Patient Education
- Care Provider Resources
- Clinical Care Research Initiatives

CareExchange™.. Immune Therapy Monitoring System

AxelaCare is entirely focused on improving patient outcomes and helping them to achieve a better quality of life. CareExchange™ a new technology-driven research tool, ensures our success in this critical area.

CareExchange was built and designed with expert input from thought leaders in, Immune Globulin, pharmacy, nursing, peripheral neuropathy, neurology, immunology and many others. This outcomes management tool captures and tracks data about the treatment of rare and complex diseases and patients' responses to them.

Ultimately, our main goal is simple: We strive every day to achieve better outcomes for our patients.

Cost vs. Benefit Analysis

Published data has shown a significant number of IVIg patients (natural responders) can come off of therapy and retain the treatment benefits. Identifying these patients is only possible by diligently tracking patient outcomes.

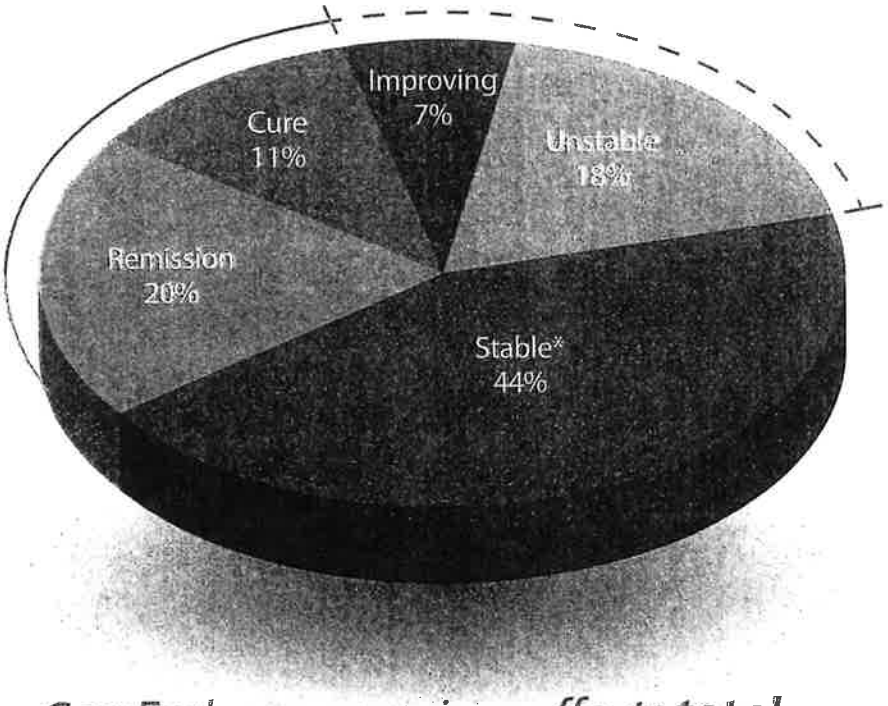
We can help you manage costly infusion medications while providing optimal patient outcomes.

Partnership with AxelaCare also gives your members access to the CareExchange home infusion outcomes management tool, a bedside, patient reporting treatment resource that provides:

- Tenured and educated professional infusion nurses
- Proven compliance (JCAHO Gold Seal of Approval)
- Higher patient and physician satisfaction and performance
- Better patient outcomes resulting in lower expected ancillary costs
- Data for physicians to more quickly identify natural and non-responders

CIDP (Peripheral Neuropathy Example) - Long-Term Response to IVIg Therapy (2010 U.S. Data)

Targeted CareExchange™ Savings



Cure > 5 years	11%
Remission < 5 years	20%
Stable, Active	44%
Improving	7%
Unstable Active Disease	18%
Treatment Naive	6%
Off Treatment	7%
On Treatment	5%

* Stable: Patients on long-term IVIg Therapy

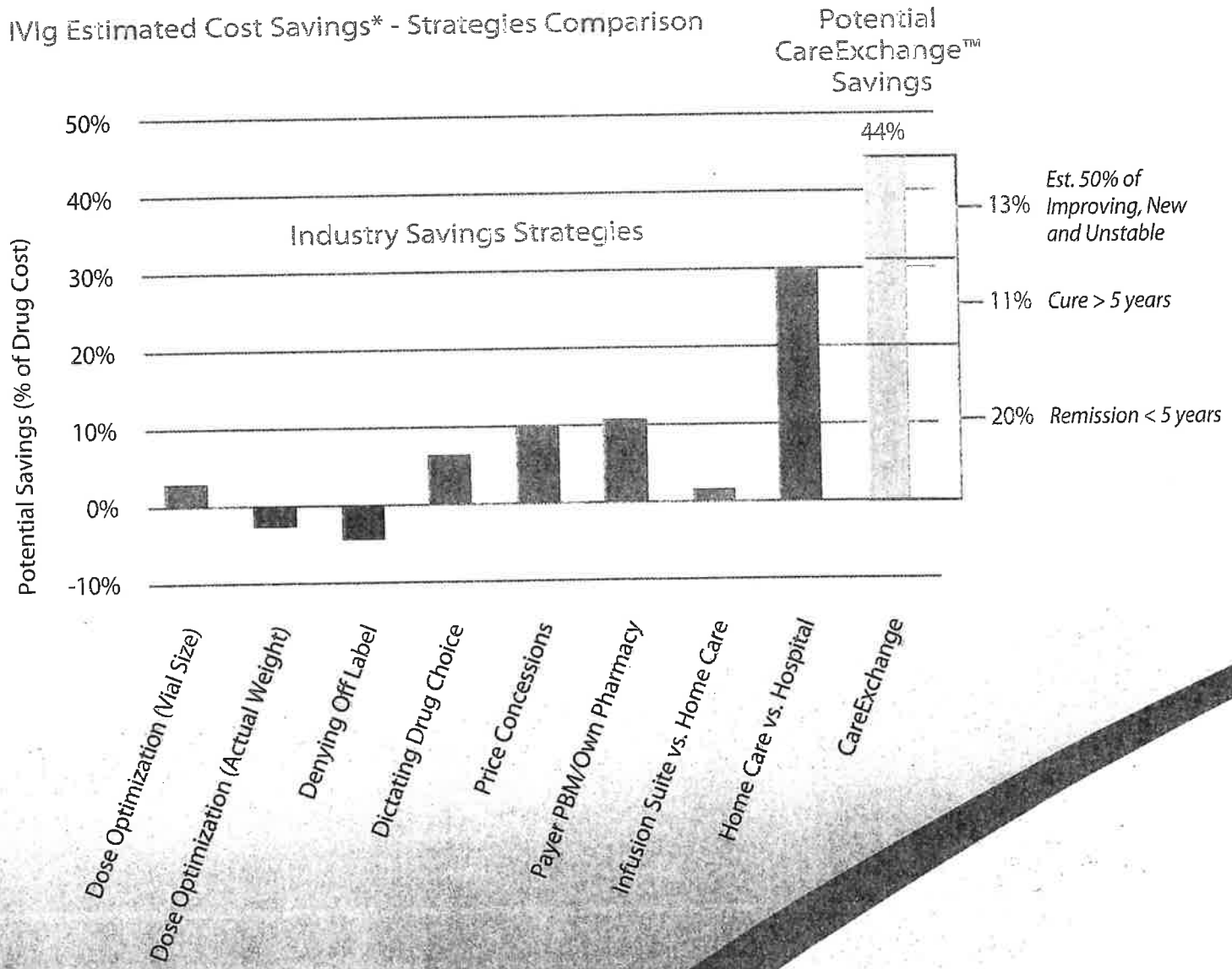
*CareExchange™ savings effects **total** volume of drug, not incremental price concessions.*

Just like other home infusion providers, AxelaCare has all of these strategies at our disposal. However, we are the only company that has CareExchange. CareExchange is the cost-savings strategy that has the most profound impact on the **total** cost of home infusion therapy.

CareExchange has the inherent ability to identify patients who are not responding to IgG therapy and enhance the treatment for those who do need it.

CareExchange outcomes management technology provides the right patients, the right dose at the right frequency, for the right treatment length.

We believe a reduction in the cost of care should not have to result in a reduction in quality and service. The patient is at the heart of all we do and CareExchange was designed with the patient in mind. CareExchange is an extension of the compassionate care AxelaCare is known for.



* Based on published costs and AxelaCare analysis of market prices for IgG, nursing and pharmacy services.

The features of CareExchange™ innovation include:

- Web-based, wireless connectivity for immediate data upload and access
- Simple iPad data collection tool for nurse and patient ease-of-use
- Dose vs. outcomes analysis and graphs
- Validated outcomes assessments, including:

Physical Assessments

- Timed Up and Go (TUGS), Grip Strength (Jamar)

Disability Scores

- RODS, ONLS, mFSS (Fatigue), VAS (Pain)

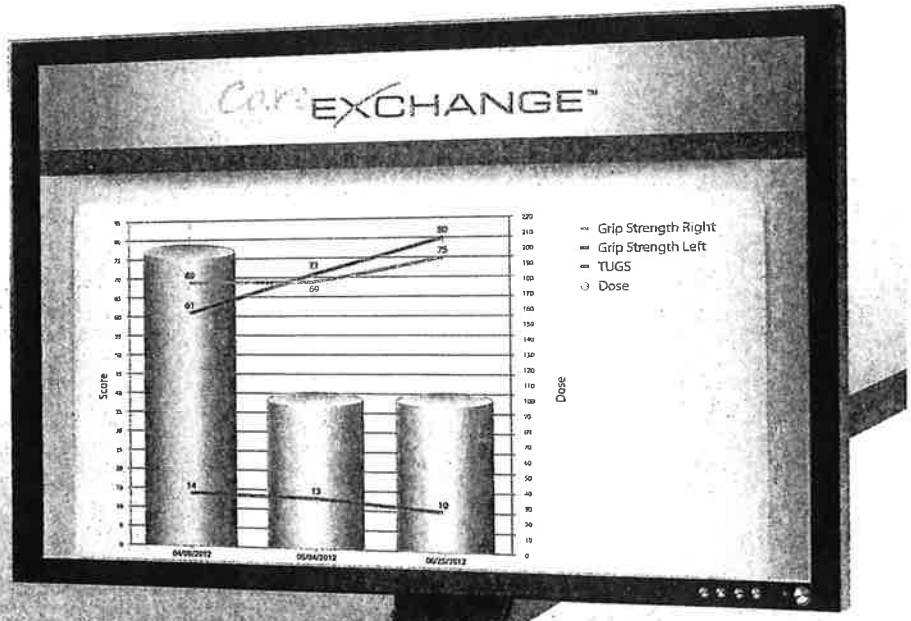
Quality of Life Measures

- SF-36

Superior care at a lower cost. CareExchange™ creates a win-win-win for patients, healthcare professionals and Managed Care companies.

At-home infusion costs are typically 30% less than in-hospital treatments, as a result lowering the financial burden while providing convenience and comfort for the patient.

CareExchange makes home infusion an even more desirable treatment option, as the resulting data empowers physicians with the information needed to optimize dosing, determine the best therapy strategies, and identify natural and non-responders.



g. Use of Patient Data for Research

The AxelaCare program does not end with completion of the dosing. With patient consent, the clinical data gathered by CareExchange is compiled centrally at AxelaCare and is used to advance medical knowledge in this complex and evolving area of care. It is used in clinical trials with independent researchers. It is used in research published in clinical journals and in seminars presented at professional gatherings.

AxelaCare is currently working on clinical trials and journal publications with medical staff at Northwestern University, the University of Minnesota, the University of Virginia, Columbia University Medical Center, the University of Kansas and the "Neurology at John's Creek" practice group in Georgia. AxelaCare's ongoing contributions to clinical research is one of the special benefits of permitting AxelaCare to expand across Tennessee. Its program will contribute to the orderly development of more effective healthcare services not only in Tennessee, but also throughout the field of infusion medicine.

h. Examples of Disorders That Often Require Immune Globulin (IVIG) Therapy

• Peripheral neuropathy--This is a disorder of the peripheral nervous system (the system connecting the brain and spine to limbs, muscles, skin, and internal organs). It affects approximately 60% of all diabetics. Symptoms often start in the fingers and toes, and can include muscle weakness and even paralysis if motor nerves are affected. Other symptoms may include burning pain in the hands and feet; sharp electric shock pains; problems in gripping; sensitivity to pain, touch and temperature; bowel and bladder dysfunction; sweating; and abnormal blood pressure.

• Small fiber neuropathy--Most prevalent among the elderly and many diabetics (50% prevalence), this peripheral nervous system disorder most often starts with numbness in the toes and a burning sensation in the feet. It is often worse at night, creating sleep difficulties. It may develop into pain and burning, or loss of feeling, or "pins and needles" feelings or numbness in hands and feet. It may cause cramping, fatigue, inability to sweat, dry eyes, dizziness, difficulty in breathing, difficulty with elimination and increased heart rate.

• Primary immunodeficiency (PIDD)--There are over 200 types of PIDD, and they are inherited disorders all involving a shortage of antibodies that result in more frequent sicknesses and decreased ability to get better from an infection. Maladies typically experienced include frequent pneumonia and bronchitis, ear and sinus infections, sore throats, coughs, colds and flu, fungal infections, rare viruses and slowness of wound healing. In children, PIDD can also result in slow growth and below-normal weight.

• Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)--This disorder is very difficult to correctly diagnose. It afflicts men at twice the rate of women. It is a chronic disorder requiring long-term treatment. Symptoms can be mild or can progress to the point where they impair motor skills. Symptoms may include weakness of loss of feeling in extremities; difficulty of movement in climbing stairs or standing on tip-toe; weakness of hands; loss of balance; and sensations of numbness, tingling, prickling or burning.qq

• Guillain-Barre Syndrome (GBS)--This is rare illness of unknown origin. Patient symptoms typically begin as weakness or tingling in the feet and legs, spreading in an upward direction through arms, legs and torso. Extreme cases can result in paralysis. Potential symptoms include

unsteadiness and clumsiness in walking; muscle contraction and blurred vision; back pain; difficulty in eye movement, facial movement, speaking, chewing or swallowing; and breathing difficulty when diaphragm and chest areas are affected.

• Multifocal Motor Neuropathy (MMN)--This rare muscle disorder causes increasing muscle weakness over time. It is often misdiagnosed as ALS or Lou Gehrig's Disease. Its symptoms include muscle cramps, wasting and shrinkage; involuntary twitching and spasms; numbness and tingling; difficulty getting up from a seated position and in climbing steps.

• Myasthenia Gravis (MG)-- This disorder is rare, most often affecting men over 60 years of age and women under 40. Persons with this condition may have difficulty in breathing, chewing, swallowing, climbing steps, lifting and gripping objects, speaking and rising from a seated position. They may often suffer from weak arm and chest muscles, drooping head or eyes, fatigue, double vision and balance issues.

• Multiple Sclerosis (MS)--Most commonly diagnosed between the ages of 20 and 40, MS symptoms vary from mild to severe. If is difficult to predict the onset or affects of patients; symptoms are often triggered by events such as fevers, hot baths, sun exposure or stress. Symptoms include blurred or double vision or vision loss; distorted perception of red/green colors; tremors; pain; "pins and needles" feelings in spots; and difficulty walking or getting up from a seated position. Other symptoms may include arm and leg weakness; coordination and balance problems; spasms; dizziness; loss of sensation; hearing loss; issues of bowel and bladder control; and fatigue and depression. Patients may have periods of relief of symptoms; or the symptoms may get progressively worse with few or no remission periods.

i. FDA-Approved Uses of IVIG

Infusion products have different FDA-approved indications. Please see the chart on the following page for some major examples. Also see the "Miscellaneous" attachment to the application, for a summary of eight clinical indications for which IVIG has been licensed by the FDA.

Product	Manufacturer	Indications
Gammagard Liquid	Baxter Healthcare Corporation	• Primary Humoral Immunodeficiency • Multifocal Motor Neuropathy
Gammagard S/D	Baxter Healthcare Corporation	• Primary Humoral Immunodeficiency • B-cell Chronic Lymphocytic Leukemia • Immune Thrombocytopenic Purpura • Kawasaki syndrome
Gammaplex	Bio Products Laboratory	• Primary Humoral Immunodeficiency • Immune Thrombocytopenic Purpura
Bivigam	Biotest Pharmaceuticals Corporation	• Primary Humoral Immunodeficiency
Carimune NF	CSL Behring AG	• Primary Humoral Immunodeficiency • Immune Thrombocytopenic Purpura
Privigen	CSL Behring AG	• Primary Humoral Immunodeficiency • Immune Thrombocytopenic Purpura
Gamunex-C Gammaked (Distributed by: Kedrion Biopharma)	Grifols Therapeutics, Inc.	• Primary Humoral Immunodeficiency • Immune Thrombocytopenic Purpura • Chronic Inflammatory Demyelinating Polyneuropathy
Flebogamma DIF 5% & 10%	Instituto Grifols, SA	• Primary Humoral Immunodeficiency
Octagam	Octapharma Pharmazeutika Produktionsges.m.b.H	• Primary Humoral Immunodeficiency

j. Investigational Studies and Off-Label Uses of IVIG

The applicant is not involved with any investigational studies. The applicant fulfills physician prescriptions of the infusion pharmaceuticals when a referral is made. Physicians currently prescribe IG (immune globulin) for both FDA-approved uses and "off-label" indications, which is considered appropriate. Please refer to the excerpt below from another publication, and see the UnitedHealth IVIG Policy document in the Attachments, which governs AxelaCare's use of IVIG for various complex patient conditions. It should be noted that commercial insurance carriers reimburse for non-FDA approved ("off-label") uses of IVIG. Each commercial carrier does so in compliance with its corporate medical policies for approval and use of IG, based on diagnosis and supporting documentation. As an example, the applicant has attached UnitedHealth's policy document in the Attachments.

"Off-Label Indications:
The number of off-label uses for IG far exceeds that of labeled indications. Although IG has been proven useful for many disease states, the likelihood of manufacturers pursuing FDA approval for already treated indications is remote given the high cost of conducting trials without the benefit of increased marketing advantages. The sometimes tenuous and limited supply of IG, combined with the high costs of treatment, require best practice standards be used when deciding to treat with IG. Some diseases commonly treated off label with IVIG are Guillain-Barré syndrome, polymyositis, dermatomyositis, multifocal motor neuropathy, stiff person syndrome, relapsing-remitting multiple sclerosis and pemphigus. Anecdotal reports suggest IVIG is effective in treating autoimmune neutropenia, autoimmune hemolytic anemia, Evans syndrome and acquired hemophilia, especially when other therapeutic modalities fail.

Indications Under Current Research
Many studies are currently being conducted to look at the efficacy of IG in non-FDA-approved indications. Three specific areas that are being explored, for which IG is not used as a standard of care, include Alzheimer's, secondary recurrent miscarriage and chronic regional pain syndrome.

Alzheimer's. IVIG appears to have promising effects for both reducing the risk of developing Alzheimer's, as well as improving the cognitive ability of those suffering from it. Results of a study presented at the International Alzheimer's Symposium in 2008 showed that the risk of developing Alzheimer's disease and related disorders (ADRD) may be reduced by about 40 percent in patients previously treated with IVIG. As of early 2009, several small clinical trials have shown promising results for treating Alzheimer's with IVIG. In March 2010, results of a Phase 2 clinical trial suggests that treatment with IVIG is associated with a reduction in ventricular enlargement rates and cognitive decline in patients with mild to moderate Alzheimer's. In the study, uninterrupted treatment with IVIG for 18 months was associated with about half the rate of ventricular enlargement reflecting brain atrophy versus a placebo, along with better scores on neuropsychological testing. A pivotal Phase 3 study is now enrolling patients from 35 sites throughout the United States.

Secondary recurrent miscarriage. Several clinical trials have been conducted to determine whether IVIG is an effective treatment for recurrent miscarriage. While clinical trials are still ongoing, one particular study consisted of a systematic review of randomized controlled trials, comparing all dosages of IVIG to a placebo or an active control. The study looked at eight trials involving 442 women that evaluated IVIG therapy used to treat recurrent miscarriage. The findings showed that, overall, IVIG did not significantly increase the odds ratio of live birth when compared with a placebo for treatment of recurrent miscarriage. However, there was a significant increase in live births following IVIG use in women with secondary recurrent miscarriage, while those with primary miscarriage did not experience the same benefit.

Chronic regional pain syndrome (CRPS). Most recently, a small study found IVIG effective for alleviating CRPS, which causes chronic and often intractable pain, usually in the arm or leg, long after recovery from an illness. Researchers at the Pain Research Institute at the University of Liverpool in England administered a half gram of IVIG per kilogram of body weight to 13 people who had been suffering from CRPS between six and 30 months and who reported pain intensity of at least five on an 11-point scale for seven consecutive months. All had failed to achieve significant relief from other conventional treatments. After being treated with IVIG, five of the 12 subjects reported median pain scores at least two points lower, and three of the five reported pain scores at least 50 percent lower.

Other diseases. There also are case reports and open label trials that show IVIG benefits some patients with rheumatoid arthritis, anti-neutrophil cytoplasmic antibody disorders, systemic sclerosis/scleroderma and Still's disease."

A-4A
Legal Status and Ownership Structure of Applicant

FEB 13 '17 PM 2:04

UnitedHealth Group Incorporated
EIN: 41-1321939
100 % Owner of United HealthCare Services, Inc.
9900 Bren Road, East, Minnetonka, MN 55343-9664

United HealthCare Services, Inc.
EIN: 41-1289245
100% Owner of Optum, Inc.
9900 Bren Road East, Minnetonka, MN 55343-9664

Optum, Inc.

EIN: 30-0580620
100 % Owner of OptumRX, Holdings, LLC.
9900 Bren Road East, Minnetonka, MN 55343-9664

OptumRX Holdings, LLC
N/A
100 % Owner of OptumRX, Inc.
9900 Bren Road East, Minnetonka, MN 55343-9664

OptumRX, Inc
(California)
EIN: 30-0441200
100% Owner of AxlelaCare Intermediate Holdings, Inc.
9900 Bren Road East, Minnetonka, MN 55343-9664

AxelaCare Intermediate Holdings, LLC
(Delaware)
EIN: 30-0842394

100% owner of AxelaCare, LLC
15529 College Blvd, Lenexa, KS 66219

AxelaCare, LLC
(Delaware)
EIN: 61-1708598

100% owner of AxelaCare Holdings, Inc
15529 College Blvd., Lenexa, KS 66219

Briova Rx Infusion Services, Inc.
(Delaware)
EIN: 27-3918706

100% Owner of (Unknown), LLC
15529 College Blvd., Lenexa, KS 66219

AxelaCare Health Solutions, LLC
(Delaware)
15529 College Blvd, Lenexa, KS 66219
EIN: Unknown

AxelaCare Health Solutions, LLC

Lenexa, KS

has been Accredited by

The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Home Care Accreditation Program

April 18, 2015

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD
Chair, Board of Commissioners

ID #473713
Print/Reprint Date: 08/03/2015

Mark R. Chassin, MD, FACP, MPP, MPH
President

The Joint Commission is an independent, not-for-profit national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at www.jointcommission.org.

Tennessee
Secretary of State
Tre Hargett

Business Services Online > Find and Update a Business Record

Business Information Search

As of February 07, 2017 we have processed all corporate filings received in our office through February 06, 2017 and all annual reports received in our office through February 06, 2017.

Click on the underlined control number of the entity in the search results list to proceed to the detail page. From the detail page you can verify the entity displayed is correct (review addresses and business details) and select from the available entity actions - file an annual report, obtain a certificate of existence, file an amendment, etc.

Search: 1-1 of 1

Search Name: AxelaCare Health Solutions, LLC ( ) Starts With (•) Contains

Control #:

Active Entities Only: ☐

Search

Control #	Entity Type	Name	Name Type	Name Status	Entity Filing Date	Entity Status
000842223	LLC	AxelaCare Health Solutions, LLC *DELAWARE*	Entity	Active	04/04/2016	Active

1-1 of 1

Information about individual business entities can be queried, viewed and printed using this search tool for free.

If you want to get an electronic file of all business entities in the database, the full database can be downloaded for a fee by Clicking Here.

Click Here for information on the Business Services Online Search logic.

Division of Business Services
312 Rosa L. Parks Avenue, Snodgrass Tower, 6th Floor
Nashville, TN 37243
615-741-2286
8:00 a.m. until 4:30 p.m. (Central) Monday - Friday.
Directions | State Holidays | Methods of Payment

Business Filings and Information (615) 741-2286 | TNSOS.CORPINFO@tn.gov
Certified Copies and Certificate of Existence (615) 741-6488 | TNSOS.CERT@tn.gov
Motor Vehicle Temporary Liens (615) 741-0529 | TNSOS.MVTL@tn.gov
Notary Commissions (615) 741-3699 | TNSOS.ATS@tn.gov
Uniform Commercial Code (UCC) (615) 741-3276 | TNSOS.UCC@tn.gov
Workers' Compensation Exemption Registrations (615) 741-0526 | TNSOS.WCER@tn.gov
Apostilles & Authentications (615) 741-0536 | TNSOS.ATS@tn.gov
Summons (615) 741-1799 | TNSOS.ATS@tn.gov
Trademarks (615) 741-0531 | TNSOS.ATS@tn.gov
Nonresident Fiduciaries (615) 741-0536 | TNSOS.ATS@tn.gov

APPLICATION FOR CERTIFICATE OF AUTHORITY LIMITED LIABILITY COMPANY (ss-4233)

Business Services Division
Tre Hargett, Secretary of State
State of Tennessee
312 Rosa L. Parks AVE, 6th Fl.
Nashville, TN 37243-1102
(615) 741-2286

Filing Fee: $50.00 per member
(minimum fee = $300, maximum fee = $3,000)

For Office Use Only

FILED

To The Secretary of the State of Tennessee:
Pursuant to the provisions of T.C.A. §48-249-904 of the Tennessee Revised Limited Liability Company Act, the undersigned hereby applies for a certificate of authority to transact business in the State of Tennessee, and for that purpose sets forth:

1. The name of the Limited Liability Company is: AxelaCare Health Solutions, LLC

   If different, the name under which the certificate of authority is to be obtained is: _____

NOTE: The Secretary of State of the State of Tennessee may not issue a certificate of authority to a foreign Limited Liability Company if its name does not comply with the requirements of T.C.A. §48-249-106 of the Tennessee Revised Limited Liability Company Act. If obtaining a certificate of authority under an assumed Limited Liability Company name, an application must be filed pursuant to T.C.A. §48-249-106(d).

2. The state or country under whose law it is formed is: Delaware

   and the date of its formation is: 05 / 05 / 2008 (Month / Day / Year) and the date it commenced doing business in Tennessee is: ___ / ___ / ___ (Month / Day / Year)

   NOTE: Additional filing fees and proof of tax clearance confirming good standing may apply if the Limited Liability Company commenced doing business in Tennessee prior to the approval of this application. See T.C.A. §48-249-913(d) and T.C.A. §48-249-905(c)

3. This company has the additional designation of:

4. The name and complete address of its registered agent and office located in the state of Tennessee is:

   Name: Corporation Service Company
   Address: 2908 Poston Avenue
   City: Nashville State: TN Zip Code: 37203 County: Davidson

5. Fiscal Year Close Month: December

6. If the document is not to be effective upon filing by the Secretary of State, the delayed effective date and time is: (Not to exceed 90 days)

   Effective Date: ___ / ___ / ___ (Month / Day / Year) Time: _____

7. The LLC will be: ☒ Member Managed ☐ Manager Managed ☐ Director Managed ☐ Board Managed ☐ Other

8. Number of Members at the date of filing: 1

9. Period of Duration: ☒ Perpetual ☐ Other ___ / ___ / ___ (Month / Day / Year)

10. The complete address of its principal executive office is:

    Address: 15529 College Boulevard
    City: Lenexa State: KS Zip Code: 66219

APPLICATION FOR CERTIFICATE OF AUTHORITY
LIMITED LIABILITY COMPANY (ss-4233)

Business Services Division
Tre Hargett, Secretary of State
State of Tennessee
312 Rosa L. Parks AVE, 6th Fl.
Nashville, TN 37243-1102
(615) 741-2286

Filing Fee: $50.00 per member
(minimum fee = $300, maximum fee = $3,000)

For Office Use Only

The name of the Limited Liability Company is: AxelaCare Health Solutions, LLC

11. The complete mailing address of the entity (If different from the principal office) is:

Address: _____

City: _____ State: _____ Zip Code: _____

12. Non-Profit LLC (required only if the Additional Designation of "Non-Profit LLC" is entered in section 3.)

☐ I certify that this entity is a Non-Profit LLC whose sole member is a nonprofit corporation, foreign or domestic, incorporated under or subject to the provisions of the Tennessee Nonprofit Corporation Act and who is exempt from franchise and excise tax as not-for-profit as defined in T.C.A. §67-4-2004. The business is disregarded as an entity for federal income tax purposes.

13. Professional LLC (required only if the Additional Designation of "Professional LLC" is entered in section 3.)

☐ I certify that this PLLC has one or more qualified persons as members and no disqualified persons as members or holders.

☐ I certify that this entity meets the requirement of T.C.A. §48-249-1123(b)(3)

Licensed Profession: _____

14. Series LLC (required only if the Additional Designation of "Series LLC" is entered in section 3.)

☐ I certify that this entity meets the requirements of T.C.A. §48-249-309(i)

If the provisions of T.C.A. §48-249-309(i) (relating to foreign series LLCs) apply, then the information required by that section should be attached as part of this document.

15. Obligated Member Entity (list of obligated members and signatures must be attached)

☐ This entity will be registered as an Obligated Member Entity (OME) Effective Date: ____/____/____ (Month Day Year)

☐ I understand that by statute: THE EXECUTION AND FILING OF THIS DOCUMENT WILL CAUSE THE MEMBER(S) TO BE PERSONALLY LIABLE FOR THE DEBTS, OBLIGATIONS AND LIABILITIES FOR THE LIMITED LIABILITY COMPANY TO THE SAME EXTENT AS A GENERAL PARTNER OF A GENERAL PARTNERSHIP. CONSULT AN ATTORNEY.

16. Other Provisions: _____

3/31/2016
Signature Date

Signature

Member
Signer's Capacity (if other than individual capacity)

Edward Kramm
Name (printed or typed)

STATE OF TENNESSEE
Tre Hargett, Secretary of State
Division of Business Services
William R. Snodgrass Tower
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

AxelaCare Health Solutions, LLC
15529 COLLEGE BLVD
LENEXA, KS 66219-1351

April 4, 2016

Filing Acknowledgment

Please review the filing information below and notify our office immediately of any discrepancies.

SOS Control # :	**000842223**	Formation Locale:	DELAWARE
Filing Type:	Limited Liability Company - Foreign	Date Formed:	05/05/2008
Filing Date:	04/04/2016 10:16 AM	Fiscal Year Close:	12
Status:	Active	Annual Report Due:	04/01/2017
Duration Term:	Perpetual	Image # :	B0230-0234
Managed By:	Member Managed		

Document Receipt

Receipt # : 002615601	Filing Fee:	$300.00
Payment-Check/MO - CFS-1, NASHVILLE, TN		$300.00

Registered Agent Address:
CORPORATION SERVICE COMPANY
2908 POSTON AVE
NASHVILLE, TN 37203-1312

Principal Address:
15529 COLLEGE BLVD
LENEXA, KS 66219-1351

Congratulations on the successful filing of your **Application for Certificate of Authority** for **AxelaCare Health Solutions, LLC** in the State of Tennessee which is effective on the date shown above. Please visit the Tennessee Department of Revenue website (apps.tn.gov/bizreg) to determine your online tax registration requirements. If you need to obtain a Certificate of Existence for this entity, you can request, pay for, and recieve it from our website.

You must file an Annual Report with this office on or before the Annual Report Due Date noted above and maintain a Registered Office and Registered Agent. Failure to do so will subject the business to Administrative Dissolution/Revocation.

Tre Hargett
Secretary of State

Processed By: Jeff Cook

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AXELACARE HEALTH SOLUTIONS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF APRIL, A.D. 2016.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "AXELACARE HEALTH SOLUTIONS, LLC" WAS FORMED ON THE FIFTH DAY OF MAY, A.D. 2008.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4543052 8300

SR# 20162024445

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202079807

Date: 04-01-16

Licensed Facilities

Last Updated: 4/15/2016 1:40:11 AM

For more information, please contact:
Health Care Facilities: (615)741-7221 or 1-888-310-4650

Current Listings:

Type = Manufacturer/Wholesaler/Distributor *County* = All *Name* = AxelaCare

Click here to return to the search page

Total Facilties:1

1.
AXELACARE HEALTH
SOLUTIONS LLC
15529 COLLEGE BLVD.
Lenexa , KS 66215
Attn: TIM WILSON
(877) 342-9352
Rank:

Administrator:
Owner Information:

Facility License Number: 00003281
Status: Licensed
Date of Last Survey:
Accreditation Expires:
Date of Original Licensure: 07/20/2010
Date of Expiration: 03/31/2017

RECEIVED APR 13 2015

41352

STATE OF TENNESSEE
DEPARTMENT OF
HEALTH

ID NUMBER: 0000004637
EXPIRATION DATE: 03/31/2017

This is to certify that all requirements of the State of Tennessee have been met.

PHARMACY BOARD
PHARMACY
AXELACARE HEALTH SOLUTIONS, LLC

Rosemarie Otto
DIRECTOR, HEALTH RELATED BOARDS

AXELACARE HEALTH SOLUTIONS, LLC
15529 COLLEGE BLVD.
LENEXA KS 66219-1351

9544722

41352

State of Tennessee

TENNESSEE BOARD OF PHARMACY
PHARMACY
AXELACARE HEALTH SOLUTIONS, LLC
15529 COLLEGE BLVD.
LENEXA KS 66219

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000004637
EXPIRATION DATE: 03/31/2017

CONTROLLED SUBSTANCE REGISTRATION

Rosemarie Otto
DIRECTOR, HEALTH RELATED BOARDS

DCF171

RECEIVED APR 07 2015

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive
Nashville, TN 37243
tennessee.gov/health

TENNESSEE BOARD OF PHARMACY
(615) 741-2718 or Fax (615) 741-2722

March 31, 2015

AxelaCare Health Solutions, LLC
15529 College Blvd.
Lenexa, KS 66219

RE: STERILE COMPOUNDING MODIFIER

To Whom It May Concern:

This letter certifies that AxelaCare Health Solutions, LLC is qualified to engage in the practices of sterile compounding under Tennessee rules and regulations. This qualification is specific to the following facility:

LICENSE TYPE:	Pharmacy
ADDRESS:	15529 College Blvd. Lenexa, KS 66219
LICENSE NUMBER:	4637

COMMENTS: Please keep a copy of this letter on file at your facility. Once the board has completed implementation of the sterile compounding modifier, an updated license will be mailed to the address on record.

Sincerely,
Ailene Lynn
Administrative Assistant II
Tennessee Board of Pharmacy

RECEIVED APR 13 2015

41352

STATE OF TENNESSEE
DEPARTMENT OF
HEALTH

ID NUMBER: 0000004637
EXPIRATION DATE: 03/31/2017

This is to certify that all requirements of the State of Tennessee have been met.

PHARMACY BOARD
PHARMACY
AXELACARE HEALTH SOLUTIONS, LLC

Rosemarie Otto
DIRECTOR, HEALTH RELATED BOARDS

AXELACARE HEALTH SOLUTIONS, LLC
15529 COLLEGE BLVD.
LENEXA KS 66219-1351

9544722

41352

State of Tennessee

TENNESSEE BOARD OF PHARMACY
PHARMACY
AXELACARE HEALTH SOLUTIONS, LLC
15529 COLLEGE BLVD.
LENEXA KS 66219

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000004637
EXPIRATION DATE: 03/31/2017

CONTROLLED SUBSTANCE REGISTRATION

Rosemarie Otto
DIRECTOR, HEALTH RELATED BOARDS

DCF171

9527533

20692

State of Tennessee

TENNESSEE BOARD OF PHARMACY
MANUFACTURER/WHOLESALER/DISTRIBUTOR
AXELACARE HEALTH SOLUTIONS LLC
15529 COLLEGE BLVD.
LENEXA KS 66215

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000003281
EXPIRATION DATE: 03/31/2017

Rosemarie Otto
DIRECTOR, HEALTH RELATED BOARDS

DCF171

eLicense

Kansas Board of Pharmacy
License Portal

Search Again

Facility/Provider Information

Board of Pharmacy Home | License Verification | Exam Scores

Kansas Pharmacy Board

The Kansas Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, as well as performing hourly updates to the information represented. Therefore, the website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board.

General

Name or Business:	AXELACARE HEALTH SOLUTIONS LLC	Original Date:	2/11/2015
City/State/Zip:	LENEXA, KS 66219		
Classification:	Pharmacy/Facility	On Probation:	No
L/P/R No:	2-13075 / 1.2	Discipline on File:	No
Status:	Active		

Licenses

L/P/R #	Description	Effective	Expires	Issued	Status
2-13075	Pharmacy Permit	6/6/2016	6/30/2017	2/11/2015	Active

Notes

N/A

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www.esoftwaresolutions.com

Kansas State Board of Pharmacy

Landon State Office Building
800 Jackson Avenue, Suite 1414
Topeka, Kansas 66612-1231
Phone (785) 296-4056
Fax (785) 296-8420

FEB 03 2016

Sam Brownback
Governor

Alexandra Blasi
Executive Secretary

AXELACARE HEALTH SOLUTIONS LLC
15529 COLLEGE BLVD
LENEXA KS 66219

Kansas State Board of Pharmacy
Retail Pharmacy Inspection Form

Pharmacy: AXELACARE HEALTH SOLUTIONS LLC **Reg No.:** 2-13075 **Renewal:** 6-16

Address: 15529 COLLEGE BLVD **City:** LENEXA **County:** JO **Phone:** (877) 342-9352

Pharmacist-in-Charge: DEBORA WAGNER **License#:** 1-12933 **DEA #:** FA0905705 /

Other Pharmacist:

Type: PHARMACY **Inspector:** MELISSA MARTIN

Pharmacy Records

- ☑ Prescription Files: (21 CFR 1304.04)
- ☑ Prescription Content:(KSA 65-1637(b), KARs 68-20-18(c), 68-20-20(a))
- ☑ Daily Print-out Dispensing Log: (KAR 68-9-1,21 CFRs 1304.04, 1306.22
- ☑ OTC Sales: (KAR 68-20-22)
- ☑ Invoice Record Files: (21 CFR 1304.04)
- ☑ Biennial Inventory: (21 CFRs 1304.11,1304.04)
- ☐ Incident Reports: (KAR 68-7-12)
- ☑ Duration of Record Keeping: (KAR 68-20-16(a))
- ☑ Library: (KARs 68-7-11(b), 68-7-11(i), 68-7-11(j)(2))
- ☐ Continuous Quality Improvement Documentation: (KSA 65-1695)

Security

- ☑ Pharmacy: (KSA 65-1637, KARs 68-1-8, 68-2-11)
- ☑ Controlled Substances: (21 CFR 1301.75)

Pharmacy Practice

- ☑ Consumer Counseling: (KAR 68-2-20)
- ☑ Technician to Pharmacist Ratio: (KSA 68-5-16)
- ☑ Documentation of Technician Training: (KAR 68-5-15)

Other Miscellaneous

- ☑ Prescription Labeling: (KAR 68-7-14)
- ☑ Prepackaging / Repackaging Labels: (KARs 68-7-15, 68-7-16)
- ☑ Necessary Equipment: (KSA 65-1642(a), KAR 68-2-12a(b))
- ☑ Display of Certificates / Persons on Duty: (KSAs 65-1645(e), 65-1642(b), KAR 68-2-15)

Comments: Spoke with Debora R.Ph please review CQI and Incident Report language to meet the requirements.

Date of Inspection: 1/22/2016

Kansas State Board of Pharmacy

Landon State Office Building
800 Jackson Avenue, Suite 1414
Topeka, Kansas 66612-1231
Phone (785) 296-4056
Fax (785) 296-8420

FEB 03 2016

Sam Brownback
Governor

Alexandra Blasi
Executive Secretary

AXELACARE HOLDINGS INC
15529 COLLEGE BLVD
LENEXA KS 66219

Kansas State Board of Pharmacy
Inspection Form
Distributor

Company: AXELACARE HOLDINGS INC **Reg No.:** 5-31275 **Renewal:** 6-16

Address: 15529 COLLEGE BLVD **City:** LENEXA **County:** JO **Phone:** (877) 342-9352

Person Responsible: DEBORA WAGNER **DEA #:** FA0905705 /

Type: DISTRIBUTOR **Inspector:** MELISSA MARTIN

Record Keeping

- [x] Distribution Records: (KARs 68-14-7(f) if applicable…68-14-8)
- [ ] Bi-ennial Inventory: (21 CFRs 1304.04, 1304.11)
- [x] Duration of Record Keeping: (KAR 68-14-7(f)(2))

Work Area

- [x] Facilities: (KAR 68-14-7(a))
- [x] Drug Storage / Quarantine Area: (KARs 68-14-7(a)(c)(e), 68-15-4)
- [x] Security: (KAR 68-14-7(b))
- [x] Examination of Materials: (KAR 68-14-7(d))

Comments:

Date of Inspection: 1/22/2016

Kansas State Board of Pharmacy

Landon State Office Building
800 Jackson Avenue, Suite 1414
Topeka, Kansas 66612-1231
Phone (785) 296-4056
Fax (785) 296-8420

RECEIVED
FEB 03 2016

Sam Brownback
Governor

Alexandra Blasi
Executive Secretary

AXELACARE HOLDINGS INC
15529 COLLEGE BLVD
LENEXA KS 66219

Kansas State Board of Pharmacy
Inspection Form
Distributor

Company: AXELACARE HOLDINGS INC **Reg No.:** 5-31275 **Renewal:** 6-16

Address: 15529 COLLEGE BLVD **City:** LENEXA **County:** JO **Phone:** (877) 342-9352

Person Responsible: DEBORA WAGNER **DEA #:** FA0905705 /

Type: DISTRIBUTOR **Inspector:** MELISSA MARTIN

Record Keeping

- ☑ Distribution Records: (KARs 68-14-7(f) if applicable…68-14-8)
- ☐ Bi-ennial Inventory: (21 CFRs 1304.04, 1304.11)
- ☑ Duration of Record Keeping: (KAR 68-14-7(f)(2))

Work Area

- ☑ Facilities: (KAR 68-14-7(a))
- ☑ Drug Storage / Quarantine Area: (KARs 68-14-7(a)(c)(e), 68-15-4)
- ☑ Security: (KAR 68-14-7(b))
- ☑ Examination of Materials: (KAR 68-14-7(d))

Comments:

Date of Inspection: 1/22/2016

RECEIVED
MAY 20 2015

NOTICE: Display this renewal with original certificate in a prominant location site

APPLICANT MAILING ADDRESS

DEBORA WAGNER
AXELACARE HEALTH SOLUTIONS LLC
15529 COLLEGE BLVD
LENEXA, KS 66219

Pharmacy
Certificate of Renewal of Permit

Original Permit #	2-13075
Pharmacy Name	AXELACARE HEALTH SOLUTIONS LLC
P.I.C. / Lic #	DEBORA WAGNER 1-12933
Address	15529 COLLEGE BLVD
City/State/Zip	LENEXA, KS 66219
Owner	AXELACARE HEALTH SOLUTIONS LLC

KANSAS STATE BOARD OF PHARMACY

Debra L. Billingsley
Executive Secretary
(785) 296-4056

2015 - 2016
Expires June 30, 2016
(This is a renewal, not an original registration)

RECEIVED APR 07 2015

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive
Nashville, TN 37243
tennessee.gov/health

TENNESSEE BOARD OF PHARMACY
(615) 741-2718 or Fax (615) 741-2722

March 31, 2015

AxelaCare Health Solutions, LLC
15529 College Blvd.
Lenexa, KS 66219

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ADDRESS:	15529 College Blvd. Lenexa, KS 66219
LICENSE NUMBER:	4637

COMMENTS: Please keep a copy of this letter on file at your facility. Once the board has completed implementation of the sterile compounding modifier, an updated license will be mailed to the address on record.

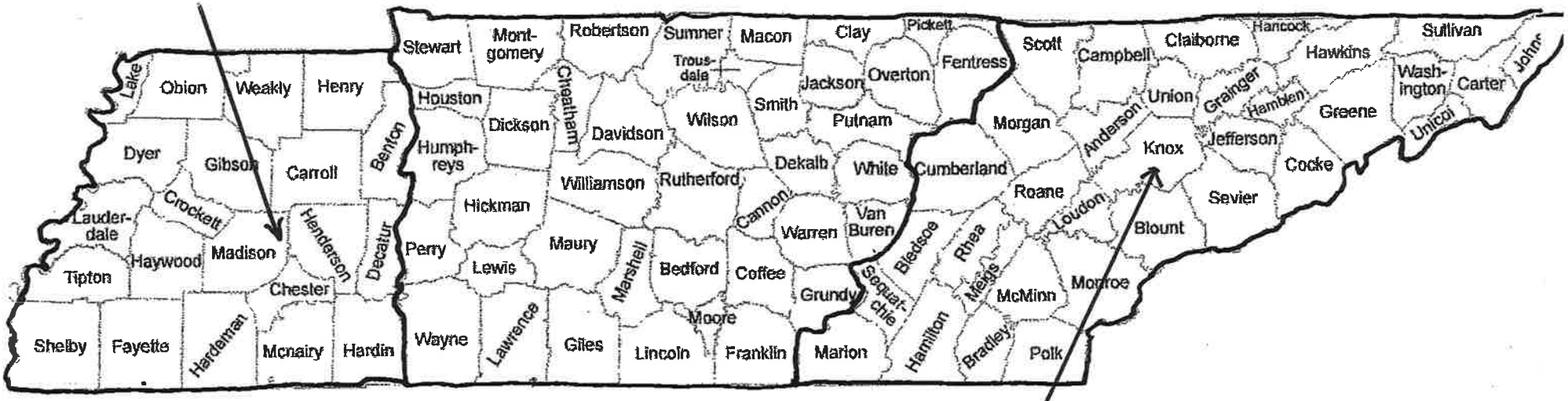
Sincerely,
Ailene Lynn
Administrative Assistant II
Tennessee Board of Pharmacy

B-Need-3

Service Area Map

AXELACARE HEALTH SOLUTIONS

CURRENT SERVICE AREA



Printable Maps From:
terproof Paper.com

PROPOSED EAST TENNESSEE EXPANSION

B-Need-5

Historic Utilization of Existing Agencies in Service Area

Table B.5-1A: Project Service Area Counties Authorized for Existing Home Health Agencies--BY AGENCY NAME

Health Statistics ID	Agency County	License Number	Agencies (76)	Anderson	Bledsoe	Blount	Bradley	Campbell	Carter	Claiborne	Cocke	Cumberland	Grainger	Greene	Hamblen	Hamilton	Hancock	Hawkins
30021	Greene	86	Advanced Home Care, Inc.							x			x	x		x	x	
82051	Sullivan	249	Advanced Home Care, Inc.														x	
33423	Hamilton	457	Alere Women's and Children's Health, LLC	x	x	x	x	x	x	x	x		x	x	x	x	x	x	
26054	Franklin	82	Amedisys Home Care												x			
33103	Hamilton	113	Amedisys Home Health	x	x	x	x					x			x			
67024	Overton	191	Amedisys Home Health									x						
90121	Washington	273	Amedisys Home Health						x					x				x	
10031	Carter	23	Amedisys Home Health Care						x					x				x	
32102	Hamblen	91	Amedisys Home Health Care	x				x		x	x		x	x	x		x	x	
47202	Knox	150	Amedisys Home Health Care	x	x	x		x	x	x	x	x	x	x	x		x	x	
75064	Rutherford	5	Amedisys Home Health Care																
13022	Claiborne	25	Amedisys Home Health of Tennessee					x		x			x				x		
05012	Blount	213	Blount Memorial Hospital Home Health Services	x		x		x		x	x		x	x	x		x	x	
47062	Knox	144	Camellia Home Health of East Tennessee	x		x	x	x		x	x	x	x		x	x	x	x	
19724	Davidson	295	Careall									x							
47232	Knox	131	Careall Home Care Services			x													
89074	Warren	265	Careall Home Care Services		x														
33253	Hamilton	103	CHI Memorial Health at Home		x		x								x				
01032	Anderson	1	Clinch River Home Health	x				x											
33213	Hamilton	98	Continuecare Healthservices, Inc. I		x		x								x				
33383	Hamilton	108	Continuecare Healthservices, Inc. II		x		x								x				
19734	Davidson	624	Coram CVS Specialty Infusion Services		x							x			x				
47402	Knox	133	Covenant Homecare	x		x		x		x	x	x	x		x				
14024	Clay	135	Cumberland River Homecare									x							
52024	Lincoln	161	Deaconess Homecare		x							x							
76032	Scott	211	Deaconess Homecare					x											
95034	Wilson	282	Deaconess Homecare I									x							
47222	Knox	132	East Tennessee Children's Hospital Home Health	x		x		x		x	x		x		x				
19494	Davidson	42	Elk Valley Health Services	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
26024	Franklin	83	Encompass Home Health of Tennessee		x		x					x				x			
06043	Bradley	13	Family Home Care - Cleveland				x									x			
33093	Hamilton	100	Gentiva Health Services		x		x									x			
47042	Knox	142	Gentiva Health Services	x		x		x			x				x				
82061	Sullivan	251	Gentiva Health Services						x					x	x		x	x	
47182	Knox	149	Gentiva Health Services 2 (Girling Health Services)	x	x	x		x		x	x	x	x	x	x		x	x	
33083	Hamilton	115	Guardian Home Care, LLC				x									x			
34011	Hancock	117	Hancock County Home Health and Hospice Agency							x			x				x	x	
71014	Putnam	197	Highland Rim Home Health Agency									x							
33363	Hamilton	338	Home Care Solutions		x		x									x			
19544	Davidson	56	Home Care Solutions, Inc.	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
06063	Bradley	14	Home Health Care of East Tennessee, Inc.		x		x									x			
37021	Hawkins	320	Hometown Home Health, Inc.										x				x	x	
	Knox	633	Implanted Pump Management	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	

Table B.5-1A: Project Service Area Counties Authorized for Existing Home Health Agencies--BY AGENCY NAME

Health Statistics ID	Jefferson	Johnson	Knox	Loudon	Marion	McMinn	Meigs	Monroe	Morgan	Polk	Rhea	Roane	Scott	Sequatchie	Sevier	Sullivan	Unicoi	Union	Washington	Number of Counties Served
30021													x			x			x	8
82051																x			x	3
33423	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	33
26054					x									x						3
33103				x	x	x	x	x		x	x			x						14
67024									x			x	x							4
90121		x														x	x		x	7
10031		x														x	x		x	7
32102	x		x												x			x		13
47202	x		x	x				x	x			x	x		x	x	x	x	x	25
75064					x															1
13022																		x		5
05012	x		x	x				x				x			x		x	x	x	19
47062	x		x	x	x	x	x	x	x	x	x	x	x	x	x			x		27
19724																				1
47232			x	x				x	x			x								6
89074														x						2
33253					x	x	x			x	x			x						9
01032			x						x			x	x					x		7
33213					x	x	x				x			x						8
33383					x	x	x			x	x			x						9
19734					x						x			x						6
47402	x		x	x				x	x			x	x		x			x		17
14024																				1
52024									x		x	x								5
76032									x				x							3
95034																				1
47222	x		x	x				x	x			x	x		x			x		16
19494	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	34
26024					x	x	x				x			x						9
06043						x	x			x										5
33093					x	x	x	x		x	x			x						10
47042	x		x	x				x				x			x			x		12
82061		x														x	x		x	9
47182	x		x	x		x	x	x	x	x	x	x	x		x	x		x		26
33083						x	x			x				x						6
34011																				4
71014																				1
33363					x	x	x			x	x			x						9
19544	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	34
06063				x	x	x	x	x	x	x	x	x		x						13
37021																				3
	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	34

Table B.5-1A: Project Service Area Counties Authorized for Existing Home Health Agencies--BY AGENCY NAME

Health Statistics ID	Agency County	License Number	Agencies (76)	Anderson	Bledsoe	Blount	Bradley	Campbell	Carter	Claiborne	Cocke	Cumberland	Grainger	Greene	Hamblen	Hamilton	Hancock	Hawkins
62052	Monroe	190	Intrepid USA Healthcare Services	x		x	x	x		x			x					
71084	Putnam	198	Intrepid USA Healthcare Services									x						
89064	Warren	263	Intrepid USA Healthcare Services									x						
46031	Johnson	130	Johnson County Home Health.						x									
30041	Greene	88	Laughlin Home Health Agency								x			x	x			x
33433	Hamilton	613	Maxim Healthcare Services				x									x		
	Washington	629	Maxim Healthcare Services						x									
47432	Knox	2	Maxim Healthcare Services, Inc.	x		x		x		x	x		x	x	x		x	x
90081	Washington	269	Medical Center Homecare - Kingsport						x					x				x
90091	Washington	271	Medical Center Homecare Services						x					x				
33033	Hamilton	111	NHC Homecare		x		x									x		
47012	Knox	143	NHC Homecare	x		x		x		x	x		x		x			
54043	McMinn	166	NHC Homecare				x											
75024	Rutherford	208	NHC Homecare									x						
90131	Washington	267	NHC Homecare						x					x				x
19654	Davidson	471	Optum Women's and Children's Health, LLC									x						
	Davidson	632	Pentec Health	x	x	x	x	x	x	x	x	x	x	x	x			x
32132	Hamblen	10	Premier Support Services, Inc.	x		x	x	x	x	x	x		x	x	x	x	x	x
30051	Greene	87	Procare Home Health Services						x					x				
01042	Anderson	620	Professional Case Management of Tennessee	x		x		x		x		x	x		x			x
96030	London Co, KY	298	Professional Home Health Care Agency	x				x		x								
25044	Fentress	287	Quality Home Health	x		x						x						
25034	Fentress	80	Quality Private Duty Care			x						x						
15032	Cocke	27	Smoky Mountain Home Health and Hospice							x	x		x	x	x		x	x
07032	Campbell	16	Sunbelt Homecare	x				x		x							x	
16034	Coffee	29	Suncrest Home Health															
13032	Claiborne	93	Suncrest Home Health and Hospice					x		x	x		x	x	x		x	x
62062	Monroe	189	Sweetwater Hospital Home Health															
33303	Hamilton	109	Tennessee Home Health		x		x									x		
47092	Knox	151	Tennova Healthcare Home Health	x		x		x		x			x		x		x	
01052	Anderson	148	The Home Option by Hardin Health Care	x		x		x		x			x					
32122	Hamblen	153	Univ. of TN Med Cntr Home Health / Hospice Service	x		x		x		x	x		x	x	x		x	x
47132	Knox	156	UTMCK - Home Care Services: Hospice & Home Care	x		x		x		x	x		x		x			
			Agencies Available to Each County	27	20	25	22	27	16	27	22	24	26	23	25	22	21	26

Note: Hemophilia Preferred Care of West Tennessee licensed 7/15 but not yet assigned a State ID as of 6-10-16.

Source: Department of Health Licensure - 10/7/2015 (Updated 2/2/2016)

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Table B.5-1A: Project Service Area Counties Authorized for Existing Home Health Agencies--BY AGENCY NAME

Health Statistics ID	Jefferson	Johnson	Knox	Loudon	Marion	McMinn	Meigs	Monroe	Morgan	Polk	Rhea	Roane	Scott	Sequatchie	Sevier	Sullivan	Unicoi	Union	Washington	Number of Counties Served
62052			x	x		x	x	x			x	x	x					x		15
71084																				1
89064																				1
46031		x																		2
30041																			x	5
33433					x	x	x				x			x						7
		x														x	x		x	5
47432	x		x	x					x			x	x		x			x		18
90081		x														x	x		x	7
90091		x														x	x		x	6
33033					x	x	x				x			x						8
47012	x		x	x		x		x				x			x			x		15
54043				x		x	x	x		x	x	x								8
75024									x											2
90131		x														x	x		x	7
19654																				1
	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	33
32132	x	x	x	x		x	x	x	x	x	x	x	x		x	x	x	x	x	30
30051		x														x	x		x	6
01042	x		x	x			x	x	x		x	x	x		x			x		19
96030			x						x				x					x		7
25044			x	x					x		x	x	x							9
25034			x	x					x			x	x							7
15032	x														x	x	x		x	12
07032			x	x					x			x	x					x		10
16034					x									x						2
13032	x															x		x		11
62062				x		x	x	x				x								5
33303					x	x	x			x	x			x						9
47092	x		x	x					x			x	x		x			x		15
01052	x		x	x				x	x			x	x		x			x		14
32122	x		x	x					x			x	x		x			x		18
47132	x		x	x				x	x			x	x		x			x		16
	23	15	28	29	21	25	25	24	28	18	25	31	26	22	22	20	17	27	20	

Note: Hemophilia Preferred Care of West Tennessee licensed 7/15 but not yet assigned a State ID as of 6-10-16.

Source: Department of Health Licensure - 10/7/2015 (Updated 2/2/2016)

Table B.5-1B: Project Service Area Counties Authorized for Existing Home Health Agencies--BY AGENCY ID

Health Statistics ID	Agency County	License Number	Agencies (76)	Anderson	Bledsoe	Blount	Bradley	Campbell	Carter	Claiborne	Cocke	Cumberland	Grainger	Greene	Hamblen	Hamilton	Hancock	Hawkins
01032	Anderson	1	Clinch River Home Health	x				x										
01042	Anderson	620	Professional Case Management of Tennessee	x		x		x		x		x	x		x			x	
01052	Anderson	148	The Home Option by Hardin Health Care	x		x		x		x			x						
05012	Blount	213	Blount Memorial Hospital Home Health Services	x		x		x		x	x		x	x	x		x	x	
06043	Bradley	13	Family Home Care - Cleveland				x									x			
06063	Bradley	14	Home Health Care of East Tennessee, Inc.		x		x									x			
07032	Campbell	16	Sunbelt Homecare	x				x		x							x		
10031	Carter	23	Amedisys Home Health Care						x					x				x	
13022	Claiborne	25	Amedisys Home Health of Tennessee					x		x			x				x		
13032	Claiborne	93	Suncrest Home Health and Hospice					x		x	x		x	x	x		x	x	
14024	Clay	135	Cumberland River Homecare									x							
15032	Cocke	27	Smoky Mountain Home Health and Hospice							x	x		x	x	x		x	x	
16034	Coffee	29	Suncrest Home Health																
19494	Davidson	42	Elk Valley Health Services	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
19544	Davidson	56	Home Care Solutions, Inc.	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
19654	Davidson	471	Optum Women's and Children's Health, LLC									x							
19724	Davidson	295	Careall									x							
19734	Davidson	624	Corum CVS Specialty Infusion Services		x							x				x			
25034	Fentress	80	Quality Private Duty Care			x						x							
25044	Fentress	287	Quality Home Health	x		x						x							
26024	Franklin	83	Encompass Home Health of Tennessee		x		x					x				x			
26054	Franklin	82	Amedisys Home Care													x			
30021	Greene	86	Advanced Home Care, Inc.								x			x	x		x	x	
30041	Greene	88	Laughlin Home Health Agency								x			x	x			x	
30051	Greene	87	Procare Home Health Services						x					x					
32102	Hamblen	91	Amedisys Home Health Care	x				x		x	x		x	x	x		x	x	
32122	Hamblen	153	Univ. of TN Med Cntr Home Health / Hospice Service	x		x		x		x	x		x	x	x		x	x	
32132	Hamblen	10	Premier Support Services, Inc.	x		x	x	x	x	x	x		x	x	x	x	x	x	
33033	Hamilton	111	NHC Homecare		x		x									x			
33083	Hamilton	115	Guardian Home Care, LLC				x									x			
33093	Hamilton	100	Gentiva Health Services		x		x									x			
33103	Hamilton	113	Amedisys Home Health	x	x	x	x					x				x			
33213	Hamilton	98	Continuecare Healthservices, Inc. I		x		x									x			
33253	Hamilton	103	CHI Memorial Health at Home		x		x									x			
33303	Hamilton	109	Tennessee Home Health		x		x									x			
33363	Hamilton	338	Home Care Solutions		x		x									x			
33383	Hamilton	108	Continuecare Healthservices, Inc. II		x		x									x			
33423	Hamilton	457	Alere Women's and Children's Health, LLC	x	x	x	x	x	x	x	x		x	x	x	x	x	x	
33433	Hamilton	613	Maxim Healthcare Services				x									x			
34011	Hancock	117	Hancock County Home Health and Hospice Agency							x			x				x	x	
37021	Hawkins	320	Hometown Home Health, Inc.										x				x	x	
46031	Johnson	130	Johnson County Home Health.						x										
47012	Knox	143	NHC Homecare	x		x		x		x	x		x		x				

Table B.5-1B: Project Service Area Counties Authorized for Existing Home Health Agencies--BY AGENCY ID

Health Statistics ID	Jefferson	Johnson	Knox	Loudon	Marion	McMinn	Meigs	Monroe	Morgan	Polk	Rhea	Roane	Scott	Sequatchie	Sevier	Sullivan	Unicoi	Union	Washington	Number of Counties Served
01032			x						x			x	x					x		7
01042	x		x	x			x	x	x		x	x	x		x			x		19
01052	x		x	x				x	x			x	x		x			x		14
05012	x		x	x				x				x			x		x	x	x	19
06043						x	x			x										5
06063				x	x	x	x	x	x	x	x	x		x						13
07032			x	x					x			x	x					x		10
10031		x														x	x		x	7
13022																		x		5
13032	x															x		x		11
14024																				1
15032	x														x	x	x		x	12
16034					x									x						2
19494	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	34
19544	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	34
19654																				1
19724																				1
19734					x						x			x						6
25034			x	x					x			x	x							7
25044			x	x					x		x	x	x							9
26024					x	x	x				x			x						9
26054					x									x						3
30021													x			x			x	8
30041																			x	5
30051		x														x	x		x	6
32102	x		x												x			x		13
32122	x		x	x					x			x	x		x			x		18
32132	x	x	x	x		x	x	x	x	x	x	x	x		x	x	x	x	x	30
33033					x	x	x				x			x						8
33083						x	x			x				x						6
33093					x	x	x	x		x	x			x						10
33103				x	x	x	x	x		x	x			x						14
33213					x	x	x				x			x						8
33253					x	x	x			x	x			x						9
33303					x	x	x			x	x			x						9
33363					x	x	x			x	x			x						9
33383					x	x	x			x	x			x						9
33423	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	33
33433					x	x	x				x			x						7
34011																				4
37021																				3
46031		x																		2
47012	x		x	x		x		x				x			x			x		15

Table B.5-1B: Project Service Area Counties Authorized for Existing Home Health Agencies--BY AGENCY ID

Health Statistics ID	Agency County	License Number	Agencies (76)	Anderson	Bledsoe	Blount	Bradley	Campbell	Carter	Claiborne	Cocke	Cumberland	Grainger	Greene	Hamblen	Hamilton	Hancock	Hawkins
47042	Knox	142	Gentiva Health Services	x		x		x			x				x			
47062	Knox	144	Camellia Home Health of East Tennessee	x		x	x	x		x	x	x	x		x	x	x	x	
47092	Knox	151	Tennova Healthcare Home Health	x		x		x		x			x		x		x		
47132	Knox	156	UTMCK - Home Care Services: Hospice & Home Care	x		x		x		x	x		x		x				
47182	Knox	149	Gentiva Health Services 2 (Girling Health Services)	x	x	x		x		x	x	x	x	x	x		x	x	
47202	Knox	150	Amedisys Home Health Care	x	x	x		x	x	x	x	x	x	x	x		x	x	
47222	Knox	132	East Tennessee Children's Hospital Home Health	x		x		x		x	x		x		x				
47232	Knox	131	Careall Home Care Services			x													
47402	Knox	133	Covenant Homecare	x		x		x		x	x	x	x		x				
47432	Knox	2	Maxim Healthcare Services, Inc.	x		x		x		x	x		x	x	x		x	x	
52024	Lincoln	161	Deaconess Homecare		x							x							
54043	McMinn	166	NHC Homecare				x												
62052	Monroe	190	Intrepid USA Healthcare Services	x		x	x	x		x			x						
62062	Monroe	189	Sweetwater Hospital Home Health																
67024	Overton	191	Amedisys Home Health									x							
71014	Putnam	197	Highland Rim Home Health Agency									x							
71084	Putnam	198	Intrepid USA Healthcare Services									x							
75024	Rutherford	208	NHC Homecare									x							
75064	Rutherford	5	Amedisys Home Health Care																
76032	Scott	211	Deaconess Homecare					x											
82051	Sullivan	249	Advanced Home Care, Inc.														x		
82061	Sullivan	251	Gentiva Health Services						x					x	x		x	x	
89064	Warren	263	Intrepid USA Healthcare Services									x							
89074	Warren	265	Careall Home Care Services		x														
90081	Washington	269	Medical Center Homecare - Kingsport						x					x				x	
90091	Washington	271	Medical Center Homecare Services						x					x					
90121	Washington	273	Amedisys Home Health						x					x				x	
90131	Washington	267	NHC Homecare						x					x				x	
95034	Wilson	282	Deaconess Homecare I									x							
96030	London Co, KY	298	Professional Home Health Care Agency	x				x		x									
	Knox	633	Implanted Pump Management	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
	Washington	629	Maxim Healthcare Services						x										
	Davidson	632	Pentec Health	x	x	x	x	x	x	x	x	x	x	x	x		x		
			Agencies Available to Each County	**27**	**20**	**25**	**22**	**27**	**16**	**27**	**22**	**24**	**26**	**23**	**25**	**22**	**21**	**26**	

Note: Hemophilia Preferred Care of West Tennessee licensed 7/15 but not yet assigned a State ID as of 6-10-16.

Source: Department of Health Licensure - 10/7/2015 (Updated 2/2/2016)

Table B.5-1B: Project Service Area Counties Authorized for Existing Home Health Agencies--BY AGENCY ID

Health Statistics ID	Jefferson	Johnson	Knox	Loudon	Marion	McMinn	Meigs	Monroe	Morgan	Polk	Rhea	Roane	Scott	Sequatchie	Sevier	Sullivan	Unicoi	Union	Washington	Number of Counties Served
47042	x		x	x				x				x			x			x		12
47062	x		x	x	x	x	x	x	x	x	x	x	x	x	x			x		27
47092	x		x	x					x			x	x		x			x		15
47132	x		x	x				x	x			x	x		x			x		16
47182	x		x	x		x	x	x	x	x	x	x	x		x	x		x		26
47202	x		x	x				x	x			x	x		x	x	x	x	x	25
47222	x		x	x				x	x			x	x		x			x		16
47232			x	x				x	x			x								6
47402	x		x	x				x	x			x	x		x			x		17
47432	x		x	x					x			x	x		x			x		18
52024									x		x	x								5
54043				x		x	x	x		x	x	x								8
62052			x	x		x	x	x			x	x	x					x		15
62062				x		x	x	x				x								5
67024									x			x	x							4
71014																				1
71084																				1
75024									x											2
75064					x															1
76032									x				x							3
82051																x			x	3
82061		x														x	x		x	9
89064																				1
89074														x						2
90081		x														x	x		x	7
90091		x														x	x		x	6
90121		x														x	x		x	7
90131		x														x	x		x	7
95034																				1
96030			x						x				x					x		7
	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	34
		x														x	x		x	5
	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	33
	23	15	28	29	21	25	25	24	28	18	25	31	26	22	22	20	17	27	20	

Note: Hemophilia Preferred Care of West Tennessee licensed 7/15 but not yet assigned a State ID as of 6-10-16.

Source: Department of Health Licensure - 10/7/2015 (Updated 2/2/2016)

Table B.5-2A: Patients Served in 2015 by Agencies in Proposed Service Area--BY AGENCY NAME

Health Statistics ID	Agency County	License Number	Agencies (76)	Anderson	Bledsoe	Blount	Bradley	Campbell	Carter	Claiborne	Cocke	Cumberland	Grainger	Greene	Hamblen	Hamilton	Hancock	Hawkins
30021	Greene	86	Advanced Home Care, Inc.							3			397	1		0	275	
82051	Sullivan	249	Advanced Home Care, Inc.														271	
33423	Hamilton	457	Alere Women's and Children's Health, LLC	0	0	0	11	0	0	0	0		0	0	0	14	0	0
26054	Franklin	82	Amedisys Home Care													0		
33103	Hamilton	113	Amedisys Home Health	0	92	2	274					5				1064		
67024	Overton	191	Amedisys Home Health									117						
90121	Washington	273	Amedisys Home Health						6					0			12	
10031	Carter	23	Amedisys Home Health Care						574					0			0	
32102	Hamblen	91	Amedisys Home Health Care	0				3		489	0		98	610	914		339	638
47202	Knox	150	Amedisys Home Health Care	703	0	222		0	0	0	426	1	62	0	4		0	0
75064	Rutherford	5	Amedisys Home Health Care															
13022	Claiborne	25	Amedisys Home Health of Tennessee					473		797			79				6	
05012	Blount	213	Blount Memorial Hospital Home Health Services	0		1409		0		0	0		0	0	0		0	0
47062	Knox	144	Camellia Home Health of East Tennessee	102		49	81	45		12	13	202	14		117	271	3	14
19724	Davidson	295	Careall									116						
47232	Knox	131	Careall Home Care Services			0												
89074	Warren	265	Careall Home Care Services		250													
33253	Hamilton	103	CHI Memorial Health at Home		45		179									2316		
01032	Anderson	1	Clinch River Home Health	190				40										
33213	Hamilton	98	Continuecare Healthservices, Inc. I		10		100									1120		
33383	Hamilton	108	Continuecare Healthservices, Inc. II		0		0									7		
19734	Davidson	624	Corum CVS Specialty Infusion Services		0							0				0		
47402	Knox	133	Covenant Homecare	722		189		101		38	55	252	83		230			
14024	Clay	135	Cumberland River Homecare									38						
52024	Lincoln	161	Deaconess Homecare		0							0						
76032	Scott	211	Deaconess Homecare					56										
95034	Wilson	282	Deaconess Homecare I									53						
47222	Knox	132	East Tennessee Children's Hospital Home Health	48		46		22		15	22		14		46			
19494	Davidson	42	Elk Valley Health Services	1	1	6	1	3	5	2	1	3	0	7	3	3	0	2
26024	Franklin	83	Encompass Home Health of Tennessee		0		192					0				466		
06043	Bradley	13	Family Home Care - Cleveland				814									396		
33093	Hamilton	100	Gentiva Health Services		0		10									390		
47042	Knox	142	Gentiva Health Services	17		9		11		1	0				2			
82061	Sullivan	251	Gentiva Health Services						30					62	0		1	39
47182	Knox	149	Gentiva Health Services 2 (Girling Health Services)	95	0	158		43		1	59	0	20	20	66		0	3
33083	Hamilton	115	Guardian Home Care, LLC				455									1160		
34011	Hancock	117	Hancock County Home Health and Hospice Agency							89			117				275	167
71014	Putnam	197	Highland Rim Home Health Agency									1						
33363	Hamilton	338	Home Care Solutions		2		15									352		
19544	Davidson	56	Home Care Solutions, Inc.	16	1	4	0	0	0	0	0	1	0	0	0	0	0	0
06063	Bradley	14	Home Health Care of East Tennessee, Inc.		21		131									277		
37021	Hawkins	320	Hometown Home Health, Inc.										6				1	101

Table B.5-2A: Patients Served in 2015 by Agencies in Proposed Service Area--BY AGENCY NAME

Health Statistics ID	Jefferson	Johnson	Knox	Loudon	Marion	McMinn	Meigs	Monroe	Morgan	Polk	Rhea	Roane	Scott	Sequatchie	Sevier	Sullivan	Unicoi	Union	Washington	Number of Patients Served
30021												1			24			144		845
82051															2,286			71		2,628
33423	0	0	0	0	1	1	1	2	0	0	2	0	0	0	0	0	0	0	0	32
26054					3									0						3
33103				158	106	367	57	81		46	309			38						2599
67024									21			1	37							176
90121		1														851	92		714	1,676
10031		297														10	1		19	901
32102	0		0												0			3		3094
47202	487		1,556	2				0	40			618	0		425	0	0	2	0	4,548
75064					0															0
13022																		196		1551
05012	0		15	46				108				0			11		0	0	0	1589
47062	50		474	109	7	204	45	51	3	22	62	152	2	5	98			6		2,213
19724																				116
47232			0	0				0	0			0								0
89074														206						456
33253					122	13	11			7	121			37						2851
01032			162						11			43	1					3		450
33213					46	10	11				42			17						1356
33383					0	0	0			0	0			0						7
19734					0						0			0						0
47402	145		1,670	379				68	131			593	32		664			37		5,389
14024																				38
52024									0		0	0								0
76032									24				236							316
95034																				53
47222	22		177	29				14	13			48	8		29			7		560
19494	2	0	27	1	2	2	0	0	3	0	0	0	5	0	5	15	2	0	13	115
26024					12	60	13				0			2						745
06043						103	59			122										1494
33093					13	0	1	0		0	7			3						424
47042	1		30	4				2				1			1			1		80
82061		0														209	102		154	597
47182	80		639	83		2	3	20	8	0	0	25	4		333	1		10		1,673
33083						149	65			63				34						1926
34011																				648
71014																				1
33363					37	27	6			8	7			11						465
19544	1	0	96	77	0	6	0	11	5	0	0	52	0	0	3	0	0	0	0	273
06063				117	279	98	17	217	4	57	111	78		47						1454
37021																				108

Table B.5-2A: Patients Served in 2015 by Agencies in Proposed Service Area--BY AGENCY NAME

Health Statistics ID	Agency County	License Number	Agencies (76)	Anderson	Bledsoe	Blount	Bradley	Campbell	Carter	Claiborne	Cocke	Cumberland	Grainger	Greene	Hamblen	Hamilton	Hancock	Hawkins
	Knox	633	Implanted Pump Management	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
62052	Monroe	190	Intrepid USA Healthcare Services	40		2	5	2		4			0					
71084	Putnam	198	Intrepid USA Healthcare Services									46						
89064	Warren	263	Intrepid USA Healthcare Services									0						
46031	Johnson	130	Johnson County Home Health.						7									
30041	Greene	88	Laughlin Home Health Agency								19			678	1			3
33433	Hamilton	613	Maxim Healthcare Services				9									36		
	Washington	629	Maxim Healthcare Services						0									
47432	Knox	2	Maxim Healthcare Services, Inc.	22		18		24		6	5		4	30	8		2	10
90081	Washington	269	Medical Center Homecare - Kingsport						89					13				86
90091	Washington	271	Medical Center Homecare Services						1,101					154				
33033	Hamilton	111	NHC Homecare		3		11									234		
47012	Knox	143	NHC Homecare	175		51		2		0	0		4		1			
54043	McMinn	166	NHC Homecare				6											
75024	Rutherford	208	NHC Homecare									74						
90131	Washington	267	NHC Homecare						40					4				3
19654	Davidson	471	Optum Women's and Children's Health, LLC									0						
	Davidson	632	Pentec Health	0	0	0	0	0	0	0	0	0	0	0	0	0		0
32132	Hamblen	10	Premier Support Services, Inc.	1		0	0	0	6	3	110		76	30	491	0	7	233
30051	Greene	87	Procare Home Health Services						84					70				
01042	Anderson	620	Professional Case Management of Tennessee	77		9		12		2		1	1		1			1
96030	London Co, KY	298	Professional Home Health Care Agency	0				4		1								
25044	Fentress	287	Quality Home Health	107		267						745						
25034	Fentress	80	Quality Private Duty Care			2						183						
15032	Cocke	27	Smoky Mountain Home Health and Hospice							52	356		24	122	217		0	49
07032	Campbell	16	Sunbelt Homecare	3				239		11							0	
16034	Coffee	29	Suncrest Home Health															
13032	Claiborne	93	Suncrest Home Health and Hospice					13		184	28		55	5	70		6	51
62062	Monroe	189	Sweetwater Hospital Home Health															
33303	Hamilton	109	Tennessee Home Health		0		207									181		
47092	Knox	151	Tennova Healthcare Home Health	149		168		563		63			87		156		0	
01052	Anderson	148	The Home Option by Hardin Health Care	24		2		0		1			0					
32122	Hamblen	153	Univ. of TN Med Cntr Home Health / Hospice Service	0		0		0		0	173		102	87	278		3	278
47132	Knox	156	UTMCK - Home Care Services: Hospice & Home Care	69		416		69		30	2		0		0			
			TOTAL PATIENTS PER COUNTY	2,561	425	3,029	2,501	1,725	1,942	1,801	1,272	1,838	846	2,289	2,606	8,287	643	2,236

Note: Hemophilia Preferred Care of West Tennessee licensed 7/15 but not yet assigned a State ID as of 6-10-16.
Source: Department of Health Licensure - 10/7/2015 (Updated 2/2/2016)

Table B.5-2A: Patients Served in 2015 by Agencies in Proposed Service Area--BY AGENCY NAME

Health Statistics ID	Jefferson	Johnson	Knox	Loudon	Marion	McMinn	Meigs	Monroe	Morgan	Polk	Rhea	Roane	Scott	Sequatchie	Sevier	Sullivan	Unicoi	Union	Washington	Number of Patients Served
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
62052			294	36		91	8	26			2	37	0					18		565
71084																				46
89064																				0
46031		437																	3	447
30041																			10	711
33433					1	4	1				2			4						57
		0														0	0		0	0
47432	5		46	6					5			3	8		10			2		214
90081		39														1,539	10		147	1,923
90091		8														10	228		2,124	3,625
33033					18	0	0				1			11						278
47012	9		514	30		0		0				38			42			4		870
54043				22		250	28	88		11	13	3								421
75024									0											74
90131		0														241	32		291	611
19654																				0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
32132	137	0	6	0		0	0	0	0	0	0	0	0		5	12	0	0	9	1126
30051		5														168	16		231	574
01042	2		60	17			2	7	5		1	41	1		1			1		242
96030			0						x				1					0		6
25044			548	127					210		107	219	448							2778
25034			2	56					43			18	36							340
15032	119														4	145	3		37	1128
07032			0	0					0			0	0					0		253
16034					29									20						49
13032	48															174		29		663
62062				61		96	35	452				7								651
33303					2	18	8			83	21			0						520
47092	250		2,057	71					0			35	1		234			195		4,029
01052	0		24	6				1	0			19	0		2			0		79
32122	222		2	0					0			0	0		0			0		1145
47132	3		879	94				55	0			29	3		441			14		2,104
	1,583	787	9,278	1,531	678	1,501	371	1,203	526	419	808	2,060	824	435	2,308	5,685	486	528	3,967	68,979

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Table B.5-2B: Patients Served in 2015 by Agencies in Project's Proposed Service Area--BY AGENCY ID

Health Statistics ID	Agency County	License Number	Agencies (76)	Anderson	Bledsoe	Blount	Bradley	Campbell	Carter	Claiborne	Cocke	Cumberland	Grainger	Greene	Hamblen	Hamilton	Hancock	Hawkins
01032	Anderson	1	Clinch River Home Health	190				40										
01042	Anderson	620	Professional Case Management of Tennessee	77		9		12		2		1	1		1			1
01052	Anderson	148	The Home Option by Hardin Health Care	24		2		0		1			0					
05012	Blount	213	Blount Memorial Hospital Home Health Services	0		1409		0		0	0		0	0	0		0	0
06043	Bradley	13	Family Home Care - Cleveland				814									396		
06063	Bradley	14	Home Health Care of East Tennessee, Inc.		21		131									277		
07032	Campbell	16	Sunbelt Homecare	3				239		11							0	
10031	Carter	23	Amedisys Home Health Care						574					0				0
13022	Claiborne	25	Amedisys Home Health of Tennessee					473		797			79				6	
13032	Claiborne	93	Suncrest Home Health and Hospice					13		184	28		55	5	70		6	51
14024	Clay	135	Cumberland River Homecare									38						
15032	Cocke	27	Smoky Mountain Home Health and Hospice							52	356		24	122	217		0	49
16034	Coffee	29	Suncrest Home Health															
19494	Davidson	42	Elk Valley Health Services	1	1	6	1	3	5	2	1	3	0	7	3	3	0	2
19544	Davidson	56	Home Care Solutions, Inc.	16	1	4	0	0	0	0	0	1	0	0	0	0	0	0
19654	Davidson	471	Optum Women's and Children's Health, LLC									0						
19724	Davidson	295	Careall									116						
19734	Davidson	624	Corum CVS Specialty Infusion Services		0							0				0		
25034	Fentress	80	Quality Private Duty Care			2						183						
25044	Fentress	287	Quality Home Health	107		267						745						
26024	Franklin	83	Encompass Home Health of Tennessee		0		192					0				466		
26054	Franklin	82	Amedisys Home Care													0		
30021	Greene	86	Advanced Home Care, Inc.								3			397	1		0	275
30041	Greene	88	Laughlin Home Health Agency								19			678	1			3
30051	Greene	87	Procare Home Health Services						84					70				
32102	Hamblen	91	Amedisys Home Health Care	0				3		489	0		98	610	914		339	638
32122	Hamblen	153	Univ. of TN Med Cntr Home Health / Hospice Service	0		0		0		0	173		102	87	278		3	278
32132	Hamblen	10	Premier Support Services, Inc.	1		0	0	0	6	3	110		76	30	491	0	7	233
33033	Hamilton	111	NHC Homecare		3		11									234		
33083	Hamilton	115	Guardian Home Care, LLC				455									1160		
33093	Hamilton	100	Gentiva Health Services		0		10									390		
33103	Hamilton	113	Amedisys Home Health	0	92	2	274					5				1064		
33213	Hamilton	98	Continuecare Healthservices, Inc. I		10		100									1120		
33253	Hamilton	103	CHI Memorial Health at Home		45		179									2316		
33303	Hamilton	109	Tennessee Home Health		0		207									181		
33363	Hamilton	338	Home Care Solutions		2		15									352		
33383	Hamilton	108	Continuecare Healthservices, Inc. II		0		0									7		
33423	Hamilton	457	Alere Women's and Children's Health, LLC	0	0	0	11	0	0	0	0		0	0	0	14	0	0
33433	Hamilton	613	Maxim Healthcare Services				9									36		
34011	Hancock	117	Hancock County Home Health and Hospice Agency							89			117				275	167
37021	Hawkins	320	Hometown Home Health, Inc.										6				1	101
46031	Johnson	130	Johnson County Home Health.						7									
47012	Knox	143	NHC Homecare	175		51		2		0	0		4		1			
47042	Knox	142	Gentiva Health Services	17		9		11		1	0				2			

Table B.5-2B: Patients Served in 2015 by Agencies in Project's Proposed Service Area--BY AGENCY ID

Health Statistics ID	Jefferson	Johnson	Knox	Loudon	Marion	McMinn	Meigs	Monroe	Morgan	Polk	Rhea	Roane	Scott	Sequatchie	Sevier	Sullivan	Unicoi	Union	Washington	Number of Patients Served
01032		162						11			43	1					3			450
01042	2	60	17			2	7	5		1	41	1		1			1			242
01052	0	24	6				1	0			19	0		2			0			79
05012	0	15	46				108				0			11		0	0	0		1589
06043					103	59			122											1494
06063			117	279	98	17	217	4	57	111	78		47							1454
07032		0	0					0			0	0					0			253
10031	297														10	1		19		901
13022																	196			1551
13032	48														174		29			663
14024																				38
15032	119													4	145	3		37		1128
16034				29									20							49
19494	2	0	27	1	2	2	0	0	3	0	0	0	5	0	5	15	2	0	13	115
19544	1	0	96	77	0	6	0	11	5	0	0	52	0	0	3	0	0	0	0	273
19654																				0
19724																				116
19734				0						0			0							0
25034		2	56					43			18	36								340
25044		548	127					210		107	219	448								2778
26024				12	60	13				0			2							745
26054				3									0							3
30021												1			24			144		845
30041																		10		711
30051	5														168	16		231		574
32102	0	0												0			3			3094
32122	222	2	0					0			0	0		0			0			1145
32132	137	0	6	0		0	0	0	0	0	0	0		5	12	0	0	9		1126
33033				18	0	0				1			11							278
33083					149	65			63				34							1926
33093				13	0	1	0		0	7			3							424
33103			158	106	367	57	81		46	309			38							2599
33213				46	10	11				42			17							1356
33253				122	13	11			7	121			37							2851
33303				2	18	8			83	21			0							520
33363				37	27	6			8	7			11							465
33383				0	0	0			0	0			0							7
33423	0	0	0	1	1	1	2	0	0	2	0	0	0	0	0	0	0	0		32
33433				1	4	1				2			4							57
34011																				648
37021																				108
46031	437																	3		447
47012	9	514	30		0		0				38			42			4			870
47042	1	30	4				2				1			1			1			80

Table B.5-2B: Patients Served in 2015 by Agencies in Project's Proposed Service Area--BY AGENCY ID

Health Statistics ID	Agency County	License Number	Agencies (76)	Anderson	Bledsoe	Blount	Bradley	Campbell	Carter	Claiborne	Cocke	Cumberland	Grainger	Greene	Hamblen	Hamilton	Hancock	Hawkins
47062	Knox	144	Camellia Home Health of East Tennessee	102		49	81	45		12	13	202	14		117	271	3	14	
47092	Knox	151	Tennova Healthcare Home Health	149		168		563		63			87		156		0		
47132	Knox	156	UTMCK - Home Care Services: Hospice & Home Care	69		416		69		30	2		0		0				
47182	Knox	149	Gentiva Health Services 2 (Girling Health Services)	95	0	158		43		1	59	0	20	20	66		0	3	
47202	Knox	150	Amedisys Home Health Care	703	0	222		0	0	0	426	1	62	0	4		0	0	
47222	Knox	132	East Tennessee Children's Hospital Home Health	48		46		22		15	22		14		46				
47232	Knox	131	Careall Home Care Services			0													
47402	Knox	133	Covenant Homecare	722		189		101		38	55	252	83		230				
47432	Knox	2	Maxim Healthcare Services, Inc.	22		18		24		6	5		4	30	8		2	10	
52024	Lincoln	161	Deaconess Homecare		0							0							
54043	McMinn	166	NHC Homecare				6												
62052	Monroe	190	Intrepid USA Healthcare Services	40		2	5	2		4			0						
62062	Monroe	189	Sweetwater Hospital Home Health																
67024	Overton	191	Amedisys Home Health									117							
71014	Putnam	197	Highland Rim Home Health Agency									1							
71084	Putnam	198	Intrepid USA Healthcare Services									46							
75024	Rutherford	208	NHC Homecare									74							
75064	Rutherford	5	Amedisys Home Health Care																
76032	Scott	211	Deaconess Homecare					56											
82051	Sullivan	249	Advanced Home Care, Inc.															271	
82061	Sullivan	251	Gentiva Health Services						30					62	0		1	39	
89064	Warren	263	Intrepid USA Healthcare Services									0							
89074	Warren	265	Careall Home Care Services		250														
90081	Washington	269	Medical Center Homecare - Kingsport						89					13				86	
90091	Washington	271	Medical Center Homecare Services						1,101					154					
90121	Washington	273	Amedisys Home Health						6					0				12	
90131	Washington	267	NHC Homecare						40					4				3	
95034	Wilson	282	Deaconess Homecare I									53							
96030	London Co, KY	298	Professional Home Health Care Agency	0				4		1									
	Knox	633	Implanted Pump Management	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	Washington	629	Maxim Healthcare Services						0										
	Davidson	632	Pentec Health	0	0	0	0	0	0	0	0	0	0	0	0		0		
			TOTAL PATIENTS PER COUNTY	2,561	425	3,029	2,501	1,725	1,942	1,801	1,272	1,838	846	2,289	2,606	8,287	643	2,236	

Note: Hemophilia Preferred Care of West Tennessee licensed 7/15 but not yet assigned a State ID as of 6-10-16.

Source: Department of Health Licensure - 10/7/2015 (Updated 2/2/2016)

Table B.5-2B: Patients Served in 2015 by Agencies in Project's Proposed Service Area--BY AGENCY ID

Health Statistics ID	Jefferson	Johnson	Knox	Loudon	Marion	McMinn	Meigs	Monroe	Morgan	Polk	Rhea	Roane	Scott	Sequatchie	Sevier	Sullivan	Unicoi	Union	Washington	Number of Patients Served
47062	50	474	109	7	204	45	51	3	22	62	152	2	5	98			6			2,213
47092	250	2,057	71					0			35	1		234			195			4,029
47132	3	879	94				55	0			29	3		441			14			2,104
47182	80	639	83		2	3	20	8	0	0	25	4		333	1		10			1,673
47202	487	1,556	2				0	40			618	0		425	0	0	2	0		4,548
47222	22	177	29				14	13			48	8		29			7			560
47232		0	0				0	0			0									0
47402	145	1,670	379				68	131			593	32		664			37			5,389
47432	5	46	6					5			3	8		10			2			214
52024								0		0	0									0
54043			22		250	28	88		11	13	3									421
62052		294	36		91	8	26			2	37	0					18			565
62062			61		96	35	452				7									651
67024								21			1	37								176
71014																				1
71084																				46
75024								0												74
75064				0																0
76032								24				236								316
82051															2,286			71		2,628
82061	0														209	102		154		597
89064																				0
89074													206							456
90081	39														1,539	10		147		1,923
90091	8														10	228		2,124		3,625
90121	1														851	92		714		1,676
90131	0														241	32		291		611
95034																				53
96030		0						0				1					0			6
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0
	0														0	0		0		0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0
	1,583	787	9,278	1,531	678	1,501	371	1,203	526	419	808	2,060	824	435	2,308	5,685	486	528	3,967	68,979

Table Eight-A: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area BY AGENCY NAME

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
30021	Greene	Advanced Home Care, Inc.	86	8/31/83	762	817	845	845	100.0%
82051	Sullivan	Advanced Home Care, Inc.	249	4/9/85	2,245	2,276	2,641	2,628	99.5%
33423	Hamilton	Alere Women's and Children's Health, LLC	457	11/13/98	61	50	40	32	80.0%
26054	Franklin	Amedisys Home Care	82	9/19/83	1,150	1,002	909	3	0.3%
33103	Hamilton	Amedisys Home Health	113	7/1/81	2,878	2,564	2,610	2,599	99.6%
67024	Overton	Amedisys Home Health	191	1/17/84	1,101	949	1,101	176	16.0%
90121	Washington	Amedisys Home Health	273	7/6/84	1,821	1,460	1,676	1,676	100.0%
10031	Carter	Amedisys Home Health Care	23	1/20/84	1,171	937	901	901	100.0%
32102	Hamblen	Amedisys Home Health Care	91	12/13/82	3,896	3,210	3,099	3,094	99.8%
47202	Knox	Amedisys Home Health Care	150	6/2/84	5,354	4,391	4,548	4,548	100.0%
75064	Rutherford	Amedisys Home Health Care	5	8/23/84	1,582	1,372	1,265	0	0.0%
13022	Claiborne	Amedisys Home Health of Tennessee	25	10/8/82	1,830	1,547	1,551	1,551	100.0%
05012	Blount	Blount Memorial Hospital Home Health Services	213	1/26/15	1,224	1,281	1,589	1,589	100.0%
47062	Knox	Camellia Home Health of East Tennessee	144	9/7/78	1,716	1,732	2,215	2,213	99.9%
19724	Davidson	Careall	295	7/5/84	1,562	1,665	891	116	13.0%
47232	Knox	Careall Home Care Services	131	8/21/89	510	686	0	0	0.0%
89074	Warren	Careall Home Care Services	265	1/31/84	637	974	749	456	60.9%
33253	Hamilton	CHI Memorial Health at Home	103	8/9/82	2,439	2,651	2,852	2,851	100.0%
01032	Anderson	Clinch River Home Health	1	10/26/76	461	481	450	450	0.0%
33213	Hamilton	Continuecare Healthservices, Inc. I	98	11/2/84	1,466	1,393	1,356	1,356	100.0%
33383	Hamilton	Continuecare Healthservices, Inc. II	108	5/7/76	8	7	7	7	100.0%
19734	Davidson	Corum CVS Specialty Infusion Services	624	1/30/13	11	26	36	0	0.0%
47402	Knox	Covenant Homecare	133	7/14/78	3,953	4,792	5,391	5,389	100.0%
14024	Clay	Cumberland River Homecare	135	12/28/82	392	393	293	38	13.0%
52024	Lincoln	Deaconess Homecare	161	2/25/76	842	1,294	731	0	0.0%
76032	Scott	Deaconess Homecare	211	9/20/85	394	603	338	316	93.5%
95034	Wilson	Deaconess Homecare I	282	12/18/78	1,222	1,706	956	53	5.5%
47222	Knox	East Tennessee Children's Hospital Home Health	132	9/13/84	586	600	560	560	100.0%
19494	Davidson	Elk Valley Health Services	42	7/17/84	277	293	457	115	25.2%
26024	Franklin	Encompass Home Health of Tennessee	83	1/29/76	2,030	2,444	2,581	745	28.9%
06043	Bradley	Family Home Care - Cleveland	13	1/10/84	598	1,454	1,494	1,494	100.0%
33093	Hamilton	Gentiva Health Services	100	8/24/84	328	348	426	424	99.5%
47042	Knox	Gentiva Health Services	142	11/28/77	779	413	80	80	100.0%
82061	Sullivan	Gentiva Health Services	251	11/3/83	936	612	598	597	99.8%
47182	Knox	Gentiva Health Services 2 (Girling Health Services)	149	8/15/84	1,467	1,815	1,675	1,673	99.9%
33083	Hamilton	Guardian Home Care, LLC	115	6/29/78	1,484	1,255	1,929	1,926	99.8%
34011	Hancock	Hancock County Home Health and Hospice Agency	117	7/23/75	463	488	648	648	100.0%
71014	Putnam	Highland Rim Home Health Agency	197	5/2/78	574	497	549	1	0.2%
33363	Hamilton	Home Care Solutions	338	11/14/96	663	540	473	465	98.3%
19544	Davidson	Home Care Solutions, Inc.	56	9/7/88	1,930	1,689	1,813	273	15.1%
06063	Bradley	Home Health Care of East Tennessee, Inc.	14	3/14/84	3,318	2,680	1,580	1,454	92.0%
37021	Hawkins	Hometown Home Health, Inc.	320	1/9/95	89	94	108	108	100.0%
	Knox	Implanted Pump Management	633				0	0	0.0%
62052	Monroe	Intrepid USA Healthcare Services	190	9/10/84	358	355	565	565	100.0%
71084	Putnam	Intrepid USA Healthcare Services	198	6/19/84	327	281	369	46	12.5%
89064	Warren	Intrepid USA Healthcare Services	263	8/1/84	822	804	843	0	0.0%
46031	Johnson	Johnson County Home Health.	130	6/29/84	446	492	447	447	100.0%
30041	Greene	Laughlin Home Health Agency	88	6/26/84	655	737	711	711	100.0%
33433	Hamilton	Maxim Healthcare Services	613	8/18/05	56	53	57	57	100.0%
	Washington	Maxim Healthcare Services	629				0	0	0.0%
47432	Knox	Maxim Healthcare Services, Inc.	2	6/20/84	159	154	214	214	0.0%
90081	Washington	Medical Center Homecare - Kingsport	269	11/4/83	1,960	1,846	1,923	1,923	100.0%
90091	Washington	Medical Center Homecare Services	271	5/4/84	3,503	3,714	3,625	3,625	0.0%
33033	Hamilton	NHC Homecare	111	6/10/77	354	411	278	278	100.0%
47012	Knox	NHC Homecare	143	6/10/77	613	883	870	870	100.0%
54043	McMinn	NHC Homecare	166	2/13/84	239	358	421	421	100.0%
75024	Rutherford	NHC Homecare	208	5/17/76	3,776	4,180	4,270	74	1.7%
90131	Washington	NHC Homecare	267	3/22/78	259	465	611	611	100.0%
19654	Davidson	Optum Women's and Children's Health, LLC	471	3/1/99	202	186	196	0	0.0%

Table Eight-A: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area
BY AGENCY NAME

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
	Davidson	Pentec Health	632				0	0	0.0%
32132	Hamblen	Premier Support Services, Inc,	10	5/16/84	1,169	1,372	1,126	1,126	100.0%
30051	Greene	Procare Home Health Services	87	7/8/82	433	522	574	574	100.0%
01042	Anderson	Professional Case Management of Tennessee	620	1/30/08	164	173	249	242	97.2%
96030	London Co, KY	Professional Home Health Care Agency	298	9/2/77	12	21	6	6	100.0%
25044	Fentress	Quality Home Health	287	3/7/84	3,404	3,591	4,278	2,778	64.9%
25034	Fentress	Quality Private Duty Care	80	10/28/83	879	894	784	340	0.0%
15032	Cocke	Smoky Mountain Home Health and Hospice	27	11/9/89	1,296	1,102	1,128	1,128	100.0%
07032	Campbell	Sunbelt Homecare	16	8/10/84	261	243	253	253	100.0%
16034	Coffee	Suncrest Home Health	29	4/16/84	1,588	2,122	1,667	49	2.9%
13032	Claiborne	Suncrest Home Health and Hospice	93	9/14/84	852	1,008	663	663	100.0%
62062	Monroe	Sweetwater Hospital Home Health	189	8/20/84	613	625	651	651	100.0%
33303	Hamilton	Tennessee Home Health (Lifecare)	109	11/7/84	956	1,298	520	520	100.0%
47092	Knox	Tennova Healthcare Home Health	151	2/29/80	3,063	3,240	4,029	4,029	100.0%
01052	Anderson	The Home Option by Hardin Health Care	148	12/13/84			79	79	0.0%
32122	Hamblen	Univ. of TN Med Cntr Home Health / Hospice Service	153	12/18/84	1,327	751	1,145	1,145	0.0%
47132	Knox	UTMCK - Home Care Services: Hospice & Home Care	156	7/20/83	3,439	771	2,104	2,104	0.0%
		AREAWIDE TOTALS AND AVERAGES			**89,395**	**88,133**	**88,667**	**68,979**	**77.8%**

Source: TDH; 2013-2015 Joint Annual Reports of Home Health Agencies

Table B.5-3B: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area BY AGENCY ID

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
01032	Anderson	Clinch River Home Health	1	10/26/76	461	481	450	450	0.0%
01042	Anderson	Professional Case Management of Tennessee	620	1/30/08	164	173	249	242	97.2%
01052	Anderson	The Home Option by Hardin Health Care	148	12/13/84			79	79	0.0%
05012	Blount	Blount Memorial Hospital Home Health Services	213	1/26/15	1,224	1,281	1,589	1,589	100.0%
06043	Bradley	Family Home Care - Cleveland	13	1/10/84	598	1,454	1,494	1,494	100.0%
06063	Bradley	Home Health Care of East Tennessee, Inc.	14	3/14/84	3,318	2,680	1,580	1,454	92.0%
07032	Campbell	Sunbelt Homecare	16	8/10/84	261	243	253	253	100.0%
10031	Carter	Amedisys Home Health Care	23	1/20/84	1,171	937	901	901	100.0%
13022	Claiborne	Amedisys Home Health of Tennessee	25	10/8/82	1,830	1,547	1,551	1,551	100.0%
13032	Claiborne	Suncrest Home Health and Hospice	93	9/14/84	852	1,008	663	663	100.0%
14024	Clay	Cumberland River Homecare	135	12/28/82	392	393	293	38	13.0%
15032	Cocke	Smoky Mountain Home Health and Hospice	27	11/9/89	1,296	1,102	1,128	1,128	100.0%
16034	Coffee	Suncrest Home Health	29	4/16/84	1,588	2,122	1,667	49	2.9%
19494	Davidson	Elk Valley Health Services	42	7/17/84	277	293	457	115	25.2%
19544	Davidson	Home Care Solutions, Inc.	56	9/7/88	1,930	1,689	1,813	273	15.1%
19654	Davidson	Optum Women's and Children's Health, LLC	471	3/1/99	202	186	196	0	0.0%
19724	Davidson	Careall	295	7/5/84	1,562	1,665	891	116	13.0%
19734	Davidson	Corum CVS Specialty Infusion Services	624	1/30/13	11	26	36	0	0.0%
25034	Fentress	Quality Private Duty Care	80	10/28/83	879	894	784	340	0.0%
25044	Fentress	Quality Home Health	287	3/7/84	3,404	3,591	4,278	2,778	64.9%
26024	Franklin	Encompass Home Health of Tennessee	83	1/29/76	2,030	2,444	2,581	745	28.9%
26054	Franklin	Amedisys Home Care	82	9/19/83	1,150	1,002	909	3	0.3%
30021	Greene	Advanced Home Care, Inc.	86	8/31/83	762	817	845	845	100.0%
30041	Greene	Laughlin Home Health Agency	88	6/26/84	655	737	711	711	100.0%
30051	Greene	Procare Home Health Services	87	7/8/82	433	522	574	574	100.0%
32102	Hamblen	Amedisys Home Health Care	91	12/13/82	3,896	3,210	3,099	3,094	99.8%
32122	Hamblen	Univ. of TN Med Cntr Home Health / Hospice Service	153	12/18/84	1,327	751	1,145	1,145	0.0%
32132	Hamblen	Premier Support Services, Inc.	10	5/16/84	1,169	1,372	1,126	1,126	100.0%
33033	Hamilton	NHC Homecare	111	6/10/77	354	411	278	278	100.0%
33083	Hamilton	Guardian Home Care, LLC	115	6/29/78	1,484	1,255	1,929	1,926	99.8%
33093	Hamilton	Gentiva Health Services	100	8/24/84	328	348	426	424	99.5%
33103	Hamilton	Amedisys Home Health	113	7/1/81	2,878	2,564	2,610	2,599	99.6%
33213	Hamilton	Continuecare Healthservices, Inc. I	98	11/2/84	1,466	1,393	1,356	1,356	100.0%
33253	Hamilton	CHI Memorial Health at Home	103	8/9/82	2,439	2,651	2,852	2,851	100.0%
33303	Hamilton	Tennessee Home Health (Lifecare)	109	11/7/84	956	1,298	520	520	100.0%
33363	Hamilton	Home Care Solutions	338	11/14/96	663	540	473	465	98.3%
33383	Hamilton	Continuecare Healthservices, Inc. II	108	5/7/76	8	7	7	7	100.0%
33423	Hamilton	Alere Women's and Children's Health, LLC	457	11/13/98	61	50	40	32	80.0%
33433	Hamilton	Maxim Healthcare Services	613	8/18/05	56	53	57	57	100.0%
34011	Hancock	Hancock County Home Health and Hospice Agency	117	7/23/75	463	488	648	648	100.0%
37021	Hawkins	Hometown Home Health, Inc.	320	1/9/95	89	94	108	108	100.0%
46031	Johnson	Johnson County Home Health.	130	6/29/84	446	492	447	447	100.0%
47012	Knox	NHC Homecare	143	6/10/77	613	883	870	870	100.0%
47042	Knox	Gentiva Health Services	142	11/28/77	779	413	80	80	100.0%
47062	Knox	Camellia Home Health of East Tennessee	144	9/7/78	1,716	1,732	2,215	2,213	99.9%
47092	Knox	Tennova Healthcare Home Health	151	2/29/80	3,063	3,240	4,029	4,029	100.0%
47132	Knox	UTMCK - Home Care Services: Hospice & Home Care	156	7/20/83	3,439	771	2,104	2,104	0.0%
47182	Knox	Gentiva Health Services 2 (Girling Health Services)	149	8/15/84	1,467	1,815	1,675	1,673	99.9%
47202	Knox	Amedisys Home Health Care	150	8/2/84	5,354	4,391	4,548	4,548	100.0%
47222	Knox	East Tennessee Children's Hospital Home Health	132	9/13/84	586	600	560	560	100.0%
47232	Knox	Careall Home Care Services	131	8/21/89	510	686	0	0	0.0%
47402	Knox	Covenant Homecare	133	7/14/78	3,953	4,792	5,391	5,389	100.0%
47432	Knox	Maxim Healthcare Services, Inc.	2	6/20/84	159	154	214	214	0.0%
52024	Lincoln	Deaconess Homecare	161	2/25/76	842	1,294	731	0	0.0%
54043	McMinn	NHC Homecare	166	2/13/84	239	358	421	421	100.0%
62052	Monroe	Intrepid USA Healthcare Services	190	9/10/84	358	355	565	565	100.0%
62062	Monroe	Sweetwater Hospital Home Health	189	8/20/84	613	625	651	651	100.0%
67024	Overton	Amedisys Home Health	191	1/17/84	1,101	949	1,101	176	16.0%
71014	Putnam	Highland Rim Home Health Agency	197	5/2/78	574	497	549	1	0.2%
71084	Putnam	Intrepid USA Healthcare Services	198	6/19/84	327	281	369	46	12.5%
75024	Rutherford	NHC Homecare	208	5/17/76	3,776	4,180	4,270	74	1.7%
75064	Rutherford	Amedisys Home Health Care	5	8/23/84	1,582	1,372	1,265	0	0.0%
76032	Scott	Deaconess Homecare	211	9/20/85	394	603	338	316	93.5%
82051	Sullivan	Advanced Home Care, Inc.	249	4/9/85	2,245	2,276	2,641	2,628	99.5%
82061	Sullivan	Gentiva Health Services	251	11/3/83	936	612	598	597	99.8%
89064	Warren	Intrepid USA Healthcare Services	263	8/1/84	822	804	843	0	0.0%
89074	Warren	Careall Home Care Services	265	1/31/84	637	974	749	456	60.9%
90081	Washington	Medical Center Homecare - Kingsport	269	11/4/83	1,960	1,846	1,923	1,923	100.0%
90091	Washington	Medical Center Homecare Services	271	5/4/84	3,503	3,714	3,625	3,625	0.0%
90121	Washington	Amedisys Home Health	273	7/6/84	1,821	1,460	1,676	1,676	100.0%
90131	Washington	NHC Homecare	267	3/22/78	259	465	611	611	100.0%
95034	Wilson	Deaconess Homecare I	282	12/18/78	1,222	1,706	956	53	5.5%
96030	London Co, KY	Professional Home Health Care Agency	298	9/2/77	12	21	6	6	100.0%
	Knox	Implanted Pump Management	633				0	0	0.0%

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Table B.5-3B: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area BY AGENCY ID

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
	Washington	Maxim Healthcare Services	629				0	0	0.0%
	Davidson	Pentec Health	632				0	0	0.0%
		AREAWIDE TOTALS AND AVERAGES			89,395	88,133	88,667	68,979	77.8%

Source: TDH; 2013-2015 Joint Annual Reports of Home Health Agencies

Table B.5-3C: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area
RANKED BY RELIANCE ON PROPOSED SERVICE AREA

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
30021	Greene	Advanced Home Care, Inc.	86	8/31/83	762	817	845	845	100.0%
90121	Washington	Amedisys Home Health	273	7/6/84	1,821	1,460	1,676	1,676	100.0%
10031	Carter	Amedisys Home Health Care	23	1/20/84	1,171	937	901	901	100.0%
47202	Knox	Amedisys Home Health Care	150	8/2/84	5,354	4,391	4,548	4,548	100.0%
13022	Claiborne	Amedisys Home Health of Tennessee	25	10/8/82	1,830	1,547	1,551	1,551	100.0%
05012	Blount	Blount Memorial Hospital Home Health Services	213	1/26/15	1,224	1,281	1,589	1,589	100.0%
33213	Hamilton	Continuecare Healthservices, Inc. I	98	11/2/84	1,466	1,393	1,356	1,356	100.0%
33383	Hamilton	Continuecare Healthservices, Inc. II	108	5/7/76	8	7	7	7	100.0%
47222	Knox	East Tennessee Children's Hospital Home Health	132	9/13/84	586	600	560	560	100.0%
06043	Bradley	Family Home Care - Cleveland	13	1/10/84	598	1,454	1,494	1,494	100.0%
47042	Knox	Gentiva Health Services	142	11/28/77	779	413	80	80	100.0%
34011	Hancock	Hancock County Home Health and Hospice Agency	117	7/23/75	463	488	648	648	100.0%
37021	Hawkins	Hometown Home Health, Inc.	320	1/9/95	89	94	108	108	100.0%
62052	Monroe	Intrepid USA Healthcare Services	190	9/10/84	356	355	565	565	100.0%
46031	Johnson	Johnson County Home Health.	130	6/29/84	446	492	447	447	100.0%
30041	Greene	Laughlin Home Health Agency	88	6/26/84	655	737	711	711	100.0%
33433	Hamilton	Maxim Healthcare Services	613	8/18/05	56	53	57	57	100.0%
90081	Washington	Medical Center Homecare - Kingsport	269	11/4/83	1,960	1,846	1,923	1,923	100.0%
33033	Hamilton	NHC Homecare	111	6/10/77	354	411	278	278	100.0%
47012	Knox	NHC Homecare	143	6/10/77	613	883	870	870	100.0%
54043	McMinn	NHC Homecare	166	2/13/84	239	358	421	421	100.0%
90131	Washington	NHC Homecare	267	3/22/78	259	465	611	611	100.0%
32132	Hamblen	Premier Support Services, Inc.	10	5/16/84	1,169	1,372	1,126	1,126	100.0%
30051	Greene	Procare Home Health Services	87	7/8/82	433	522	574	574	100.0%
96030	London Co, KY	Professional Home Health Care Agency	298	9/2/77	12	21	6	6	100.0%
15032	Cocke	Smoky Mountain Home Health and Hospice	27	11/9/89	1,296	1,102	1,128	1,128	100.0%
07032	Campbell	Sunbelt Homecare	16	8/10/84	261	243	253	253	100.0%
13032	Claiborne	Suncrest Home Health and Hospice	93	9/14/84	852	1,008	663	663	100.0%
62062	Monroe	Sweetwater Hospital Home Health	189	8/20/84	613	625	651	651	100.0%
33303	Hamilton	Tennessee Home Health (Lifecare)	109	11/7/84	956	1,298	520	520	100.0%
47092	Knox	Tennova Healthcare Home Health	151	2/29/80	3,063	3,240	4,029	4,029	100.0%
33253	Hamilton	CHI Memorial Health at Home	103	8/9/82	2,439	2,651	2,852	2,851	100.0%
47402	Knox	Covenant Homecare	133	7/14/78	3,953	4,792	5,391	5,389	100.0%
47062	Knox	Camellia Home Health of East Tennessee	144	9/7/78	1,716	1,732	2,215	2,213	99.9%
47182	Knox	Gentiva Health Services 2 (Girling Health Services)	149	8/15/84	1,467	1,815	1,675	1,673	99.9%
33083	Hamilton	Guardian Home Care, LLC	115	6/29/78	1,484	1,255	1,929	1,926	99.8%
32102	Hamblen	Amedisys Home Health Care	91	12/13/82	3,896	3,210	3,099	3,094	99.8%
82061	Sullivan	Gentiva Health Services	251	11/3/83	936	612	598	597	99.8%
33103	Hamilton	Amedisys Home Health	113	7/1/81	2,878	2,564	2,610	2,599	99.6%
33093	Hamilton	Gentiva Health Services	100	8/24/84	328	348	426	424	99.5%
82051	Sullivan	Advanced Home Care, Inc.	249	4/9/85	2,245	2,276	2,641	2,628	99.5%
33363	Hamilton	Home Care Solutions	338	11/14/96	663	540	473	465	98.3%
01042	Anderson	Professional Case Management of Tennessee	620	1/30/08	164	173	249	242	97.2%
76032	Scott	Deaconess Homecare	211	9/20/85	394	603	338	316	93.5%
06063	Bradley	Home Health Care of East Tennessee, Inc.	14	3/14/84	3,318	2,680	1,580	1,454	92.0%
33423	Hamilton	Alere Women's and Children's Health, LLC	457	11/13/98	61	50	40	32	80.0%
25044	Fentress	Quality Home Health	287	3/7/84	3,404	3,591	4,278	2,778	64.9%
89074	Warren	Careall Home Care Services	265	1/31/84	637	974	749	456	60.9%
26024	Franklin	Encompass Home Health of Tennessee	83	1/29/76	2,030	2,444	2,581	745	28.9%
19494	Davidson	Elk Valley Health Services	42	7/17/84	277	293	457	115	25.2%
67024	Overton	Amedisys Home Health	191	1/17/84	1,101	949	1,101	176	16.0%
19544	Davidson	Home Care Solutions, Inc.	56	9/7/88	1,930	1,689	1,813	273	15.1%
19724	Davidson	Careall	295	7/5/84	1,562	1,665	891	116	13.0%
14024	Clay	Cumberland River Homecare	135	12/28/82	392	393	293	38	13.0%
71084	Putnam	Intrepid USA Healthcare Services	198	6/19/84	327	281	369	46	12.5%
95034	Wilson	Deaconess Homecare I	282	12/18/78	1,222	1,706	956	53	5.5%
16034	Coffee	Suncrest Home Health	29	4/16/84	1,588	2,122	1,667	49	2.9%
75024	Rutherford	NHC Homecare	208	5/17/76	3,776	4,180	4,270	74	1.7%
26054	Franklin	Amedisys Home Care	82	9/19/83	1,150	1,002	909	3	0.3%
71014	Putnam	Highland Rim Home Health Agency	197	5/2/78	574	497	549	1	0.2%
75064	Rutherford	Amedisys Home Health Care	5	8/23/84	1,582	1,372	1,265	0	0.0%
47232	Knox	Careall Home Care Services	131	8/21/89	510	686	0	0	0.0%
01032	Anderson	Clinch River Home Health	1	10/26/76	461	481	450	450	0.0%
19734	Davidson	Corum CVS Specialty Infusion Services	624	1/30/13	11	26	36	0	0.0%
52024	Lincoln	Deaconess Homecare	161	2/25/76	842	1,294	731	0	0.0%
	Knox	Implanted Pump Management	633				0	0	0.0%
89064	Warren	Intrepid USA Healthcare Services	263	8/1/84	822	804	843	0	0.0%
	Washington	Maxim Healthcare Services	629				0	0	0.0%
47432	Knox	Maxim Healthcare Services, Inc.	2	6/20/84	159	154	214	214	0.0%
90091	Washington	Medical Center Homecare Services	271	5/4/84	3,503	3,714	3,625	3,625	0.0%
19654	Davidson	Optum Women's and Children's Health, LLC	471	3/1/99	202	186	196	0	0.0%
	Davidson	Pentec Health	632				0	0	0.0%
25034	Fentress	Quality Private Duty Care	80	10/28/83	879	894	784	340	0.0%

Table B.5-3C: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area
RANKED BY RELIANCE ON PROPOSED SERVICE AREA

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
01052	Anderson	The Home Option by Hardin Health Care	148	12/13/84			79	79	0.0%
32122	Hamblen	Univ. of TN Med Cntr Home Health / Hospice Service	153	12/18/84	1,327	751	1,145	1,145	0.0%
47132	Knox	UTMCK - Home Care Services: Hospice & Home Care	156	7/20/83	3,439	771	2,104	2,104	0.0%
		AREAWIDE TOTALS AND AVERAGES			**89,395**	**88,133**	**88,667**	**68,979**	**77.8%**

Source: TDH; 2013-2015 Joint Annual Reports of Home Health Agencies

Table B.5-4A: 2015 TennCare Payor Mix of Home Health Agencies in the Project's Proposed Primary Service Area BY AGENCY NAME

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2015 Total Gross Revenues	2015 TennCare Gross Revenues	2015 TennCare Percent of Total Gross Revenues
30021	Greene	Advanced Home Care, Inc.	86	8/31/83	$2,207,493	$49,501	2.2%
82051	Sullivan	Advanced Home Care, Inc.	249	4/9/85	$5,562,153	$84,811	1.5%
33423	Hamilton	Alere Women's and Children's Health, LLC	457	11/13/98	$403,877	$218,094	54.0%
26054	Franklin	Amedisys Home Care	82	9/19/83	$3,344,050	$0	0.0%
33103	Hamilton	Amedisys Home Health	113	7/1/81	$9,660,515	$0	0.0%
67024	Overton	Amedisys Home Health	191	1/17/84	$4,544,856	$0	0.0%
90121	Washington	Amedisys Home Health	273	7/6/84	$5,478,748	$0	0.0%
10031	Carter	Amedisys Home Health Care	23	1/20/84	$3,443,254	$0	0.0%
32102	Hamblen	Amedisys Home Health Care	91	12/13/82	$13,632,114	$0	0.0%
47202	Knox	Amedisys Home Health Care	150	8/2/84	$17,617,489	$0	0.0%
75064	Rutherford	Amedisys Home Health Care	5	8/23/84	$4,486,939	$0	0.0%
13022	Claiborne	Amedisys Home Health of Tennessee	25	10/8/82	$7,701,253	$0	0.0%
05012	Blount	Blount Memorial Hospital Home Health Services	213	1/26/15	$5,099,569	$123,190	2.4%
47062	Knox	Camellia Home Health of East Tennessee	144	9/7/78	$13,824,348	$10,667,700	77.2%
19724	Davidson	Careall	295	7/5/84	$5,110,267	$2,209,967	43.2%
47232	Knox	Careall Home Care Services	131	8/21/89	$0	$0	0.0%
89074	Warren	Careall Home Care Services	265	1/31/84	$2,657,428	$415,095	15.6%
33253	Hamilton	CHI Memorial Health at Home	103	8/9/82	$7,073,688	$246,843	3.5%
01032	Anderson	Clinch River Home Health	1	10/26/76	$744,150	$0	0.0%
33213	Hamilton	Continuecare Healthservices, Inc. I	98	11/2/84	$9,845,342	$6,995,902	71.1%
33383	Hamilton	Continuecare Healthservices, Inc. II	108	5/7/76	$19,446	$0	0.0%
19734	Davidson	Corum CVS Specialty Infusion Services	624	1/30/13	$125,000	$0	0.0%
47402	Knox	Covenant Homecare	133	7/14/78	$16,146,726	$78,622	0.5%
14024	Clay	Cumberland River Homecare	135	12/28/82	$6,412,801	$4,683,372	73.0%
52024	Lincoln	Deaconess Homecare	161	2/25/76	$1,696,102	$92,188	5.4%
76032	Scott	Deaconess Homecare	211	9/20/85	$1,228,489	$49,775	4.1%
95034	Wilson	Deaconess Homecare I	282	12/18/78	$3,252,642	$177,596	5.5%
47222	Knox	East Tennessee Children's Hospital Home Health	132	9/13/84	$16,502,872	$10,474,392	63.5%
19494	Davidson	Elk Valley Health Services	42	7/17/84	$31,824,839	$22,851,469	71.8%
26024	Franklin	Encompass Home Health of Tennessee	83	1/29/76	$10,349,580	$0	0.0%
06043	Bradley	Family Home Care - Cleveland	13	1/10/84	$40,615,843	$9,230	0.0%
33093	Hamilton	Gentiva Health Services	100	8/24/84	$2,190,756	$0	0.0%
47042	Knox	Gentiva Health Services	142	11/28/77	$336,351	$0	0.0%
82061	Sullivan	Gentiva Health Services	251	11/3/83	$2,040,611	$0	0.0%
47182	Knox	Gentiva Health Services 2 (Girling Health Services)	149	8/15/84	$8,569,163	$0	0.0%
33083	Hamilton	Guardian Home Care, LLC	115	6/29/78	$10,375,052	$0	0.0%
34011	Hancock	Hancock County Home Health and Hospice Agency	117	7/23/75	$1,465,351	$482,425	32.9%
71014	Putnam	Highland Rim Home Health Agency	197	5/2/78	$5,204,413	$3,330,075	64.0%
33363	Hamilton	Home Care Solutions	338	11/14/96	$1,447,585	$0	0.0%
19544	Davidson	Home Care Solutions, Inc.	56	9/7/88	$9,626,513	$0	0.0%
06063	Bradley	Home Health Care of East Tennessee, Inc.	14	3/14/84	$17,935,065	$9,055,836	50.5%
37021	Hawkins	Hometown Home Health, Inc.	320	1/9/95	$281,775	$46,927	16.7%
	Knox	Implanted Pump Management	633				0.0%
62052	Monroe	Intrepid USA Healthcare Services	190	9/10/84	$2,176,139	$5,170	0.2%
71084	Putnam	Intrepid USA Healthcare Services	198	6/19/84	$1,207,450	$0	0.0%
89064	Warren	Intrepid USA Healthcare Services	263	8/1/84	$4,963,344	$0	0.0%
46031	Johnson	Johnson County Home Health.	130	6/29/84	$1,294,289	$25,418	2.0%
30041	Greene	Laughlin Home Health Agency	88	6/26/84	$2,035,049	$438,302	21.5%
33433	Hamilton	Maxim Healthcare Services	613	8/18/05	$5,656,599	$5,240,303	92.6%
	Washington	Maxim Healthcare Services	629				0.0%
47432	Knox	Maxim Healthcare Services, Inc.	2	6/20/84	$18,967,419	$17,056,250	89.9%
90081	Washington	Medical Center Homecare - Kingsport	269	11/4/83	$4,316,785	$714,443	16.6%
90091	Washington	Medical Center Homecare Services	271	5/4/84	$8,044,443	$412,325	5.1%
33033	Hamilton	NHC Homecare	111	6/10/77	$1,078,792	$0	0.0%
47012	Knox	NHC Homecare	143	6/10/77	$3,464,418	$0	0.0%
54043	McMinn	NHC Homecare	166	2/13/84	$1,855,338	$0	0.0%
75024	Rutherford	NHC Homecare	208	5/17/76	$17,986,702	$0	0.0%
90131	Washington	NHC Homecare	267	3/22/78	$2,624,808	$0	0.0%
19654	Davidson	Optum Women's and Children's Health, LLC	471	3/1/99	$222,266	$106,643	48.0%
	Davidson	Pentec Health	632				0.0%
32132	Hamblen	Premier Support Services, Inc.	10	5/16/84	$7,789,380	$4,910,848	63.0%
30051	Greene	Procare Home Health Services	87	7/8/82	$9,005,133	$6,863,406	76.2%

Table B.5-4A: 2015 TennCare Payor Mix of Home Health Agencies in the Project's Proposed Primary Service Area
BY AGENCY NAME

01042	Anderson	Professional Case Management of Tennessee	620	1/30/08	$20,844,100	$0	0.0%
96030	London Co, KY	Professional Home Health Care Agency	298	9/2/77	$18,875,234	$0	0.0%
25044	Fentress	Quality Home Health	287	3/7/84	$32,695,363	$8,536,311	26.1%
25034	Fentress	Quality Private Duty Care	80	10/28/83	$13,270,601	$6,187,248	46.6%
15032	Cocke	Smoky Mountain Home Health and Hospice	27	11/9/89	$4,019,505	$84,667	2.1%
07032	Campbell	Sunbelt Homecare	16	8/10/84	$1,011,042	$82,959	8.2%
16034	Coffee	Suncrest Home Health	29	4/16/84	$13,745,111	$2,523,808	18.4%
13032	Claiborne	Suncrest Home Health and Hospice	93	9/14/84	$3,477,190	$81,590	2.3%
62062	Monroe	Sweetwater Hospital Home Health	189	8/20/84	$2,900,006	$329,663	11.4%
33303	Hamilton	Tennessee Home Health (Life Care)	109		$2,178,922	$0	0.0%
47092	Knox	Tennova Healthcare Home Health	151	2/29/80	$11,214,161	$431,655	3.8%
01052	Anderson	The Home Option by Hardin Health Care	148	12/13/84	$3,534,722	$0	0.0%
32122	Hamblen	Univ. of TN Med Cntr Home Health / Hospice Service	153	12/18/84	$5,339,604	$7,479	0.1%
47132	Knox	UTMCK - Home Care Services: Hospice & Home Care	156	7/20/83	$6,200,579	$48,954	0.8%
		AREAWIDE TOTALS AND AVERAGES			**$542,069,002**	**$126,430,452**	**23.3%**

Source: TDH; 2015 Joint Annual Reports of Home Health Agencies
Note: Hemophilia Preferred Care is omitted because it was not operational in this period.

Table B.5-4B: 2015 TennCare Payor Mix of Home Health Agencies in the Project's Proposed Primary Service Area BY AGENCY ID

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2015 Total Gross Revenues	2015 TennCare Gross Revenues	2015 TennCare Percent of Total Gross Revenues
01032	Anderson	Clinch River Home Health	1	10/26/76	$744,150	$0	0.0%
01042	Anderson	Professional Case Management of Tennessee	620	1/30/08	$20,844,100	$0	0.0%
01052	Anderson	The Home Option by Hardin Health Care	148	12/13/84	$3,534,722	$0	0.0%
05012	Blount	Blount Memorial Hospital Home Health Services	213	1/26/15	$5,089,569	$123,190	2.4%
06043	Bradley	Family Home Care - Cleveland	13	1/10/84	$40,615,843	$9,230	0.0%
06063	Bradley	Home Health Care of East Tennessee, Inc.	14	3/14/84	$17,935,065	$9,055,836	50.5%
07032	Campbell	Sunbelt Homecare	16	8/10/84	$1,011,042	$82,959	8.2%
10031	Carter	Amedisys Home Health Care	23	1/20/84	$3,443,254	$0	0.0%
13022	Claiborne	Amedisys Home Health of Tennessee	25	10/8/82	$7,701,253	$0	0.0%
13032	Claiborne	Suncrest Home Health and Hospice	93	9/14/84	$3,477,190	$81,590	2.3%
14024	Clay	Cumberland River Homecare	135	12/28/82	$6,412,801	$4,683,372	73.0%
15032	Cocke	Smoky Mountain Home Health and Hospice	27	11/9/89	$4,019,505	$84,667	2.1%
16034	Coffee	Suncrest Home Health	29	4/16/84	$13,745,111	$2,523,808	18.4%
19494	Davidson	Elk Valley Health Services	42	7/17/84	$31,824,839	$22,851,469	71.8%
19544	Davidson	Home Care Solutions, Inc.	56	9/7/88	$9,626,513	$0	0.0%
19654	Davidson	Optum Women's and Children's Health, LLC	471	3/1/99	$222,266	$106,643	48.0%
19724	Davidson	Careall	295	7/5/84	$5,110,267	$2,209,967	43.2%
19734	Davidson	Corum CVS Specialty Infusion Services	624	1/30/13	$125,000	$0	0.0%
25034	Fentress	Quality Private Duty Care	80	10/28/83	$13,270,601	$6,187,248	46.6%
25044	Fentress	Quality Home Health	287	3/7/84	$32,695,363	$8,536,311	26.1%
26024	Franklin	Encompass Home Health of Tennessee	83	1/29/76	$10,349,580	$0	0.0%
26054	Franklin	Amedisys Home Care	82	9/19/83	$3,344,050	$0	0.0%
30021	Greene	Advanced Home Care, Inc.	86	8/31/83	$2,207,493	$49,501	2.2%
30041	Greene	Laughlin Home Health Agency	88	6/26/84	$2,035,049	$438,302	21.5%
30051	Greene	Procare Home Health Services	87	7/8/82	$9,005,133	$6,863,406	76.2%
32102	Hamblen	Amedisys Home Health Care	91	12/13/82	$13,632,114	$0	0.0%
32122	Hamblen	Univ. of TN Med Cntr Home Health / Hospice Service	153	12/18/84	$5,339,604	$7,479	0.1%
32132	Hamblen	Premier Support Services, Inc.	10	5/16/84	$7,789,380	$4,910,848	63.0%
33033	Hamilton	NHC Homecare	111	6/10/77	$1,078,792	$0	0.0%
33083	Hamilton	Guardian Home Care, LLC	115	6/29/78	$10,375,052	$0	0.0%
33093	Hamilton	Gentiva Health Services	100	8/24/84	$2,190,756	$0	0.0%
33103	Hamilton	Amedisys Home Health	113	7/1/81	$9,660,515	$0	0.0%
33213	Hamilton	Continuecare Healthservices, Inc. I	98	11/2/84	$9,845,342	$6,995,902	71.1%
33253	Hamilton	CHI Memorial Health at Home	103	8/9/82	$7,073,688	$246,843	3.5%
33303	Hamilton	Tennessee Home Health (Life Care)	109		$2,178,922	$0	0.0%
33363	Hamilton	Home Care Solutions	338	11/14/96	$1,447,585	$0	0.0%
33383	Hamilton	Continuecare Healthservices, Inc. II	108	5/7/76	$19,446	$0	0.0%
33423	Hamilton	Alere Women's and Children's Health, LLC	457	11/13/98	$403,877	$218,094	54.0%
33433	Hamilton	Maxim Healthcare Services	613	8/18/05	$5,656,599	$5,240,303	92.6%
34011	Hancock	Hancock County Home Health and Hospice Agency	117	7/23/75	$1,465,351	$482,425	32.9%
37021	Hawkins	Hometown Home Health, Inc.	320	1/9/95	$281,775	$46,927	16.7%
46031	Johnson	Johnson County Home Health.	130	6/29/84	$1,294,289	$25,418	2.0%
47012	Knox	NHC Homecare	143	6/10/77	$3,464,418	$0	0.0%
47042	Knox	Gentiva Health Services	142	11/28/77	$336,351	$0	0.0%
47062	Knox	Camellia Home Health of East Tennessee	144	9/7/78	$13,824,348	$10,667,700	77.2%
47092	Knox	Tennova Healthcare Home Health	151	2/29/80	$11,214,161	$431,655	3.8%
47132	Knox	UTMCK - Home Care Services: Hospice & Home Care	156	7/20/83	$6,200,579	$48,954	0.8%
47182	Knox	Gentiva Health Services 2 (Girling Health Services)	149	8/15/84	$8,569,163	$0	0.0%
47202	Knox	Amedisys Home Health Care	150	8/2/84	$17,617,489	$0	0.0%
47222	Knox	East Tennessee Children's Hospital Home Health	132	9/13/84	$16,502,872	$10,474,392	63.5%
47232	Knox	Careall Home Care Services	131	8/21/89	$0	$0	0.0%
47402	Knox	Covenant Homecare	133	7/14/78	$16,146,726	$78,622	0.5%
47432	Knox	Maxim Healthcare Services, Inc.	2	6/20/84	$18,967,419	$17,056,250	89.9%
52024	Lincoln	Deaconess Homecare	161	2/25/76	$1,696,102	$92,188	5.4%
54043	McMinn	NHC Homecare	166	2/13/84	$1,855,338	$0	0.0%
62052	Monroe	Intrepid USA Healthcare Services	190	9/10/84	$2,176,139	$5,170	0.2%
62062	Monroe	Sweetwater Hospital Home Health	189	8/20/84	$2,900,006	$329,663	11.4%
67024	Overton	Amedisys Home Health	191	1/17/84	$4,544,856	$0	0.0%
71014	Putnam	Highland Rim Home Health Agency	197	5/2/78	$5,204,413	$3,330,075	64.0%
71084	Putnam	Intrepid USA Healthcare Services	198	6/19/84	$1,207,450	$0	0.0%
75024	Rutherford	NHC Homecare	208	5/17/76	$17,986,702	$0	0.0%
75064	Rutherford	Amedisys Home Health Care	5	8/23/84	$4,486,939	$0	0.0%
76032	Scott	Deaconess Homecare	211	9/20/85	$1,228,489	$49,775	4.1%

Table B.5-4B: 2015 TennCare Payor Mix of Home Health Agencies in the Project's Proposed Primary Service Area BY AGENCY ID

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2015 Total Gross Revenues	2015 TennCare Gross Revenues	2015 TennCare Percent of Total Gross Revenues
82051	Sullivan	Advanced Home Care, Inc.	249	4/9/85	$5,562,153	$84,811	1.5%
82061	Sullivan	Gentiva Health Services	251	11/3/83	$2,040,611	$0	0.0%
89064	Warren	Intrepid USA Healthcare Services	263	8/1/84	$4,963,344	$0	0.0%
89074	Warren	Careall Home Care Services	265	1/31/84	$2,657,428	$415,095	15.6%
90081	Washington	Medical Center Homecare - Kingsport	269	11/4/83	$4,316,785	$714,443	16.6%
90091	Washington	Medical Center Homecare Services	271	5/4/84	$8,044,443	$412,325	5.1%
90121	Washington	Amedisys Home Health	273	7/6/84	$5,478,748	$0	0.0%
90131	Washington	NHC Homecare	267	3/22/78	$2,624,808	$0	0.0%
95034	Wilson	Deaconess Homecare I	282	12/18/78	$3,252,642	$177,596	5.5%
96030	London Co, KY	Professional Home Health Care Agency	298	9/2/77	$18,875,234	$0	0.0%
	Knox	Implanted Pump Management	633				0.0%
	Washington	Maxim Healthcare Services	629				0.0%
	Davidson	Pentec Health	632				0.0%
		AREAWIDE TOTALS AND AVERAGES			**$542,069,002**	**$126,430,452**	**23.3%**

Source: TDH; 2015 Joint Annual Reports of Home Health Agencies

Note: Hemophilia Preferred Care is omitted because it was not operational in this period.

Table B.5-4C: 2015 TennCare Payor Mix of Home Health Agencies in the Project's Proposed Service Area
BY TENNCARE PERCENT OF AGENCY GROSS CHARGES

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2015 Total Gross Revenues	2015 TennCare Gross Revenues	2015 TennCare Percent of Total Gross Revenues
33433	Hamilton	Maxim Healthcare Services	613	8/18/05	$5,656,599	$5,240,303	92.6%
47432	Knox	Maxim Healthcare Services, Inc.	2	6/20/84	$18,967,419	$17,056,250	89.9%
47062	Knox	Camellia Home Health of East Tennessee	144	9/7/78	$13,824,348	$10,667,700	77.2%
30051	Greene	Procare Home Health Services	87	7/8/82	$9,005,133	$6,863,406	76.2%
14024	Clay	Cumberland River Homecare	135	12/28/82	$6,412,801	$4,683,372	73.0%
19494	Davidson	Elk Valley Health Services	42	7/17/84	$31,824,839	$22,851,469	71.8%
33213	Hamilton	Continuecare Healthservices, Inc. I	98	11/2/84	$9,845,342	$6,995,902	71.1%
71014	Putnam	Highland Rim Home Health Agency	197	5/2/78	$5,204,413	$3,330,075	64.0%
47222	Knox	East Tennessee Children's Hospital Home Health	132	9/13/84	$16,502,872	$10,474,392	63.5%
32132	Hamblen	Premier Support Services, Inc.	10	5/16/84	$7,789,380	$4,910,848	63.0%
33423	Hamilton	Alere Women's and Children's Health, LLC	457	11/13/98	$403,877	$218,094	54.0%
06063	Bradley	Home Health Care of East Tennessee, Inc.	14	3/14/84	$17,935,065	$9,055,836	50.5%
19654	Davidson	Optum Women's and Children's Health, LLC	471	3/1/99	$222,266	$106,643	48.0%
25034	Fentress	Quality Private Duty Care	80	10/28/83	$13,270,601	$6,187,248	46.6%
19724	Davidson	Careall	295	7/5/84	$5,110,267	$2,209,967	43.2%
34011	Hancock	Hancock County Home Health and Hospice Agency	117	7/23/75	$1,465,351	$482,425	32.9%
25044	Fentress	Quality Home Health	287	3/7/84	$32,695,363	$8,536,311	26.1%
30041	Greene	Laughlin Home Health Agency	88	6/26/84	$2,035,049	$438,302	21.5%
16034	Coffee	Suncrest Home Health	29	4/16/84	$13,745,111	$2,523,808	18.4%
37021	Hawkins	Hometown Home Health, Inc.	320	1/9/95	$281,775	$46,927	16.7%
90081	Washington	Medical Center Homecare - Kingsport	269	11/4/83	$4,316,785	$714,443	16.6%
89074	Warren	Careall Home Care Services	265	1/31/84	$2,657,428	$415,095	15.6%
62062	Monroe	Sweetwater Hospital Home Health	189	8/20/84	$2,900,006	$329,663	11.4%
07032	Campbell	Sunbelt Homecare	16	8/10/84	$1,011,042	$82,959	8.2%
95034	Wilson	Deaconess Homecare I	282	12/18/78	$3,252,642	$177,596	5.5%
52024	Lincoln	Deaconess Homecare	161	2/25/76	$1,696,102	$92,188	5.4%
90091	Washington	Medical Center Homecare Services	271	5/4/84	$8,044,443	$412,325	5.1%
76032	Scott	Deaconess Homecare	211	9/20/85	$1,228,489	$49,775	4.1%
47092	Knox	Tennova Healthcare Home Health	151	2/29/80	$11,214,161	$431,655	3.8%
33253	Hamilton	CHI Memorial Health at Home	103	8/9/82	$7,073,688	$246,843	3.5%
05012	Blount	Blount Memorial Hospital Home Health Services	213	1/26/15	$5,089,569	$123,190	2.4%
13032	Claiborne	Suncrest Home Health and Hospice	93	9/14/84	$3,477,190	$81,590	2.3%
30021	Greene	Advanced Home Care, Inc.	86	8/31/83	$2,207,493	$49,501	2.2%
15032	Cocke	Smoky Mountain Home Health and Hospice	27	11/9/89	$4,019,505	$84,667	2.1%
46031	Johnson	Johnson County Home Health.	130	6/29/84	$1,294,289	$25,418	2.0%
82051	Sullivan	Advanced Home Care, Inc.	249	4/9/85	$5,562,153	$84,811	1.5%
47132	Knox	UTMCK - Home Care Services: Hospice & Home Care	156	7/20/83	$6,200,579	$48,954	0.8%
47402	Knox	Covenant Homecare	133	7/14/78	$16,146,726	$78,622	0.5%
62052	Monroe	Intrepid USA Healthcare Services	190	9/10/84	$2,176,139	$5,170	0.2%
32122	Hamblen	Univ. of TN Med Cntr Home Health / Hospice Service	153	12/18/84	$5,339,604	$7,479	0.1%
06043	Bradley	Family Home Care - Cleveland	13	1/10/84	$40,615,843	$9,230	0.0%
26054	Franklin	Amedisys Home Care	82	9/19/83	$3,344,050	$0	0.0%
33103	Hamilton	Amedisys Home Health	113	7/1/81	$9,660,515	$0	0.0%
67024	Overton	Amedisys Home Health	191	1/17/84	$4,544,856	$0	0.0%
90121	Washington	Amedisys Home Health	273	7/6/84	$5,478,748	$0	0.0%
10031	Carter	Amedisys Home Health Care	23	1/20/84	$3,443,254	$0	0.0%
32102	Hamblen	Amedisys Home Health Care	91	12/13/82	$13,632,114	$0	0.0%
47202	Knox	Amedisys Home Health Care	150	8/2/84	$17,617,489	$0	0.0%
75064	Rutherford	Amedisys Home Health Care	5	8/23/84	$4,486,939	$0	0.0%
13022	Claiborne	Amedisys Home Health of Tennessee	25	10/8/82	$7,701,253	$0	0.0%
47232	Knox	Careall Home Care Services	131	8/21/89	$0	$0	0.0%
01032	Anderson	Clinch River Home Health	1	10/26/76	$744,150	$0	0.0%
33383	Hamilton	Continuecare Healthservices, Inc. II	108	5/7/76	$19,446	$0	0.0%
19734	Davidson	Corum CVS Specialty Infusion Services	624	1/30/13	$125,000	$0	0.0%
26024	Franklin	Encompass Home Health of Tennessee	83	1/29/76	$10,349,580	$0	0.0%
33093	Hamilton	Gentiva Health Services	100	8/24/84	$2,190,756	$0	0.0%
47042	Knox	Gentiva Health Services	142	11/28/77	$336,351	$0	0.0%
82061	Sullivan	Gentiva Health Services	251	11/3/83	$2,040,611	$0	0.0%
47182	Knox	Gentiva Health Services 2 (Girling Health Services)	149	8/15/84	$8,569,163	$0	0.0%
33083	Hamilton	Guardian Home Care, LLC	115	6/29/78	$10,375,052	$0	0.0%
33363	Hamilton	Home Care Solutions	338	11/14/96	$1,447,585	$0	0.0%
19544	Davidson	Home Care Solutions, Inc.	56	9/7/88	$9,626,513	$0	0.0%
	Knox	Implanted Pump Management	633				0.0%
71084	Putnam	Intrepid USA Healthcare Services	198	6/19/84	$1,207,450	$0	0.0%

Table B.5-4C: 2015 TennCare Payor Mix of Home Health Agencies in the Project's Proposed Service Area
BY TENNCARE PERCENT OF AGENCY GROSS CHARGES

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2015 Total Gross Revenues	2015 TennCare Gross Revenues	2015 TennCare Percent of Total Gross Revenues
89064	Warren	Intrepid USA Healthcare Services	263	8/1/84	$4,963,344	$0	0.0%
	Washington	Maxim Healthcare Services	629				0.0%
33033	Hamilton	NHC Homecare	111	6/10/77	$1,078,792	$0	0.0%
47012	Knox	NHC Homecare	143	6/10/77	$3,464,418	$0	0.0%
54043	McMinn	NHC Homecare	166	2/13/84	$1,855,338	$0	0.0%
75024	Rutherford	NHC Homecare	208	5/17/76	$17,986,702	$0	0.0%
90131	Washington	NHC Homecare	267	3/22/78	$2,624,808	$0	0.0%
	Davidson	Pentec Health	632				0.0%
01042	Anderson	Professional Case Management of Tennessee	620	1/30/08	$20,844,100	$0	0.0%
96030	London Co, KY	Professional Home Health Care Agency	298	9/2/77	$18,875,234	$0	0.0%
33303	Hamilton	Tennessee Home Health (Life Care)	109		$2,178,922	$0	0.0%
01052	Anderson	The Home Option by Hardin Health Care	148	12/13/84	$3,534,722	$0	0.0%
		AREAWIDE TOTALS AND AVERAGES			**$542,069,002**	**$126,430,452**	**23.3%**

Source: TDH; 2015 Joint Annual Reports of Home Health Agencies
Note: Hemophilia Preferred Care is omitted because it was not operational in this period.

B-Economic Feasibility--2

Documentation of Funding/Financing Availability

BriovaRx Home Infusion Services, Inc.
15529 College Blvd
Lenexa, KS 66219

February 10, 2017

Melanie Hill, Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application to Expand the Home Health Service Area
for AxelaCare Health Solutions, LLC

Dear Mrs. Hill:

AxelaCare Health Solutions, LLC is filing a Certificate of Need application to expand its service area to include 34 East Tennessee counties. AxelaCare Health Solutions is wholly owned by Briova Rx Home Infusion Services, Inc., of which I am Controller. Briova Rx in turn is wholly owned through a chain of wholly owned subsidiaries by UnitedHealth Group, Incorporated, a publicly traded company.

I am writing to confirm that the project's capital cost, estimated at $70,000, will be funded by a cash transfer to the applicant LLC from our ultimate parent company, UnitedHealth Group, through Briova Rx. I am authorized to make that commitment. The availability of sufficient cash for this is shown in the financial statements included in the application. The attached statements are for both Briova and UnitedHealth Group.

Clay Collins
Controller
Briova Rx Home Infusion Services, Inc.

B-Economic Feasibility-6A

Applicant's Financial Statements

BRIOVA Rx INFUSION SERVICES, INC. INCOME STATEMENT CY 2016 (UNAUDITED)	
Revenues	
Premium Revenues	$0
Service Revenues	$0
Product Revenues	$482,559,862
Total Revenues	$482,559,862
Medical Costs	
Med Costs excl KEFR/EBR	$0
KEFR/EBR	$0
Total Medical Costs	$0
Cost of Products Sold	
Cost Of Prod Ext	$373,898,328
Total Cost of Products Sold	$373,898,328
Gross Margin	$108,661,534
Selling, General, and Admn Exp	
SG&A Expense less other comp	$94,700,251
Other Compensation	$0
Selling, General, and Admn Exp	$94,700,251
Internal Operating Income	$13,961,283

BRIOVA Rx INFUSION SERVICES, INC. BALANCE SHEET CY 2016 (UNAUDITED)	
Cash and Cash Equivalents	$17,097,615.54
Accounts Receivable	$61,201,959.32
Allowances	($5,666,993.97)
Accts Receivable, net of allow	$55,534,965.35
Other Receivables	$3,918,091.91
Other Current Receivables	$3,918,091.91
Prepaid Expenses	$210,916.06
Other Current Assets	$31,512,806.60
Ppd Exp and Other Curr Assets	$31,723,722.66
Current Assets	$108,274,395.46
Ppty, Equip, and Cap Sftw, net	$12,068,571.03
Other Assets	$1,799,887.37
Assets	**$122,142,853.86**
Intercompany Payable (Rec)	$6,866,567.26
Taxes Payable	$1,836,495.20
Other Payables and Accrd Liabs	$18,162,006.11
Accts Payble and Accrued Liabs	$26,865,068.57
Current Liabilities	$26,865,068.57
Liabilities	**($2,342,441.91)**
Additional Paid In Capital	$96,023,855.89
Retained Earnings	$28,461,439.88
Shareholders Equity	$124,485,295.77
Total Equity	**$124,485,295.77**

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number: 1-10864

UNITEDHEALTH GROUP®

UnitedHealth Group Incorporated

(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**41-1321939** **(I.R.S. Employer Identification No.)**
UnitedHealth Group Center **9900 Bren Road East** **Minnetonka, Minnesota** **(Address of principal executive offices)**	**55343** **(Zip Code)**

(952) 936-1300

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 31, 2016, there were 951,816,220 shares of the registrant's Common Stock, $.01 par value per share, issued and outstanding.

PART I

ITEM 1. FINANCIAL STATEMENTS

UnitedHealth Group
Condensed Consolidated Balance Sheets
(Unaudited)

(in millions, except per share data)	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 12,796	$ 10,923
Short-term investments	2,871	1,988
Accounts receivable, net	7,347	6,523
Other current receivables, net	7,502	6,801
Assets under management	2,952	2,998
Prepaid expenses and other current assets	2,300	2,406
Total current assets	35,768	31,639
Long-term investments	23,324	18,792
Property, equipment and capitalized software, net	5,524	4,861
Goodwill	47,183	44,453
Other intangible assets, net	8,719	8,391
Other assets	3,124	3,118
Total assets	$ 123,642	$ 111,254
Liabilities, redeemable noncontrolling interests and equity		
Current liabilities:		
Medical costs payable	$ 16,500	$ 14,330
Accounts payable and accrued liabilities	12,994	11,994
Other policy liabilities	8,670	7,798
Commercial paper and current maturities of long-term debt	7,202	6,634
Unearned revenues	5,730	2,142
Total current liabilities	51,096	42,898
Long-term debt, less current maturities	26,022	25,331
Future policy benefits	2,509	2,496
Deferred income taxes	2,492	3,587
Other liabilities	2,032	1,481
Total liabilities	84,151	75,793
Commitments and contingencies (Note 9)		
Redeemable noncontrolling interests	1,937	1,736
Equity:		
Preferred stock, $0.001 par value — 10 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.01 par value — 3,000 shares authorized; 952 and 953 issued and outstanding	10	10
Additional paid-in capital	—	29
Retained earnings	39,945	37,125
Accumulated other comprehensive loss	(2,303)	(3,334)
Nonredeemable noncontrolling interest	(98)	(105)
Total equity	37,554	33,725
Total liabilities, redeemable noncontrolling interests and equity	$ 123,642	$ 111,254

See Notes to the Condensed Consolidated Financial Statements

UnitedHealth Group
Condensed Consolidated Statements of Operations
(Unaudited)

(in millions, except per share data)	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Revenues:				
Premiums	$36,142	$31,801	$107,366	$ 95,436
Products	6,696	6,482	19,699	8,935
Services	3,264	3,036	9,673	8,607
Investment and other income	191	170	567	530
Total revenues	46,293	41,489	137,305	113,508
Operating costs:				
Medical costs	29,040	25,729	87,342	77,646
Operating costs	7,033	6,178	20,584	17,750
Cost of products sold	6,125	6,112	18,108	8,350
Depreciation and amortization	515	452	1,528	1,209
Total operating costs	42,713	38,471	127,562	104,955
Earnings from operations	3,580	3,018	9,743	8,553
Interest expense	(269)	(229)	(799)	(530)
Earnings before income taxes	3,311	2,789	8,944	8,023
Provision for income taxes	(1,333)	(1,171)	(3,579)	(3,407)
Net earnings	1,978	1,618	5,365	4,616
Earnings attributable to noncontrolling interests	(10)	(21)	(32)	(21)
Net earnings attributable to UnitedHealth Group common shareholders	$ 1,968	$ 1,597	$ 5,333	$ 4,595
Earnings per share attributable to UnitedHealth Group common shareholders:				
Basic	$ 2.07	$ 1.68	$ 5.60	$ 4.82
Diluted	$ 2.03	$ 1.65	$ 5.51	$ 4.75
Basic weighted-average number of common shares outstanding	952	953	952	953
Dilutive effect of common share equivalents	17	14	16	14
Diluted weighted-average number of common shares outstanding	969	967	968	967
Anti-dilutive shares excluded from the calculation of dilutive effect of common share equivalents	1	8	3	8
Cash dividends declared per common share	$ 0.625	$ 0.500	$ 1.750	$ 1.375

See Notes to the Condensed Consolidated Financial Statements

UnitedHealth Group
Condensed Consolidated Statements of Comprehensive Income
(Unaudited)

(in millions)	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Net earnings	$ 1,978	$ 1,618	$ 5,365	$ 4,616
Other comprehensive (loss) income:				
Gross unrealized (losses) gains on investment securities during the period	(21)	66	473	(51)
Income tax effect	7	(26)	(173)	17
Total unrealized (losses) gains, net of tax	(14)	40	300	(34)
Gross reclassification adjustment for net realized gains included in net earnings	(26)	(28)	(97)	(99)
Income tax effect	9	11	35	37
Total reclassification adjustment, net of tax	(17)	(17)	(62)	(62)
Total foreign currency translation (losses) gains	(69)	(1,063)	793	(1,859)
Other comprehensive (loss) income	(100)	(1,040)	1,031	(1,955)
Comprehensive income	1,878	578	6,396	2,661
Comprehensive income attributable to noncontrolling interests	(10)	(21)	(32)	(21)
Comprehensive income attributable to UnitedHealth Group common shareholders	$ 1,868	$ 557	$ 6,364	$ 2,640

See Notes to the Condensed Consolidated Financial Statements

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2015

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 1-10864

UNITEDHEALTH GROUP®

UnitedHealth Group Incorporated
(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**41-1321939** **(I.R.S. Employer Identification No.)**
UnitedHealth Group Center **9900 Bren Road East** **Minnetonka, Minnesota** **(Address of principal executive offices)**	**55343** **(Zip Code)**

(952) 936-1300
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

COMMON STOCK, $.01 PAR VALUE **(Title of each class)**	**NEW YORK STOCK EXCHANGE, INC.** **(Name of each exchange on which registered)**

Securities registered pursuant to Section 12(g) of the Act: NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 30, 2015 was $114,440,856,791 (based on the last reported sale price of $122.00 per share on June 30, 2015, on the New York Stock Exchange), excluding only shares of voting stock held beneficially by directors, executive officers and subsidiaries of the registrant.

As of January 29, 2016, there were 950,673,998 shares of the registrant's Common Stock, $.01 par value per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this report, to the extent not set forth herein, is incorporated by reference from the registrant's definitive proxy statement relating to its 2016 Annual Meeting of Shareholders. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

UnitedHealth Group
Consolidated Balance Sheets

(in millions, except per share data)	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 10,923	$ 7,495
Short-term investments	1,988	1,741
Accounts receivable, net of allowances of $333 and $260	6,523	4,252
Other current receivables, net of allowances of $138 and $156	6,801	5,498
Assets under management	2,998	2,962
Deferred income taxes	860	556
Prepaid expenses and other current assets	1,546	1,052
Total current assets	31,639	23,556
Long-term investments	18,792	18,827
Property, equipment and capitalized software, net of accumulated depreciation and amortization of $3,173 and $2,954	4,861	4,418
Goodwill	44,453	32,940
Other intangible assets, net of accumulated amortization of $3,128 and $2,685	8,391	3,669
Other assets	3,247	2,972
Total assets	$ 111,383	$ 86,382
Liabilities, redeemable noncontrolling interests and equity		
Current liabilities:		
Medical costs payable	$ 14,330	$ 12,040
Accounts payable and accrued liabilities	11,994	9,247
Other policy liabilities	7,798	5,965
Commercial paper and current maturities of long-term debt	6,634	1,399
Unearned revenues	2,142	1,972
Total current liabilities	42,898	30,623
Long-term debt, less current maturities	25,460	16,007
Future policy benefits	2,496	2,488
Deferred income taxes	3,587	2,065
Other liabilities	1,481	1,357
Total liabilities	75,922	52,540
Commitments and contingencies (Note 13)		
Redeemable noncontrolling interests	1,736	1,388
Equity:		
Preferred stock, $0.001 par value — 10 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.01 par value — 3,000 shares authorized; 953 and 954 issued and outstanding	10	10
Additional paid-in capital	29	—
Retained earnings	37,125	33,836
Accumulated other comprehensive loss	(3,334)	(1,392)
Nonredeemable noncontrolling interest	(105)	—
Total equity	33,725	32,454
Total liabilities, redeemable noncontrolling interests and equity	$ 111,383	$ 86,382

See Notes to the Consolidated Financial Statements

UnitedHealth Group
Consolidated Statements of Operations

(in millions, except per share data)	For the Years Ended December 31, 2015	2014	2013
Revenues:			
Premiums	$127,163	$115,302	$109,557
Products	17,312	4,242	3,190
Services	11,922	10,151	8,997
Investment and other income	710	779	745
Total revenues	157,107	130,474	122,489
Operating costs:			
Medical costs	103,875	93,633	89,659
Operating costs	24,312	21,263	18,941
Cost of products sold	16,206	3,826	2,891
Depreciation and amortization	1,693	1,478	1,375
Total operating costs	146,086	120,200	112,866
Earnings from operations	11,021	10,274	9,623
Interest expense	(790)	(618)	(708)
Earnings before income taxes	10,231	9,656	8,915
Provision for income taxes	(4,363)	(4,037)	(3,242)
Net earnings	5,868	5,619	5,673
Earnings attributable to noncontrolling interests	(55)	—	(48)
Net earnings attributable to UnitedHealth Group common stockholders	$ 5,813	$ 5,619	$ 5,625
Earnings per share attributable to UnitedHealth Group common stockholders:			
Basic	$ 6.10	$ 5.78	$ 5.59
Diluted	$ 6.01	$ 5.70	$ 5.50
Basic weighted-average number of common shares outstanding	953	972	1,006
Dilutive effect of common share equivalents	14	14	17
Diluted weighted-average number of common shares outstanding	967	986	1,023
Anti-dilutive shares excluded from the calculation of dilutive effect of common share equivalents	8	6	8
Cash dividends declared per common share	$ 1.8750	$ 1.4050	$ 1.0525

See Notes to the Consolidated Financial Statements

UnitedHealth Group
Consolidated Statements of Comprehensive Income

(in millions)	For the Years Ended December 31, 2015	2014	2013
Net earnings	$ 5,868	$ 5,619	$ 5,673
Other comprehensive loss:			
Gross unrealized (losses) gains on investment securities during the period	(123)	476	(543)
Income tax effect	44	(173)	196
Total unrealized (losses) gains, net of tax	(79)	303	(347)
Gross reclassification adjustment for net realized gains included in net earnings	(141)	(211)	(181)
Income tax effect	53	77	66
Total reclassification adjustment, net of tax	(88)	(134)	(115)
Total foreign currency translation losses	(1,775)	(653)	(884)
Other comprehensive loss	(1,942)	(484)	(1,346)
Comprehensive income	3,926	5,135	4,327
Comprehensive income attributable to noncontrolling interests	(55)	—	(48)
Comprehensive income attributable to UnitedHealth Group common stockholders	$ 3,871	$ 5,135	$ 4,279

See Notes to the Consolidated Financial Statements

C, Need--1.A
Documentation of Project-Specific Criteria

Policies and Procedures

SUBJECT:	Performance Improvement Plan	REFERENCE #:	6501
DEPARTMENT	Operations	EFFECTIVE DATE:	09/15/2014 10/2/2015
APPROVED BY:	Ted Kramm, CEO	REVIEWED DATE:	05/20/2015, 08/20/2015 10/02/2015
		APPROVED DATE:	03/15/2014 08/28/2015 10/02/2015
REVISIONS:		REVISION DATE:	08/09/2015, 08/28/2015 10/02/2015 10/05/2015

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of AxelaCare Holdings, Inc. (the Company).

PURPOSE AND PROGRAM SCOPE

The Performance Improvement Plan provides the framework for maximizing positive patient outcomes by continuously designing, measuring, assessing and improving performance. This will be accomplished via a dynamic process that monitors all functional activities of the organization, including patient focused functions and organizational functions.

Improving and sustaining improved performance is the goal of each office performance improvement program and activities. Nothing will be gained by data collection and analysis without an organization-wide strategy for improvement of performance. This may be accomplished in a single action or by a series of smaller actions to redesign a process to be more effective.

Most offices will identify more opportunities to improve than they have time to measure. It is important that priorities be set when the plan is first developed and then re-set as goals are achieved throughout the year. If measurement and assessment reveals no opportunities or need to improve, then priorities must be re-set and new processes selected to measure. Reassessment of the programs will be completed no less than annually.

This policy will also articulate the functions, roles and responsibilities of the corporate Performance Improvement/Quality Management Committee

This program description applies to both acute infusion and specialty pharmacy programs.

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RESPONSIBILITY

The Governing Body of AxelaCare Holdings is led by the CEO. He is ultimately responsible for the quality of patient/client care and will authorize adequate resources and support to establish and maintain a Performance Improvement Plan. The Governing Body of AxelaCare consists of the Senior Management. Authority over the company Performance Improvement is granted to the corporate performance improvement committee/Quality Management Leadership group from the CEO and Senior Leadership. This group/committee consists of members of senior leadership and relevant department heads. See Quality Org Chart. The program addresses all home care and specialty pharmacy programs and services, whether provided directly or through a written contract. The COO or designee has responsibility for assuring that there is an ongoing plan, and systematic process for the monitoring and evaluation of the quality and appropriateness of patient/client care and the clinical performance of the home care staff. In addition, he/she is responsible for the overall organization and coordination of the Quality Assurance activities. He/she must assure implementation of the Performance Improvement Program as it relates on high-risk, high-volume, and/or problem-prone activities.

The program shall be evaluated annually in the first quarter of each calendar year.

METRICS

Ongoing tracking of events are rolled into monthly data and evaluated quarterly. Benchmarks will reflect month over month changes as well as comparison to national rates based on therapy days and catheter days. Program metrics and progress towards goals are reported from the corporate PI committee to senior management. The CEO serves as chair of senior management and board of director representative. Evaluation of metrics are completed at a minimum of annually

Clinical

DEFINITIONS

Organizational Performance Trending (OPT)

Quality Improvement Project (QIP)

Senior Leadership-Senior Executives of AxelaCare Holdings reporting into CEO

POLICY

1. Each branch shall have a planned, systematic approach to process design and performance measurement and improvement utilizing data and statistical tools to determine progress towards goals

2. Based on the company mission and goals, the leaders will help set improvement priorities. The governing body and leaders are ultimately responsible for the actions and activities of the branches.

3. The performance improvement program and policy and QIP's are reviewed as needed by corporate quality leadership at a minimum of annually and updated as necessary

4. The performance improvement activities shall be planned in a collaborative and interdisciplinary manner. Each branch will have a multi-disciplinary committee.

5. Each branch shall designate a person or persons to be responsible for coordinating all Performance Improvement (PI) activities.

6. This person or persons responsible for PI activities (PI Coordinator) can be a clinician or a non-clinician that has the ability to keep a multi-disciplinary group on task. This position is not solely responsible for implementation of the Performance Improvement program.

7. The PI coordinator is not necessarily a specific position, but a role incorporated into an individual job description . In specialty pharmacy branches the Pharmacy Manager also serves as the PI coordinator.

8. Each branch reports quarterly performance improvement activities to the corporate performance improvement committee for data review and trending of all locations

9. The VP of Nursing is designated as the responsible member of senior leadership responsible for the overall operation of the performance improvement program and serves as chair of the performance improvement committee. The VP of Pharmacy is designated as the alternate.

10. All staff, managers and owners share in the responsibility of performance improvement and will be involved in different aspects as priorities are identified. Orientation and training in their respective roles within the PI program **will occur upon hire and be documented in personnel files.**

11. Performance Improvement Plans are based in the principles of plan, do, check, act- PDCA. Plans are developed using data and statistical measures using and the use of national benchmarks based on patient and catheter days. Graphs and comparison data to national benchmarks are used to track improvement

12. All elements of the specialty program evaluation process will be reported at the quarterly Performance Improvement/Quality Management meetings

PROCEDURE

1. Duties of the PI Coordinator include:

   1.1 Assisting with overall development and implementation of the PI plan;

   1.2 Assisting with modifications to the PI Plan;

   1.3 Assisting in the identification of goals and related patient outcomes;

   1.4 Coordinating, participating and reporting of activities and results.;

1.5 Assisting in monthly, quarterly and annual analysis of the problems, solutions and the PI Plan.

2. PI activities and program evaluation must include ongoing monitoring (data collection) of at least one important aspect of care (high risk, high volume or problem prone) related to each clinical service provided. Ongoing monitoring will also address at least one important administrative/operational aspect of function or service. Accreditation standards require data collection to measure the performance of medication management and blood/blood product use, when provided. Branch and corporate committees meet no less than quarterly

Examples for various programs include:

2.1 Pharmacy Services:

- Medication monitoring (effectiveness; medication errors; ADRs)
- Medication availability (e.g. stockouts, backorders, etc.)
- Dispensing accuracy and process (i.e. dispensing errors, prescription fill times)
- Adverse Drug Reactions including frequency of side effects
- Pain assessment
- Care planning (past due)
- Pediatric dosage calculations
- Monitoring of narrow therapeutic index drugs
- Monitoring of sterile preparation technique and environment i.e. end product testing and environmental testing
- Monitoring of product integrity i.e. temperature control during transport of products to patients
- Monitoring of sterile preparation technique and environment i.e. end product testing and environmental testing
- Compliance
- Delivery failures

2.2 Specialty Drug Management Program (potential source of data)

- Medication monitoring (effectiveness; medication errors)
- Medication availability (e.g. stockouts, backorders, etc.)
- Dispensing accuracy and process (i.e. dispensing errors, prescription fill times)
- Adverse Drug Reactions including frequency of side effects (assessment)
- Monitoring of narrow therapeutic index drugs
- Monitoring of product integrity i.e. temperature control during transport of products to patients; storage conditions (temperature logs, Inventory adjustment reports)
- Compliance-drug product selection and patient adherence (e.g. refill assessment)
- Delivery failures (e.g. FedEx exception report)
- Access to and availability of care (e.g. denial rate, appeal turnaround)
- Patient satisfaction/complaints
- Ig dosing optimization utilizing CareExchange data

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- Financial benefits of a specified program utilizing performance measures
  - Previous financial outcomes
  - Previous financial outcomes for purchasers
  - Projected financial outcomes for current or prospective purchasers

2.3 Nursing Services

- Patient education
- Skilled procedures (PICC insertions)
- Trouble-shooting pump problems
- Pediatric assessment
- Administration of new drugs/therapies
- Documentation compliance

3. Data shall be routinely collected monthly utilizing CPR+, Care Link and Care Exchange as appropriate. Data shall be reported monthly and quarterly to the General Manager who will review and forward reports to Clinical Services. Clinical Services will report trended data the corporate to the Senior Leadership Team on a quarterly basis. Data reports and meeting minutes will be maintained by the corporate PI committee and can be located in the Company Z drive in the PI folder.

4. OPT reports will be used as data collection tools and information from the OPT will be a component of the PI plan and trended data.

5. Patient, referral source and payor satisfaction results and complaints will be included in PI data collection.

6. Chart Audits

   6.1 Clinical chart reviews will be conducted using a standard tool and opportunities for improvement will be identified from the monthly audits and reported to the General Manager.

   6.2 Either 10% of active census or a minimum of 10 charts are to be reviewed monthly. Audits are due by the 10th of the month from the previous month

   6.3 Quarterly chart review reports are to be sent to corporate clinical services by the 10th day of the month after the completion of the quarter

7. The performance management committee shall meet a minimum of at least quarterly and has authority for the AxelaCare performance improvement program. The committee develops and/or modifies branch quality improvement plans. All members review data and discuss trends, identifying opportunities for improvement , and approve new QIP's. The committee provides and guidance in the development and ongoing monitoring of all indicators and QIP's. Duties of the corporate performance improvement committee include, but are not limited to:

   7.1 COO

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7.11 Meeting participation with focus on ensuring PI is cohesive with AxelaCare mission, vision and values

7.2 VP Nursing.

7.21 Meeting participation, serves as chair of corporate PI and AD-Hoc groups, provides reports to senior leadership

7.3 VP Pharmacy

7.31 Meeting participation, serves as alternate chair of corporate PI and AD-Hoc groups, evaluates need for policy revisions based on data review

7.4 Chief Compliance Officer/General Counsel

7.41 Meeting attendance, provides guidance on privacy issues

7.5 Branch Pharmacy Manager

7.51 Meeting attendance, presents branch quality data and core measures specific to pharmacy

7.6 Regional VP Operations

7.61 Meeting attendance, presents branch quality data related to operations

7.7 Director if Intake

7.71 Meeting attendance, presents data on service access

7.8 Director IT

7.81 Meeting attendance, presents system generated data and call center reports

8. The program evaluation of outcomes, clinical, and patient are tracked through SHP and reports that are reviewed by the local office and then reviewed by the corporate PI committee.

9. Program indicators or metrics that fall below threshold require an action plan to improve or correct the identified problem or meet acceptable levels of performance measures. Implementation of improvement plans shall be submitted no later than 1 month later quarterly report and quarterly meeting. The improvement plan will be included in the quality meeting minutes and a review of progress at the following quarterly meeting.

10. In the event of a payor requesting outcomes data, reports will be submitted with requested data and will be made available within 30 days of request.

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FORMS and DOCUMENTS

6501.F1 OPT Quality Report

6501.F2 Chart Audit Tool (2014)

6501. F3 Pharmacy Quality Control PI Quarterly Check

6501. F4 Branch Specific Performance Improvement Plan

Quality Org Chart

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Date of Event:

Patient Information __N/A
Patient Number_____
Start of Care____/____/_____
__Male __Female Age_____
Admitting Diagnosis_____

SERVICE
__Pharmacy
__Nursing Branch
__Nursing Agency
__DME
__Other_____

THERAPY
__Anti-Infective
__Ig
__Chemotherapy
__Enteral
__Hydration
__Pain Management
__TPN
__Transplant
__Wound
__Other:_____

ACCESS DEVICE EVENTS **Therapy interrupted (>2hrs)?** __Yes __No **Therapy discontinued?** __Yes __No

ACCESS DEVICE
__Central Catheter (tunneled)
__Central Catheter (non-tunneled)
__Epidural
__Implanted Pump
__Intrathecal
__Peripheral
__PIC/Midline
__PICC
__Midclavicular
__Port: Chest
__Port: Peripheral
__SUBCUTANEOUS
__Enteral
__Other_____
Access Device Brand

__LOSS OF PATENCY
Caused by: __Infiltration/Extravasation, *site_____ *approximate amount_____mg _____ml
*treatment_____
__Catheter breakage/damage __Catheter pulled/fell out/dislodged __Thrombosis __Inability to re-access __*Malposition
__Other_____ __Unknown
Intervention __Replaced __Removed __Repaired __Declotted (*method) __None

__PHLEBITIS
INS Grade __0 __1 __2 __3 __4 __Unknown Intervention __Replaced __Discontinued __None

__PRIMARY BLOODSTREAM INFECTION
Diagnosed By _____culture, Results_____ _____not cultured _____
Intervention __Replaced __Discontinued __Anti-Infective_____ (*medication) __None

__CATHETER SITE/TUNNEL INFECTION
Intervention
__Replaced __Removed __Treated w/Anti-Infective_____ __None
Diagnosed By _____culture, Results_____ _____not cultured

Therapy Occurrence **Therapy interrupted (>2hrs)?** __Yes __No **Medication discontinued?** __Yes __No
Medication_____ **DOSE**_____ **FREQUENCY**_____
Medication_____ **DOSE**_____ **FREQUENCY**_____

__ADVERSE DRUG REACTION
Intervention __Changed to a different drug __Changed route
__Changed dosage __Changed frequency
__Drug/fluids ordered to treat ADR __None
Severity __Minor __Major __Death __Unknown
Duration __Temporary __Permanent __Unknown
Type of Reaction __Diarrhea __Nausea/Vomiting __SOB
__Skin rash/hives __Unconsciousness __*Anaphylaxis
__Other_____ __Unknown
Other suspected drugs:_____ __None

__DELAYED/MISSED DOSE
Causes
__Pt/Caregiver refused
__Clinician unavailable
__Damaged/Insufficient Meds/Supplies
__Catheter-related occurrence
__Pt/Caregiver non-compliant
__Unknown
__Incorrect Medication
__Other_____

__MEDICATION INCIDENT (*attach details)
Incorrect: __medication __frequency __preparation __duration __ dosage __ route __ wrong patient
Caused by Pump Programming __Yes __No by: __*RPh __*RN - Branch/HHA/SNF
__*Patient/caregiver __*Other_____
__*Caused by patient non-compliance

PATIENT EVENTS **Therapy interrupted (>2hrs)?** __Yes __No **Therapy discontinued?** __Yes __No

__Unplanned Admission/Observation
To __Hospital __E/R-Urgent Care __Other_____
Due to Therapy-related occurrence:
__Phlebitis"
__Catheter/Tunnel Site Infection"
__Adverse Drug Reaction^
__Noncompliance^
__Primary Blood Stream Infection"
__Loss of Catheter Patency"
__Medication Incident^
__Equipment Failure

__ Clinical Decline, not related to an event
__ Symptoms _____
__*Infection, not catheter related
__ Other:_____

__EQUIPMENT/*PRODUCT FAILURE
Was product or equipment damaged? __ Yes ___No
Did product perform as expected? __ Yes __ No
Manufacturer/Brand_____
Supplier_____
Catalog/Model Number_____
Expiration Date_____/_____/_____ __N/A
Item Description_____
*Form 3500A or 3500 completed and sent to:
*Manufacturer __Yes __No
*FDA __Yes __No
*Date____/____/____ By whom?_____

__PATIENT NONCOMPLIANCE
Describe

__INSUFFICIENT MEDS/SUPPLIES
Describe (or attach additional document)_____

PATIENT EVENTS (continued) **Therapy interrupted (>2hrs)?** __Yes __No **Therapy discontinued?** __Yes __No

__*INFECTION, NOT CATHETER RELATED
(acquired post admission, not requiring hospitalization)
__URI __UTI __Wound __Other_____
Describe_____

__*PATIENT SAFETY
__***Fall** __***Chemo Spill**
__***Needlestick:** __Clean __Contaminated
__***Other,** explain_____

__OTHER
Describe (attach details)_____

*** IMMEDIATE ACTIONS**
Physician Notified: __Yes __No __N/A
Date____/____/____ Time_____ am/pm
Physician Response_____
Others notified_____
Date____/____/____
Responses_____

***Is this a Reviewable Event?** __Yes __No If yes, refer to policy.

***EVALUATION & FOLLOW-UP STRATEGY TO PREVENT RE-OCCURRENCE**
(Use additional document if needed)

*Signature of Person Completing Report*_____ Date____/____/____
*Signature of General Manager*_____ Date____/____/____

AXELACare

Policies and Procedures

SUBJECT:	Patient Satisfaction Surveys	REFERENCE #:	6570
DEPARTMENT	Operations	EFFECTIVE DATE:	07/01/2014
APPROVED BY:	Ted Kramm, CEO	REVIEWED DATE:	05/20/2015
		APPROVED DATE:	05/22/2015
REVISIONS:	AHS: 92(Inf4.2); SHI: POP021	REVISION DATE:	05/22/2015

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of AxelaCare Holdings, Inc. (the Company).

PURPOSE

To provide a means to assess patient satisfaction with the service provided.

POLICY

Each patient on service will receive a Patient Satisfaction Survey

PROCEDURE

1. At appropriate intervals and no greater than monthly a Satisfaction Survey Report will be generated from CPR+.
2. Inactive (Discharged) patients or significant other will be handed or mailed a Satisfaction Survey Form.
3. Long-term active patients will be mailed a survey annually.
4. A self-addressed stamped envelope shall be provided to facilitate return.
5. The mailed and returned surveys will be tracked on the CPR+ satisfaction survey report and reported at the branch Performance Improvement meetings
6. The survey results will be entered into the SHP patient satisfaction database.
7. On a quarterly basis, the branch will review their patient satisfaction survey outcomes. The review will be submitted to the Corporate PI/QM committee as a standing agenda item at their quarterly meeting.

EXHIBITS/ATTACHMENTS

6570.A1 Satisfaction Survey Infusion Cover Letter
6570.A2 Patient Satisfaction Infusion Survey

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Strategic Healthcare Programs, LLC
510 Castillo Street, 2nd Floor
Santa Barbara, California 93101

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SatisfactionSurvey

Please take a few minutes to complete the survey by filling in the circle that best indicates your opinion about service you received. If a question does not apply to your situation, fill in the bubble that reads "Not Applicable". Simply return the survey to us using the enclosed envelope.

1. The staff explained what to expect during your home care.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

2. The staff allowed you to participate in decisions that affect the care.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

3. The staff explained financial responsibility, insurance coverage, and cost (if any).

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

4. The staff explained your right to have personal health information kept private.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

5. The staff helped you if you complained about problems with the service.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

6. The staff explained your rights and responsibilities.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

7. The staff explained how to voice a complaint.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

8. The medication(s) or supplies were delivered on time.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

9. The equipment was clean when delivered.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

10. The equipment remained in good working order.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

11. The instructions were adequate for safe use of the equipment.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

12. The instructions were adequate to teach you or your caregiver how to give the intravenous (IV) medication(s).

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

13. Your pain was adequately controlled most of the time.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

14. The staff was respectful and courteous in your home.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

15. You were told who to call if you had problems with your intravenous (IV) medications.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

16. You had the supplies you needed to take your intravenous (IV) medication(s) on time.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

17. You were satisfied with the response you received if you called for assistance on weekends or during evening hours.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

18. You were satisfied with the timeliness of response to your billing or payment questions, problems, and concerns.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

19. You received information about possible side effects caused by your intravenous (IV) medication(s).

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

20. You were told what to do if the services were interrupted due to the weather or a natural disaster.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

21. You received instructions on how to wash your hands and handle your supplies to prevent infection.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

22. The services provided met your needs and expectations.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

23. You were satisfied with the overall quality of care and services.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

24. You would likely recommend the services to your family and friends.

- O Disagree
- O Mostly Disagree
- O Neither Agree nor Disagree
- O Mostly Agree
- O Strongly Agree
- O Not Applicable

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25. Do you give permission to provide your survey answers linked to your name to the home health/hospice agency?

O Yes O No

Comments

Thank you for answering these questions. Please add any comments here and return the completed survey in the postage paid envelope.

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Please limit your comments to the space within the box or contact the health care agency directly.

SUBJECT:	Resuscitation CPR	REFERENCE #:	7030
DEPARTMENT	Clinical Operations	EFFECTIVE DATE:	03/01/2015
APPROVED BY:	Donald J Filibeck, Donald J. Filibeck VP Pharmacy Operations	REVIEWED DATE:	11/14/2014
		APPROVED DATE:	01/19/2015
REVISIONS:		REVISION DATE:	01/29/2016

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of AxelaCare Holdings, Inc. (the Company).

PURPOSE

To establish company policy for the resuscitation of patients in the home.

DEFINITIONS/REFERENCES/REQUIREMENTS

CPR: Cardiopulmonary Resuscitation

ALS: Advanced Life Support

BLS: Basic Life Support

C-A-B: Compressions-Airway-Breathing

DNR: Do Not Resuscitate

AMA: American Heart Association

AED: Automated External defibrillator- a portable device used to treat sudden cardiac arrest. It sends an electric shock to the heart to restore normal heart rhythm.

POLICY

1. All Direct patient-care clinical staff shall be ALS or BLS CPR certified through an accepted training course. Online CPR certification is not accepted.

2. Any patient found without pulse or respiration, and does not have a DNR Order, will be resuscitated.

3. Clinician will utilize the most current American Heart Association procedures when performing CPR. Current method is: C-A-B

4. Non-clinical staff will not be required to obtain CPR certified or provide CPR in the event of Cardio Pulmonary Arrest.

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5. Patients/clients will be provided information about the organization's policies for resuscitation, medical emergencies and accessing "911" emergency services.

6. If an AED is available, use based on BLS guidelines.

PROCEDURE

1. Clinician establishes that the patient is without pulse and respirations.

2. Call 911 or ask someone else to do so. If no caretaker is present, the clinician is to call 911 first, then start CPR.

   a. Inform 911 operator that CPR has been started

   b. Provide patients address

3. Continue compressions and breaths -- 30 compressions, two breaths -- until help arrives.

4. The Clinician will give the paramedics the patient's medical history as required.

5. The Clinician will notify the physician, agency and family members after the support staff has arrived and when appropriate.

FORMS

EXHIBITS/ATTACHMENTS

7030A1 CPR Summary of Steps and Recommendations

Policies and Procedures

SUBJECT:	Handling Allergy /Anaphylaxis	REFERENCE #:	7035
DEPARTMENT	Clinical Operations	EFFECTIVE DATE:	03/01/2015
APPROVED BY:	Donald J Filibeck, Donald J. Filibeck VP Pharmacy Operations	REVIEWED DATE:	02/08/2015
		APPROVED DATE:	02/14/2015
REVISIONS:		REVISION DATE:	12/30/2015

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of AxelaCare Holdings, Inc. (the Company).

PURPOSE

To detail an intervention plan in the event that a patient presents with an allergic/anaphylactic reaction.

DEFINITIONS/REFERENCES/REQUIREMENTS

Anaphylaxis Orders sheet

POLICY

If a patient experiences an allergic/anaphylactic reaction, patient management will be per procedure and/or physician order.

PROCEDURE

1. A physician's order for treating anaphylactic reactions should be obtained on all patients as needed.
2. The anaphylaxis kit may contain the following:
   a. An adult and pediatric epinephrine injector (Epipen™).
   b. An ampule of epinephrine as well as an appropriate syringe, needle and filter to draw up and administer - OPTIONAL
   c. Diphenhydramine 50 mg capsule or syrup (25 mg/ml) - OPTIONAL.
   d. Diphenhydramine Injection, 50ml/ml 1ml VL - OPTIONAL
3. The pharmacist and/or nurse must document in the patient's chart a medical, drug and allergy history and should be aware of cross sensitivity to related drugs.
4. If the patient develops a urticarial rash, the infusion should be discontinued until such time that the physician can be contacted and has indicated whether or not the infusion should be continued.

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5. If the patient develops any symptoms of anaphylaxis, the following should occur:

   a. Mild Reaction (rash, itching, nausea, vomiting):

      1) Stop the infusion of the medication immediately.

      2) Call the physician for intervention instructions.

   b. Severe Reaction (wheezing, difficulty in breathing, swelling of eyes, eyelids, or lips)

      1) Stop the infusion immediately (immediate action is required before notifying the physician).

      2) Establish and/or maintain an airway.

      3) Call the local paramedics (have another person call if possible).

      4) Follow the directions for use of the epinephrine injector.

      5) Call the physician.

6. The nurse will stay with the patient and be prepared to administer cardiopulmonary resuscitation (CPR). All nurses and pharmacists, who have direct patient contact, shall be certified in basic life support and have an understanding of the basic emergency intervention.

7. The nurse will stay with the patient and monitor vital signs every 30 minutes for a minimum of hour hours once the patient is symptom free if the physician does not order transportation to the hospital or the patient will be admitted to the hospital.

8. AxelaCare staff shall not transport the patient for additional medical intervention. Only family, caregivers or emergency personnel may transport the patient.

FORMS

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Policy

AxelaCare Health Solutions, LLC ("AxelaCare") shall comply with all federal, state and local laws and regulations applicable to billing and collecting patients' co-insurance and deductible amounts. This policy may be revised at the discretion of the President and the Patient Financial Assistance Program Director. It is the policy of AxelaCare to make reasonable effort to collect a patient's co-insurance and deductible amounts on a regular basis by generating monthly statements to the patient and making follow up collections phone calls as required. Decisions to waive financial liability are made only on a case-by-case basis with final determination by the Review Committee.

Definitions

Requirements

Procedure

Responsibilities of AxelaCare

It is AxelaCare policy to bill for all applicable out-of-pocket amounts related to both medication and nursing services and to make reasonable efforts to collect such amounts in accordance with AxelaCare Collections Policies and Procedures (see AR Policies and Procedures Manual). However, if AxelaCare determines, in accordance with this policy, that a patient is financially unable to pay any out-of-pocket amounts, based upon satisfactory documentation to support the financial hardship, AxelaCare may cease any billing or collection efforts with respect to the patient's out-of-pocket obligations for a period not to exceed one year, as the patient's financial profile may have significantly changed after one year's time. Eligibility for this Patient Financial Assistance Program must be established yearly.

The Patient Financial Assistance Program Administrator will monitor the annual expiration of each participating patient's eligibility and notify the Review Committee of upcoming expirations (with at least two month's notice). The Patient Financial Assistance Program Administrator will send each participating patient whose eligibility is due to expire a new financial worksheet update for completion at least thirty (30) days before the date on which his or her eligibility expires. If there is no response from a patient after ten (10) days, an AxelaCare representative who regularly works with the patient may make a follow-up phone call to the patient to verify receipt and understanding of the new Patient Financial Assistance Program application.

Responsibility for implementation of this Patient Financial Assistance Application Policy and Procedure lies ultimately with the Review Committee chaired by the President and will include the Department head of the Accounts Receivable Department and Clinical Department or assignee. A member of the Compliance Committee may also be included. The Patient Financial Assistance Program Administrator will regularly monitor and update the status of each

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patient enrolled in the program and report his/her findings to the Review Committee at a regularly scheduled monthly meeting. The President may assign responsibility for individual determinations of waivers of co-insurance and/or deductible amounts to other members of the Review Committee who may make such determinations in accordance with this Policy and Procedure. The Review Committee may consult with the Legal Department on an as-needed basis regarding the application of this Policy and Procedure to ensure compliance with all applicable governing law.

- A copy of the final determination, with signature of the delegated representative of the Review Committee, will be maintained by the Reimbursement staff for a minimum period of one year.
- The Patient Financial Assistance Program Administrator will maintain each patient's individual Patient Financial Assistance program file (a file separate from his/her primary patient file) and keep these files under lock and key at all times to ensure compliance with HIPAA guidelines and patient confidentiality regulations.

Further to the above, it is understood that no employee shall engage in the following practices under any circumstances:

- Refuse care or treatment to any patient based on their written or verbal inability to pay for services for which they may incur financial expense.
- Imply or advertise that insurance payment will constitute "payment in full" or that the automatic waiver of co-insurance, deductibles and or out-of-pocket expenses will apply, or partially apply, without the express written authorization from the Review Committee following application.
- Waive co-insurance, deductibles or other out-of-pocket expenses without the express written authorization from the Review Committee following application.
- Target a specific patient-base, such as those with lower co-pays, those covered by a particular payor, or those referred by a particular physician or group, for the purpose of influencing reimbursement or to gain referrals.
- Solicit or distribute financial hardship forms without the verbal or written request of a patient.
- Inform a patient about the Patient Financial Assistance Program without a patient first addressing the issue of financial hardship. It is understood that billing and collection personnel may initiate contact with patients who have outstanding accounts to discuss payment of such accounts. Personnel may inform such patients of the Patient Financial Assistance Program and discuss the Patient Financial Assistance Program with such patients only after the patients express a concern about making payment on the account due to financial hardship.
- Complete a financial hardship form on behalf of any patient.
- Routinely use financial hardship forms.
- Charge patients who have obtained a waiver in accordance with this policy higher amounts than those charged to other patients for similar services for the purpose of offsetting the waiver.
- Fail to make reasonable efforts to collect a patient's balance (except where a waiver has been obtained).

Determination of Financial Need

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FEB 18 17 PM 2:05

Any patient who qualifies for state assistance for medical services (Medicaid) will be automatically approved for a full waiver of drug and nursing coverage, from Axelacare (less any contractual or required drug co-payment amounts), without providing for the full compliment of required paperwork. This qualification will remain in place as long as the patient is eligible for the state assistance.

If a patient is applying for SSI, proof of the application submission must be provided for before any waivers of co-insurance and/or deductible amounts can be performed.

The decision to waive any co-insurance and/or deductible amounts owed by a patient is made on a case-by-case basis. In order to ensure that decisions to waive co-insurance and/or deductible amounts are documented and based on standardized, objective criteria, and to verify that such waivers are granted in compliance with AxelaCare's charitable intent, each patient who desires financial assistance on any co-insurance and/or deductible amounts receives a letter (sample attached hereto as **Exhibit A**) describing AXELACARE's policy. The responsible party is invited to complete a Confidential Financial Worksheet (attached hereto as **Exhibit B)** and to submit the same to the Review Committee or to the Program Administrator. The Review Committee is not able to make financial eligibility determinations without a complete and executed Confidential Financial Worksheet being submitted by the patient.

The decision to waive co-insurance and/or deductible amounts is based on the financial information provided by the patient in the Confidential Financial Worksheet. No decision regarding financial inability may be made unless and until the patient has submitted a complete and executed Confidential Financial Worksheet. In reviewing Confidential Financial Worksheets, the criteria set forth in **Exhibit C**, attached hereto, is considered. AxelaCare reserves the right to modify the criteria considered in reviewing Confidential Financial Worksheets without notice. Once a request for a waiver of co-insurance and/or deductible amounts is reviewed, the Reimbursement staff or other representative of the Finance Department, along with the patient's sales representative via conference call or in person, notifies the recipient and informs him or her as to the waiver. A Sample Waiver Request Determination Letter is attached hereto as **Exhibit D**.

Such permitted waivers of co-insurance and deductible amounts only may be granted, in whole or in part, on receipt of satisfactory documentation of the patient's financial hardship and upon approval of the Review Committee.

If a waiver is approved in whole or in part, the Accounts Receivable representative that is part of the Review Committee is responsible for documenting the patient's record in CPR+ in the insurance tab and for notifying the Patient Accounts Director so that the appropriate adjustments can be made to the account.

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Records

Records will be maintained in accordance with policy INF 4.2 Document Retention.

Forms

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AxelaCare
Compassionate Care in a Bio-Tech World

AxelaCare Health Solutions, LLC Policy and Procedure Manual		Policy Title: Financial Assistance Program
Standard:	Policy Number: AR 4.1	Pages: 15
Effective Date: May 5, 2008	Reviewed Date: August 8, 2008	Revised Date: January 19, 2010
Created By: KK	Approved By: KK	

Purpose:

The purpose of the Patient Financial Assistance Program and Application is to respond to patients' concerns regarding their documented inability to pay their patient responsibility expenses which include, but are not limited to the following: Patient Deductibles, Patient Co-Payments, Patient Co-Insurance, and Non-Covered Items. These expenses may be related to medications, nursing, supplies, or associated per diems.

Policy:

AxelaCare Health Solutions, LLC ("AxelaCare") shall comply with all federal, state and local laws and regulations applicable to billing and collecting patients' co-insurance and deductible amounts. This policy may be revised at the discretion of the President and the Patient Financial Assistance Program Director. It is the policy of AxelaCare to make reasonable effort to collect a patient's co-insurance and deductible amounts on a regular basis by generating monthly statements to the patient and making follow up collections phone calls as required. Decisions to waive financial liability are made only on a case-by-case basis with final determination by the Review Committee.

Procedure:

Responsibilities of AxelaCare

1. It is AxelaCare policy to bill for all applicable out-of-pocket amounts related to both medication and nursing services and

to make reasonable efforts to collect such amounts in accordance with AxelaCare Collections Policies and Procedures (see AR Policies and Procedures Manual). However, if AxelaCare determines, in accordance with this policy, that a patient is financially unable to pay any out-of-pocket amounts, based upon satisfactory documentation to support the financial hardship, AxelaCare may cease any billing or collection efforts with respect to the patient's out-of-pocket obligations for a period not to exceed one year, as the patient's financial profile may have significantly changed after one year's time. Eligibility for this Patient Financial Assistance Program must be established yearly.

2. The Patient Financial Assistance Program Administrator will monitor the annual expiration of each participating patient's eligibility and notify the Review Committee of upcoming expirations (with at least two month's notice). The Patient Financial Assistance Program Administrator will send each participating patient whose eligibility is due to expire a new financial worksheet update for completion at least thirty (30) days before the date on which his or her eligibility expires. If there is no response from a patient after ten (10) days, an AxelaCare representative who regularly works with the patient may make a follow-up phone call to the patient to verify receipt and understanding of the new Patient Financial Assistance Program application.

3. Responsibility for implementation of this Patient Financial Assistance Application Policy and Procedure lies ultimately with the Review Committee chaired by the President and will include the Department head of the Accounts Receivable Department and Clinical Department or assignee. A member of the Compliance Committee may also be included. The Patient Financial Assistance Program Administrator will regularly monitor and update the status of each patient enrolled in the program and report his/her findings to the Review Committee at a regularly

scheduled monthly meeting. The President may assign responsibility for individual determinations of waivers of co-insurance and/or deductible amounts to other members of the Review Committee who may make such determinations in accordance with this Policy and Procedure. The Review Committee may consult with the Legal Department on an as-needed basis regarding the application of this Policy and Procedure to ensure compliance with all applicable governing law.

4. A copy of the final determination, with signature of the delegated representative of the Review Committee, will be maintained by the Reimbursement staff for a minimum period of one year.

5. The Patient Financial Assistance Program Administrator will maintain each patient's individual Patient Financial Assistance program file (a file separate from his/her primary patient file) and keep these files under lock and key at all times to ensure compliance with HIPAA guidelines and patient confidentiality regulations.

Further to the above, it is understood that no employee shall engage in the following practices under any circumstances:

- Refuse care or treatment to any patient based on their written or verbal inability to pay for services for which they may incur financial expense.

- Imply or advertise that insurance payment will constitute "payment in full" or that the automatic waiver of co-insurance, deductibles and or out-of-pocket expenses will apply, or partially apply, without the express written authorization from the Review Committee following application.

- Waive co-insurance, deductibles or other out-of-pocket expenses without the express written authorization from the Review

Committee following application.

- Target a specific patient-base, such as those with lower co-pays, those covered by a particular payor, or those referred by a particular physician or group, for the purpose of influencing reimbursement or to gain referrals.

- Solicit or distribute financial hardship forms without the verbal or written request of a patient.

- Inform a patient about the Patient Financial Assistance Program without a patient first addressing the issue of financial hardship. It is understood that billing and collection personnel may initiate contact with patients who have outstanding accounts to discuss payment of such accounts. Personnel may inform such patients of the Patient Financial Assistance Program and discuss the Patient Financial Assistance Program with such patients only after the patients express a concern about making payment on the account due to financial hardship.

- Complete a financial hardship form on behalf of any patient.

- Routinely use financial hardship forms.

- Charge patients who have obtained a waiver in accordance with this policy higher amounts than those charged to other patients for similar services for the purpose of offsetting the waiver.

- Fail to make reasonable efforts to collect a patient's balance (except where a waiver has been obtained).

Determination of Financial Need

1. Any patient who qualifies for state assistance for medical services (Medicaid) will be automatically approved for a full waiver of drug and nursing coverage, from Axelacare (less any contractual or required drug co-payment amounts), without providing for the full compliment of required paperwork. This qualification will remain

in place as long as the patient is eligible for the state assistance.

2. If a patient is applying for SSI, proof of the application submission must be provided for before any waivers of co-insurance and/or deductible amounts can be performed.

3. The decision to waive any co-insurance and/or deductible amounts owed by a patient is made on a case-by-case basis. In order to ensure that decisions to waive co-insurance and/or deductible amounts are documented and based on standardized, objective criteria, and to verify that such waivers are granted in compliance with AxelaCare's charitable intent, each patient who desires financial assistance on any co-insurance and/or deductible amounts receives a letter (sample attached hereto as **Exhibit A**) describing AXELACARE's policy. The responsible party is invited to complete a Confidential Financial Worksheet (attached hereto as **Exhibit B)** and to submit the same to the Review Committee or to the Program Administrator. The Review Committee is not able to make financial eligibility determinations without a complete and executed Confidential Financial Worksheet being submitted by the patient.

4. The decision to waive co-insurance and/or deductible amounts is based on the financial information provided by the patient in the Confidential Financial Worksheet. No decision regarding financial inability may be made unless and until the patient has submitted a complete and executed Confidential Financial Worksheet. In reviewing Confidential Financial Worksheets, the criteria set forth in **Exhibit C**, attached hereto, is considered. AxelaCare reserves the right to modify the criteria considered in reviewing Confidential Financial Worksheets without notice. Once a request for a waiver of co-insurance and/or deductible amounts is reviewed, the Reimbursement staff or other representative of the Finance Department, along with the patient's sales representative via conference call or in person, notifies the recipient and informs him or her as to the waiver. A Sample Waiver Request Determination Letter is attached hereto as **Exhibit D**.

5. Such permitted waivers of co-insurance and deductible amounts only may be granted, in whole or in part, on receipt of satisfactory documentation of the patient's financial hardship and upon approval of the Review Committee.

6. If a waiver is approved in whole or in part, the Accounts Receivable representative that is part of the Review Committee is responsible for documenting the patient's record in CPR+ in the insurance tab and for notifying the Patient Accounts Director so that the appropriate adjustments can be made to the account.

Date

Patient Name
Address 1
Address 2

Dear:

Thank you for contacting AxelaCare Health Solutions, LLC regarding assistance with your deductible and/or co-insurance payment. We realize the financial difficulties that may arise when a patient has deductible and continuing co-insurance obligations for long-term health management. At the same time, we respect the Federal Office of Inspector General guidelines regarding the waiver of deductible and co-payment obligations. These guidelines require us to bill you for deductible and co-payment amounts that are determined to be due based on your health insurance benefits program. It is not our intent to place a severe financial burden on you and your family or to intrude upon the privacy concerns of your family. Your request for a waiver of deductible and co-insurance payments will be reviewed by the appropriate individuals in our organization.

Enclosed is a Financial Review Form. The completed Form will enable us to independently evaluate whether assistance may be extended to you in relation to your co-payment and/or deductible, and if so, the level that can be provided. Please complete the Form in its entirety using your **NET** (after deductions for payroll taxes) income totals. Return the Form to our office at your earliest convenience. As requested on the form, we do require that supporting documentation be included with your request so that we can accurately evaluate it. Supporting documentation includes proof of wages earned for all wage earners in your household (W-2s, pay stubs, SSI statements, child support documentation and / or tax returns) and proof of expenses (copies of monthly utility bills, mortgage payment stubs and other bills and expenses that you list on the form). Applications submitted without supporting documentation will be returned to you with a request for the additional information and will only be evaluated once the package is complete.

Your request will be treated confidentially and expeditiously. We will contact as soon as the review is completed.

Please contact me if you have any questions and/or concerns.

Sincerely,

Janet R. Gardner, RN, BSN
Program Administrator
(877) 342-9352

Please return completed form and supporting documentation to:

AxelaCare Health Solutions, LLC
9730 Pflumm Rd
Lenexa, KS 66215

Demographic Information

Patient Name: _____ Date of Birth: _____

Spouse/Parent Name: _____ SS#: _____

Address: _____ _____ Home Phone: _____

_____ Cell _____

Phone: _____

Name of Employer

Patient: _____

Spouse/Parent: _____

Spouse/Parent: _____

Family Size

Total # of persons in Household: _____

Number of Residents in School: _____

Other Dependents: _____

Net Income	**Monthly**
Total Household Income	_____
Child Support	_____
Social Security	_____
SSI/Disability	_____
Other:	_____
Other:	_____
Other:	_____

Expenses	**Monthly**
Rent/House Payment	
Bank, educational and other loans	
Car/Truck Payments	
Utilities (electric, phone, gas, water)	
Car Insurance	
Health/Dental Insurance	
Life Insurance	
Property Insurance	
Property Tax	
Medical Fees (Dr, Pharmacy, Hosp)	
Food/Clothing	

Educational Expenses

_____

Other (child care, bus, etc.)

_____

Explain:

_____

_____

Total Monthly Income _____ **Total Monthly Expenses $:**

_____

Remarks (use an additional sheet if necessary):

_____

_____

_____

_____

_____

_____

_____

By signing below you certify that the above information is true and accurate and that this application is made to enable AxelaCare to judge your eligibility for reduced out-of-pocket expenses. If any of the information that you have given proves to be untrue, AxelaCare may re-evaluate your financial status and take action necessary to collect on your account.

Applicant Signature: _____ Date:

_____

****** SUPPORTING DOCUMENTS MUST BE ATTACHED FOR THE APPLICATION TO BE REVIEWED ******

Exhibit C

Review of Confidential Financial Worksheet

In reviewing the Confidential Financial Worksheet, personnel should take into account: (i) the reasonableness of expenses in each category, such as the amount of housing obligations (mortgage, rent/house payment) in relation to the area in which the beneficiary lives (*i.e.*, urban v. rural); (ii) the number of people in the beneficiary's household versus expenses and type of expenses; and (iii) the beneficiary's total cash flow compared to total assets.

Criteria for Financial Assistance Determination

Following the lead of other documented Patient Assistance/Hardship Policies that are available as public information AxelaCare will consider that any family's income that is equal to or less than 200% of the National Poverty Level will be approved for a full (*i.e.*, 100%) waiver of all co-payments and/or deductibles. Poverty levels are determined by the U.S. Department of Health and Human Services ("HHS"). The 2009 HHS Poverty Guidelines are as follows:

The Department of Health and Human Services' poverty guidelines for 2009

Department of Health and Human Services 2009 Poverty Guidelines			
Persons in Family or Household	48 Contiguous States and D.C.	Alaska	Hawaii
1	$10,830	$13,530	$12,460
2	14,570	18,210	16,760
3	18,310	22,890	21,060
4	22,050	27,570	25,360
5	25,790	32,250	29,660
6	29,530	36,930	33,960
7	33,270	41,610	38,260
8	37,010	46,290	42,560
>8 persons	Add $3,740 for each additional person	Add $4,680 for each additional person	Add $4,300 for each additional person
Source: U.S. Department of Health and Human Services, 2009 Poverty Guidelines, released February 28, 2009.			

SOURCE: *Federal Register*, Vol. 74, No. 14, January 23, 2009, pp. 4199-4201

Families that do not qualify for a waiver under the above criteria may be eligible for a full or partial waiver of co-pays and deductibles based on the family's discretionary income, as set forth below. Discretionary income is defined as the difference between the family's total net monthly income and total monthly expenses.

Family of 1 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
$0 - $224	Full Waiver
$225 - $280	$29.00
$281 - $335	$43.00
$336 - $391	$56.00
$392 - $446	$70.00
$447 - $503	$84.00
$504 - $560	$112.00
Family of 2 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
$0 - $301	Full Waiver
$302 - $377	$38.00
$378 - $451	$58.00
$452 - $526	$75.00
$527 - $601	$94.00
$602 - $678	$114.00
$679 - $753	$151.00
Family of 3 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
$0 - $378	Full Waiver
$379 - $473	$48.00
$474 - $567	$72.00
$568 - $662	$95.00
$662 - $755	$119.00
$756 - $852	$143.00
$853 - $947	$189.00
Family of 4 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
$0 - $456	Full Waiver
$457 - $570	$58.00
$571 - $683	$87.00
$684 - $797	$ 114.00
$798 - $909	$143.00

$910 - $1026	$172.00
$1027 - $1141	$228.00
Family of 5 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
$0 - $533	Full Waiver
$534 - $667	$68.00
$668 - $799	$102.00
$800 - $932	$133.00
$933 - $1064	$167.00
$1065 - $1200	$201.00
$1201 - $1334	$267.00
Family of 6 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
$0 - $611	Full Waiver
$612 - $764	$78.00
$765 - $914	$117.00
$915 - $1068	$153.00
$1069 - $1218	$191.00
$1219 - $1375	$231.00
$1376 - $1528	$306.00
Family of 7 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
$0 - $688	Full Waiver
$689 - $861	$88.00
$862 - $1030	$131.00
$1031 - $1203	$172.00
$1204 - $1373	$216.00
$1374 - $1549	$260.00
$1550 - $1722	$344.00
Family of 8 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
$0 - $765	Full Waiver
$766 - $958	$ 98.00
$959 - $1146	$146.00

$1147 - $1339	$192.00
$1340 - $1527	$240.00
$1528 - $1723	$289.00
$1724 - $1915	$383.00

Job Description

TITLE: PRN Infusion Nurse - Registered Nurse (RN)

REPORTS TO: Regional Nurse Manager

The primary role of the Staff Nurse is to provide infusion nursing services to patients receiving infusion medications from AxelaCare Health Solutions LLC. (AxelaCare) pharmacy and /or provide clinical coordination for infusion services for all AxelaCare's patients. Service delivery will occur in patient's home or alternate site per patient's request. All infusion services and medication delivery will be provided utilizing accepted Infusion therapy clinical technique and AxelaCare's established policy and procedures ordered by a licensed physician or licensed practioner. All clinical operations will be consistent with established goals, objectives, and policies, and specifically focused on delivery of infusion therapy nursing and medication delivery.

REQUIREMENTS and TRAINING:

- Graduate of an accredited school of nursing.
- Registered Nurse - Licensed in the state of practice.
- Minimum of 3 years' experience and proficiency in infusion therapy. Infusion in home health setting is highly desirable.
- MUST HAVE a high level of proficiency with the use of technology, thru exposure to EMR, use of data phones or tablets with WiFi access, and proficiency in Microsoft Office Suite (Excel and Word).
- Knowledge of the Infusion Nursing standards (INS) and nursing process including assessment, problem identification or nursing diagnosis, outcome identification, planning and communicating, implementation, and evaluation.
- Knowledgeable and/or experience with current state licensure requirements
- Knowledgeable and/or experience in HIPAA and JCAHO; a plus
- Excellent interpersonal, listening, organizational, and critical thinking skills.
- Ability to work with an interdisciplinary team of professionals including clinical, pharmacy, physicians, outside infusion nursing agencies, patients, families, and significant caregivers.
- Professional appearance, and teaching skills

Job Description

- Ability to work independently in home or alternate site settings
- Ability to work under pressure with clinical emergencies if required
- Ability to meet attendance, overtime, on-call, and other reliability requirements of the job.
  Comply with nursing professional practice acts or title acts relating to reporting and peer review.

FUNCTIONS AND RESPONSIBILITIES

- Ability to establish and maintain positive clinical rapport with all patients and their families, representing AxelaCare including working directly with patients and their families, maintain contact and clinically monitor all patients providing direct infusion therapy services.
- Infuse medications on a regular basis in patient's home setting including monitoring and tracking vital signs, performing procedures such as IV placement, phlebotomy, and medication administration via peripheral infusion device; or PICC line; Implantable port; and/or Central Venous Catheters and as ordered by a licensed physician or licensed practioner.
- Assess patient in home environments, including clinical assessment safety of environment, pain assessment, monitor effectiveness of medication treatment, develop plan of care, education for patients and patient's family members, including providing care.
- Establish and maintain all clinical documentation including Plans of Care/Treatment (POC/POT), Clinical Summaries, medication changes and updates for AxelaCare pharmacy.
- Willingness to work with most ages and diagnosis of patients receiving infusion therapy medication.
- May work with numerous infused or Injectable medications including orals per AxelaCare protocols
- Clinical oversight of all patient functions provided by AxelaCare Health Solutions, LLC.
- Collaborative relationships involving all agencies delivering services on behalf of/or in conjunction with AxelaCare, including all nursing agencies in a contracted relationship, patient, families, significant caregivers, and other healthcare team members.
- Maintaining current State Nursing licensure, as required by the State Department of Health, is mandatory.

Job Description

- Assist in securing and maintaining all licensure and accreditations warranted by AxelaCare, including required Home Health Licensure, JCAHO, and any other licensure or credentialing as necessary.
- Compliance and adherence to all State and Federal regulations and laws, JCAHO, OSHA, HIPAA, CPR, all infusion pharmacy and nursing licensure accepted standards of practice.
- Maintain all mandatory education required upon hire and annually per policy.
- May be required to represent the company in clinical interactions as requested.
- May provide education regarding AxelaCare Health Solutions services, for both internally and external customers.
- Function as clinical educator, and resource.
- May work in office or alternate settings including home settings
- Ability to travel on occasion
- Excellent driving record
- Maintains automobile liability insurance
- May be required to work any day or shift as required to accommodate patient schedules in administering medications
- May be required to lift or carry equipment and supplies to patients home
- May be required to participate in afterhours on call responsibilities
- Other duties as requested

Employee Signature Date

Dennis Perkins

6275 Piney River Road
Bartlett, TN 38135

901-864-6815
dennybobbie@bellsouth.net

EDUCATION: 1991 RN graduate of Baptist Hospital School of Nursing

EXPERIENCE:
June 2014- present: Benevere Specialty Pharmacy
POSITION: Infusion Nurse Coordinator
RESPONSIBILITIES: Responsible for teaching and administration of all medications requiring nursing support. Competent in administration of IVIG, Humira, Cimzia, Stelara, Growth Hormone, Hemophilia agents, and most other medications. Skilled at venipuncture, PICC and Central Line care in the pediatric and adult population. Also responsible for all aspects of obtaining and maintaining state licensure for 2 pharmacy branches, including procuring insurance contracts, such as multiple state Medicaid programs, Aetna, Humana, United HealthCare, Cigna, and BCBS. Our company grew from being licensed in 5 states to 51 states and territories in both branches during my first year of working with contracts.

March 2007- Present: Home Health Care of West TN
POSITION: Field Nurse, High-Tech Nurse, On-Call Nurse; worked part-time and on call since 2007; took full time position in 2012, continuing weekends on-call
RESPONSIBILITIES: All aspects of patient care, coordination of care, communication with physicians, supervisors, and other staff; all oasis reassessments per computer; frequently utilized as a clinical resource for high-tech nursing and complicated patient care; skilled with IV infusions, lab draws, PICC lines, central lines

March 2003-November 2011: PSA then Hemophilia Health Services/Accredo
(status post acquisition)
POSITION: Nurse Manager
RESPONSIBILITIES: Management of nursing team; patient care coordination; scheduling; QI; upkeep of client records; JACHO; state compliance; inservices; patient care; skilled nurse visits; assessments of patients; supervisory visits; computerized documentation; plan of treatments; fostering relationships with patients, staff, insurance case managers, and referral sources

March 2000-2003: Tender Loving Care Staffbuilders
POSITION: Pediatric Care Coordinator, then Director of Clinical Services, then Care Team Manager
RESPONSIBILITIES: Supervising and managing all aspects of the patient care of pediatrics and adults who received intermittent skilled nurse visits, full therapy services, CAN services, and nursing and CAN private duty; duties included maintaining state and JACHO regulations; extensive communication with multiple case managers; liason with hospitals, physicians, and insurance companies; organizing plans of treatment and supervising a multi-disciplinary team to maximize patient care; scheduling of all staff as DCS; management of a team of 70

patients, including scheduling and supervisory visits; multi-team approach with nurses, therapists, and CNAs; all oasis events; frequencies to assist with PPS to obtain best financial reimbursement

1999-March 2000: Medshares Nursing Service
POSITION: Director of Clinical Services (Began as Pediatric Care Coordinator)
RESPONSIBILITIES: Same as listed for Tender Loving Care Staffbuilders

1998-1999: Trinity Home Health
POSITION: High-Tech Visit Nurse
RESPONSIBILITIES: Full range of visit specialties, including pediatrics, geriatrics, high-tech, and extensive wound care; Intermittently worked scheduling desk to coordinate patient care with all disciplines; Intermittently worked orders desk to communicate with hospitals, physicians, and case managers in order to coordinate care

1994-1998: Alverno Home Health
POSITION: High-Tech Skilled Visit Nurse
RESPONSIBILITIES: Similar to Trinity position above

1991-1994: St. Jude Children's Research Hospital
POSITION: ICU Staff Nurse/Charge Nurse
RESPONSIBILITIES: Total patient care of critically ill pediatric oncology patients in a research teaching facility; Experience with administration of neoplastic agents; facilitation of the grieving process of terminally ill patients and their families; experience as charge nurse; overseeing patient care team

1988-1991: Regional Medical Center Trauma ICU
POSITION: Nurse Extern
RESPONSIBILITIES: Performed total patient care of critically ill trauma patients; exposed to the worst of the worst accident victims and other graphic injuries; performed quick decision making in crisis situations; worked in an exciting and challenging environment.

1985-1988: Kord's Ambulance Service, Tucson, AZ
POSITION: EMT/First Responder
RESPONSIBILITIES: First Responder for Emergency 911 calls, hospital based

4953 Trotter Drive, Raleigh, NC 27603
e-mail: tennis3215@aol.com
mmonroe@axelacare.com

518 527-6564(C) 919-803-3602 (H)

Marilyn A. Monroe, BSN, RN

Profile

HEALTHCARE PROFESSIONAL WITH OVER TWENTY-FIVE YEARS EXPERIENCE IN HOME INFUSION SERVICES. EXPERTISE IN LOCAL, REGIONAL AND NATIONAL NURSING MANAGEMENT AND A DIVERSE CLINICAL BACKGROUND IN INTENSIVE CARE NURSING, PEDIATRICS, INTRAVENOUS THERAPY, AND HOME CARE NURSING. EXTENSIVE EXPERIENCE IN THE IMPLENTATION OF AND COMPLIANCE WITH JCAHO, CHAP AND ACHC POLICIES AND PROCEDURES AND DEPARTMENT OF HEALTH REGULATIONS. PROFICIENT IN PATIENT ASSESSMENT, DEVELOPMENT OF PATIENT CARE PLANS AND CLINICAL POLICIES.

Experience

AXELACARE HEALTH SOLUTIONS Lenexa, KS December 2012- Present
National Director of Nursing

- Responsible for recruiting, interviewing, onboarding, orientation and training of all regional nurse mangers.
- Responsible for assessing staffing needs and recruiting/training agencies to care for patients.
- Assists in annual competency evaluations for field staff as needed.
- Serves as resource person for pharmacists and as mentor for all nurses within the organization.
- Participates in national conferences as needed.
- Assists with patient care as needed throughout the country, as permitted by licensure. Proficient in all aspects of IV and Subcutaneous infusions.
- Performs all annual evaluations for regional nurse manager team.
- Proficient in multiple systems including Microsoft Office, CPR+. CareLink and LincDoc.
- Participates in chart audits to maintain compliance with all state regulatory and accreditation organizations.
- Reviews agency invoices to assure compliance with timely filing, accuracy of visit notes and adherence to physician orders.
- Member of clinical team to assist in addressing clinical questions from staff, development of policies and procedures, and performing agency audits for maintaining compliance.

WALGREENS INFUSION SERVICES (Formerly OptionCare), Morrisville, NC 2009 – December 2012)
Director of Nursing (November 2009 –December 2012) Per-diem RN (October 2009-November 2009)

- Assesses all referrals prior to admission in the North Carolina, South Carolina and Virginia.
- Responsible for training and maintaining competency for all clinical staff in multiple locations.
- Maintains quality care for patients while staying within budget of organization.
- Increased per-diem, full time staff and initiated contracts with Home Care Agencies to meet patient need and reduce cost.
- Provides monthly statistical report to national director to report current issues, identify trends in patient care and develop an appropriate plan of care for correction.
- Performs clinical instruction to newly hired, existing full time, and per-diem nurses.
- Recruits, interviews and provides orientation to new members of the clinical team.
- Collects and assesses report data of current care practices and initiates change to promote optimal services.
- Reviews personnel records to assure compliance with state and regulatory board standards.
- Performs annual evaluations and competencies to all team members.
- Serves as a resource person for pharmacists and mentor to nurses within the organization.
- Selected to be a lead participant in national pilot programs to trial new policies/procedures.
- Proficient with multiple software programs including Microsoft Office, MRO, i-emphsys, Cognos, and CPR +.
- Coordinates case management reviews to assure compliance with all policies and program requirements.
- Assists with direct patient care when necessary. Proficient in all aspects of Subcutaneous and IV therapy including patient education, initiating of peripheral access, maintaining central catheters for pediatric and adult patients.
- Initiates Plan of Treatment and developed tracking procedure for monitoring receipt of signed orders

EMPIRE HOME INFUSION SERVICES, Malta, NY (2007- July 2009) CLINICAL NURSE EDUCATOR

- Provided direct patient care for patients with chronic and acute illnesses including Cancer, Lyme, infections and patients in need of pain management.
- Administered IVIG, chemotherapy, antibiotic therapy, TPN, IV and Subcutaneous PCA. Initiation and maintenance of IV access for patients with PICC, peripheral, and central IV devices.
- Provided in-services for staff/caregivers on pumps, medication, policy, and new procedures.
- Developed NYSNA approved continuing education programs.
- Developed current teaching programs for patient receiving IV therapy in the home care setting.
- Provided monthly statistical reports to management.
- Reported directly to Branch Manager/VP.
- Provided education services to patients in New York, Massachusetts, and Vermont.
- Worked as liaison with hospital case managers to facilitate patient discharge.

TRINITY HOMECARE/OptionCare (1999-2009) NURSING SUPERVISOR/DIRECTOR OF NURSING
SALES ACCOUNT MANAGER ON CALL TELEPHONE TRIAGE NURSE

OPTION CARE/HMSS Farmingdale, New York & Wayne, New Jersey (1988 – 1994)
NURSE CLINICIAN/SUPERVISOR/INSTRUCTOR

- Provided direct patient care for patients at home with intravenous, intrathecal, and SubCu infusions.
- Administered home chemotherapy, TPN, IV, IT and subcutaneous pain management.
- Initiation and maintenance of IV access for patients with PICC, peripheral, and central IV devices.
- Certified to reprogram and refill Synchromed Medtronic Pumps.
- Provided in-services for staff/caregivers as it related to use of pumps, medication, policy, or procedure.
- Developed NYSNA approved continuing education programs.
- Developed current teaching programs for patient receiving IV therapy in the home.
- Provided monthly statistical reports to management.
- Reported directly to president as director of nursing.
- Worked as liaison with hospital case managers to facilitate patient discharge.
- On call telephone triage responsibilities to assist patients with treatments.
- Prepared for JCAHO certification and assisted in development of new policy and procedures to meet certification requirements.
- Trainer for use of new computer programs

NORTH SHORE UNIVERSITY HOSPITAL Manhasset, New York
NICU STAFF/Research RN 1977-1986 and 1998-1999

- Direct patient care for the premature or critically ill newborn, infant, and pediatric patients.
- Developed policy, procedure, and care plans for unit operations.
- Experienced with Jet, Oscillator, Bear Cub, and VIP Bird Ventilators.
- Proficient in venipuncture and IV placement for neonates.
- Developed policy, procedure, and care plans for unit operations.
- Primary nurse responsible for the use of ECMO (Extracorporeal Membrane Oxygenation System.)
- Wrote research proposals from grants.
- Preceptor for staff on orientation.

OMNI HEALTH CARE Coram, New York
VICE PRESIDENT 1993 - 1997

- Developed all policy and procedure manuals to meet JCAHO standards.
- Director of quality assurance.
- Provided direct patient care for patients at home with chronic and acute illnesses.
- Administered home chemotherapy, total parenteral nutrition and IV and Subcu PCA.
- Initiate and maintain IV access for patients with PICC, peripheral, and central lines
- Responsible for patient and staff education regarding therapies.
- Responsible for supervision of office and field staff.

MID ATLANTIC MEDICAL East Rutherford, New Jersey
SALES/TERRITORY MANAGER 1986 – 1988

- Directed five technical and professional staff members.
- Managed all sales to hospitals in New York's five boroughs, and Long Island.
- Direct sales to physicians, nursing homes, hospital nursing staff and purchasing departments.
- Increased territory revenues by 250% and increased new accounts by 50%.
- Maintained all communication to hospital staff, physicians, and purchasing agents.

Education

Molloy College, Rockville Centre, New York B.S.N. Nursing, 1977
Honors: Dean's List 1976, 1977

CPR Certified 1988 to Present ◊ IV Certified 1980 PICC Certified 1991 ◊ NC Licensed RN: 90293

- REFERENCES AVAILABLE UPON REQUEST

References:

Nora Bondi, General Manager
Walgreens Infusion Services
919-481-9110 (work)
919-870-0340 (cell)

Diana Boschi, President
Empire Infusion
(518) 899-8103

John Mullen, Vice President
Trinity HomeCare
516-594-0288 (home)
917-273-9323 (cell)

Jay Cantor, Nurse
Regional Patient Advocate at Affinity Biotech, Inc.
347-446-2546

Miscellaneous Information

1. **TennCare Enrollment**
2. **Publications Concerning Immune Globulin Infusion**
3. **HHA's Currently Serving Area Residents**
4. **URAC--Specialty Pharmacy**

TennCare Enrollment Report for December 2016

MCO	REGION	Total
AMERIGROUP COMMUNITY CARE		453,010
BLUECARE	East Tennessee	215,614
BLUECARE	Middle Tennessee	177,002
BLUECARE	West Tennessee	155,401
UnitedHealthcare Community Plan	East Tennessee	168,040
UnitedHealthcare Community Plan	Middle Tennessee	176,848
UnitedHealthcare Community Plan	West Tennessee	142,104
TENNCARE SELECT HIGH	All	52,829
TENNCARE SELECT LOW	All	17,931
PACE		284
Awaiting MCO assignment		146
Grand Total		**1,559,209**

AXELACARE
EAST TN

	Female				Female	Male					
COUNTY	0 - 18	19 - 20	21 - 64	65 -->	Total	0 - 18	19 - 20	21 - 64	65 -->	Male Total	Grand Total
ANDERSON	4,309	361	4,534	647	9,851	4,643	291	2,250	293	7,477	17,328
BEDFORD	3,984	278	3,223	261	7,746	4,150	256	1,350	123	5,879	13,625
BENTON	1,062	94	1,190	144	2,490	1,117	85	617	79	1,898	4,388
BLEDSOE	833	72	859	130	1,894	924	74	506	62	1,566	3,460
BLOUNT	6,325	529	6,385	698	13,937	6,464	431	2,896	326	10,117	24,054
BRADLEY	6,276	485	6,262	703	13,726	6,570	407	2,789	302	10,068	23,794
CAMPBELL	3,028	265	3,805	700	7,798	3,239	226	2,141	391	5,997	13,795
CANNON	823	74	892	132	1,921	838	66	440	56	1,400	3,321
CARROLL	1,916	188	2,268	317	4,689	2,114	170	1,187	125	3,596	8,285
CARTER	3,289	260	3,655	703	7,907	3,481	229	1,937	278	5,925	13,832
CHEATHAM	2,105	175	2,089	169	4,538	2,261	184	946	95	3,486	8,024
CHESTER	1,071	93	1,101	143	2,408	1,112	82	462	73	1,729	4,137
CLAIBORNE	2,164	199	2,570	554	5,487	2,266	181	1,582	272	4,301	9,788
CLAY	540	35	571	118	1,264	565	46	367	62	1,040	2,304
COCKE	2,849	255	3,233	470	6,807	3,008	228	1,770	244	5,250	12,057
COFFEE	3,825	304	3,796	428	8,353	3,951	237	1,726	177	6,091	14,444
CROCKETT	1,112	83	1,024	200	2,419	1,089	67	485	87	1,728	4,147
CUMBERLAND	3,455	277	3,437	510	7,679	3,622	222	1,731	241	5,816	13,495
DAVIDSON	44,499	2,893	38,064	3,489	88,945	45,763	2,585	15,995	1,934	66,277	155,222
DECATUR	695	62	790	189	1,736	799	49	437	60	1,345	3,081
DEKALB	1,376	113	1,381	194	3,064	1,526	99	762	114	2,501	5,565
DICKSON	3,067	244	3,058	325	6,694	3,240	225	1,351	134	4,950	11,644
DYER	2,876	244	3,134	427	6,681	3,031	204	1,363	158	4,756	11,437
FAYETTE	1,891	166	1,883	288	4,228	1,990	138	772	156	3,056	7,284
FENTRESS	1,402	129	1,606	381	3,518	1,516	123	1,067	200	2,906	6,424
FRANKLIN	2,099	198	2,226	277	4,800	2,291	163	1,101	117	3,672	8,472
GIBSON	3,506	269	3,718	598	8,091	3,664	271	1,704	252	5,891	13,982
GILES	1,773	155	1,842	250	4,020	1,768	124	830	129	2,851	6,871
GRAINGER	1,544	134	1,594	306	3,578	1,599	121	955	156	2,831	6,409
GREENE	3,887	326	4,439	735	9,387	4,156	288	2,256	390	7,090	16,477
GRUNDY	1,084	119	1,287	217	2,707	1,214	103	755	127	2,199	4,906
HAMBLEN	4,839	335	4,012	550	9,736	5,010	308	1,867	241	7,426	17,162

	Female				Female	Male					
COUNTY	0 - 18	19 - 20	21 - 64	65 -->	Total	0 - 18	19 - 20	21 - 64	65 -->	Male Total	Grand Total
HAMILTON	19,057	1,330	19,036	2,432	41,855	19,974	1,249	7,872	1,137	30,232	**72,087**
HANCOCK	529	58	644	158	1,389	570	40	364	72	1,046	**2,435**
HARDEMAN	1,834	173	2,041	335	4,383	1,841	141	971	160	3,113	**7,496**
HARDIN	1,774	154	2,070	381	4,379	1,919	147	1,051	205	3,322	**7,701**
HAWKINS	3,493	287	3,844	604	8,228	3,669	270	2,048	296	6,283	**14,511**
HAYWOOD	1,485	115	1,716	256	3,572	1,629	130	614	102	2,475	**6,047**
HENDERSON	1,891	165	2,061	275	4,392	2,015	140	973	102	3,230	**7,622**
HENRY	2,097	156	2,251	297	4,801	2,251	165	1,119	102	3,637	**8,438**
HICKMAN	1,597	149	1,722	190	3,658	1,779	150	898	106	2,933	**6,591**
HOUSTON	499	44	573	125	1,241	546	23	274	68	911	**2,152**
HUMPHREYS	1,156	91	1,241	146	2,634	1,227	67	607	62	1,963	**4,597**
JACKSON	683	57	806	138	1,684	776	56	458	93	1,383	**3,067**
JEFFERSON	3,415	301	3,340	510	7,566	3,598	251	1,721	207	5,777	**13,343**
JOHNSON	1,087	99	1,155	258	2,599	1,127	84	758	143	2,112	**4,711**
KNOX	21,410	1,615	21,971	2,559	47,555	22,406	1,420	9,932	1,196	34,954	**82,509**
LAKE	484	39	639	167	1,329	565	42	310	90	1,007	**2,336**
LAUDERDALE	2,127	193	2,267	299	4,886	2,219	186	989	126	3,520	**8,406**
LAWRENCE	2,877	206	2,931	410	6,424	3,072	190	1,480	151	4,893	**11,317**
LEWIS	796	72	788	128	1,784	801	63	404	59	1,327	**3,111**
LINCOLN	2,099	179	2,024	272	4,574	2,228	141	959	104	3,432	**8,006**
LOUDON	2,674	203	2,423	287	5,587	2,826	142	1,154	125	4,247	**9,834**
MACON	1,925	148	1,796	236	4,105	2,011	142	896	116	3,165	**7,270**
MADISON	6,983	529	7,176	858	15,546	7,062	445	2,676	386	10,569	**26,115**
MARION	1,913	154	2,132	238	4,437	1,924	154	946	129	3,153	**7,590**
MARSHALL	1,976	141	1,842	178	4,137	2,052	119	784	76	3,031	**7,168**
MAURY	5,357	397	5,136	516	11,406	5,728	331	2,090	198	8,347	**19,753**
MCMINN	3,283	256	3,481	496	7,516	3,567	220	1,648	230	5,665	**13,181**
MCNAIRY	1,838	185	2,171	350	4,544	2,008	147	1,210	190	3,555	**8,099**
MEIGS	850	85	889	82	1,906	881	77	455	41	1,454	**3,360**
MONROE	3,059	273	3,164	481	6,977	3,309	206	1,682	256	5,453	**12,430**
MONTGOMERY	10,490	736	10,252	727	22,205	10,875	543	3,647	277	15,342	**37,547**
MOORE	231	15	195	52	493	249	24	100	14	387	**880**
MORGAN	1,242	128	1,251	197	2,818	1,301	109	670	96	2,176	**4,994**
OBION	2,169	177	2,348	303	4,997	2,285	141	1,013	129	3,568	**8,565**
OVERTON	1,260	142	1,359	286	3,047	1,375	121	772	141	2,409	**5,456**
PERRY	566	48	546	89	1,249	577	49	306	36	968	**2,217**
PICKETT	260	28	308	75	671	291	19	170	50	530	**1,201**
POLK	1,083	95	1,167	164	2,509	1,114	98	626	86	1,924	**4,433**
PUTNAM	4,517	369	4,665	745	10,296	4,795	297	2,517	332	7,941	**18,237**
RHEA	2,525	195	2,458	366	5,544	2,598	177	1,216	146	4,137	**9,681**
ROANE	2,858	243	3,316	509	6,926	3,156	241	1,802	247	5,446	**12,372**
ROBERTSON	4,124	309	3,490	385	8,308	4,329	265	1,455	152	6,201	**14,509**
RUTHERFORD	15,424	1,075	13,360	1,014	30,873	16,150	848	5,005	472	22,475	**53,348**
SCOTT	1,979	173	2,156	379	4,687	2,090	159	1,207	190	3,646	**8,333**
SEQUATCHIE	1,036	100	1,107	149	2,392	1,081	96	584	57	1,818	**4,210**
SEVIER	6,197	436	5,458	494	12,585	6,626	370	2,459	187	9,642	**22,227**
SHELBY	79,841	6,140	73,289	6,949	166,219	81,910	5,664	24,705	3,157	115,436	**281,655**
SMITH	1,217	114	1,227	175	2,733	1,252	74	570	64	1,960	**4,693**
STEWART	819	73	869	118	1,879	848	57	444	59	1,408	**3,287**
SULLIVAN	8,694	690	9,794	1,323	20,501	9,173	624	5,026	598	15,421	**35,922**
SUMNER	8,684	709	8,041	811	18,245	9,174	597	3,252	301	13,324	**31,569**
TIPTON	3,882	304	3,701	394	8,281	4,092	285	1,493	142	6,012	**14,293**

	Female				Female	Male					
COUNTY	**0 - 18**	**19 - 20**	**21 - 64**	**65 -->**	**Total**	**0 - 18**	**19 - 20**	**21 - 64**	**65 -->**	**Male Total**	**Grand Total**
TROUSDALE	571	53	583	71	1,278	566	33	267	40	906	**2,184**
UNICOI	994	81	1,117	250	2,442	1,108	97	550	125	1,880	**4,322**
UNION	1,469	112	1,395	158	3,134	1,438	108	759	89	2,394	**5,528**
VAN BUREN	342	29	358	63	792	370	22	194	49	635	**1,427**
WARREN	3,121	235	3,037	454	6,847	3,245	189	1,513	199	5,146	**11,993**
WASHINGTON	6,405	477	7,061	971	14,914	6,646	442	3,475	432	10,995	**25,909**
WAYNE	877	70	924	158	2,029	919	66	476	74	1,535	**3,564**
WEAKLEY	1,939	180	2,093	290	4,502	1,972	160	1,022	122	3,276	**7,778**
WHITE	1,845	161	1,978	287	4,271	2,020	140	1,080	119	3,359	**7,630**
WILLIAMSON	3,777	275	3,137	368	7,557	3,980	278	1,363	154	5,775	**13,332**
WILSON	5,748	436	5,203	491	11,878	5,946	359	2,073	201	8,579	**20,457**
Other	4,096	405	3,871	174	8,546	4,449	326	1,538	100	6,413	**14,959**
Grand Total	**414,034**	**32,081**	**404,372**	**48,354**	**898,841**	**432,561**	**28,299**	**177,089**	**22,419**	**660,368**	**1,559,209**

Reports include some membership additions that are the result of retroactivity; however, additional retroactivity may still occur. The "Other" county category reflects recipients who are Tennessee residents for which their domicile is temporarily located outside of the state.

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Side-effects of intravenous immune globulins

C. DUHEM, M. A. DICATO & F. RIES *Centre Hospitalier de Luxembourg, Luxembourg*

SUMMARY

Intravenous immune globulin (IVIG) preparations are efficacious and safe products in use worldwide. Although rare, side-effects of IVIG may be serious, even life-threatening, and clinicians should be aware of their potential occurrence. This article summarizes most of the adverse experiences with IVIG reported in the literature since its introduction into clinical practice almost 15 years ago.

Keywords IVIG side-effects management prevention

INTRODUCTION

The clinical benefit of immune globulin prophylaxis in patients with primary antibody deficiency syndromes has been clearly established. In the past, replacement therapy was provided through intramuscular injections. In the early 1980s, highly purified monomeric suspensions of IgG for intravenous use became available and more than 10 commercial preparations of intravenous immune globulin (IVIG) are now at the disposal of the clinician. The indications for administration of IVIG have been enlarged to include transitory primary antibody deficiencies (such as low birth-weight premature babies), secondary hypogammaglobulinaemic states [as in chronic lymphatic leukaemia (CLL) or multiple myeloma], and conditions with increased susceptibility to infections (such as bone marrow transplant or the post-surgery period). In addition to its efficacy as replacement therapy, IVIG now has well-established therapeutic applications in some haematological and autoimmune diseases: IVIG preparations are used successfully in immune thrombocytopenic purpura (ITP), in Kawasaki disease, and for some desperate diseases for which there is no other efficient treatment [reviewed in refs 1 and 2]. The mechanisms of action of IVIG in these conditions, although not yet fully determined, include a reticulo-endothelial blockade, an immunomodulatory effect (by supplying anti-idiotype antibodies), and an anti-inflammatory action.

This growing usage has increased the need for high quality immune globulin products and, indeed, high-dose IVIG can be administered with only mild, self-limited side-effects. This paper reviews the most frequent adverse reactions reported with IVIG therapy from the time of its introduction into the clinic. Possible underlying causes of these reactions and their current management are described briefly.

SIDE-EFFECTS OF IVIG

The side-effects of IVIG can be separated into adverse reactions due to the relative 'impurity' of the commercial preparations (viruses, soluble substances or immunoglobulins other than IgG) and undesirable effects of their active component, the IgG. However, some of the mechanisms underlying these side-effects are speculative and probably complex. The side-effects are enumerated here according to their major manifestations, irrespective of their putative cause.

Correspondence: Dr M. A. Dicato, Centre Hospitalier de Luxembourg, Département d'hémato-cancérologie, 4 Rue Barblé, L-1210 Luxembourg.

Generalized reactions

The incidence of generalized reactions occurring during and/or after the administration of IVIG is reported to be in the range of 1–15 % (usually less than 5%). Most of them begin 30–60 min after the onset of the infusion; they are often mild, self-limited and include the following: pyrogenic reactions; minor systemic reactions such as headache, myalgia, fever, chills, low back pain, nausea and/or vomiting; vasomotor and cardiovascular manifestations marked by changes in blood pressure and tachycardia—these may be related to occasional reports of shortness of breath and chest tightness.

These reactions are generally considered to be due to aggregated immunoglobulin molecules which cause the complement system to be activated. They may be due to antigen–antibody reactions as well, or to possible contaminants or even stabilizers that may have been used during the manufacturing process. Frequently, these manifestations can be managed quite easily, sometimes just by reducing the rate of IVIG infusion or stopping it.

Far less frequently, the onset of symptoms of a generalized reaction is delayed until a few days after IVIG infusion, suggesting a type III allergic reaction [3].

Hypersensitivity and anaphylactic reactions

Severe and even fatal anaphylactoid reactions [4,5] may occur during IVIG treatment in patients with IgA deficiency; the appearance of anaphylactic shock is correlated with the presence of anti-IgA antibodies of the IgG and IgE isotypes in the patient's serum [5]. Among hypogammaglobulinaemic patients, those with combined subclass deficiency (for example, IgG2 and IgA deficiency) are more likely to develop this complication. Patients with autoimmune diseases have an increased prevalence of selective IgA deficiency when compared to normal blood donors (1/50 in systemic lupus erythematosus

versus 1/700 in a normal Caucasian population). Furthermore, anti-IgA antibodies seem to be more frequent in those IgA-deficient subjects with autoimmune diseases [6].

Seriously ill patients with a compromised cardiac function may be at increased risk of vasomotor cardiac complications, manifested by elevated blood pressure and/or cardiac failure. The kallikrein activity of some IVIG preparations has been incriminated as contributing to these adverse vasomotor reactions. Moreover, the volume of fluid delivered with IVIG (700 ml with standard preparations) is intolerable in a subset of fluid-restricted patients with congestive disease, especially at a high infusion rate.

Haemolytic anaemia

Two cases of acute Coombs-positive haemolytic anaemia developing during IVIG treatment have been published. The patients, a 30-year-old man and a 9-month-old child, were treated for ITP and Kawasaki disease, respectively [7,8]. In both cases, haemolysis mediated by antibodies to blood-group antigen could be demonstrated. When high doses of IVIG are infused, their isoagglutinin content can be sufficient to explain a Coombs-positive haemolytic anaemia. Furthermore, decreased haptoglobin levels and mild reticulocytosis have been described in normal volunteers receiving IVIG, but without any change in haemoglobin level, suggesting that clinically insignificant, well-compensated haemolysis may occur during IVIG treatment [9].

Viral contamination

Several papers published between 1983 and 1987 reported clusters of non-A, non-B hepatitis after IVIG treatment [10–13]. Hepatitis seemed to run a more severe course in hypogammaglobulinaemic patients with cirrhosis, and death by hepatic failure resulted in some of them. The mechanisms whereby some preparations (and not others during the same period) could be infectious remain unclear. They could include problems with the method of manufacture, either an isolated error in production or a basic defect in the manufacturing procedure, or an insufficient level of specific neutralizing antibody in the source plasma, allowing the presence of an excessive amount of virus. Finally, there is the possibility that the infection could be the result of non-parenteral transmission of the so-called non-A, non-B hepatitis [14].

It now appears clear that anti-hepatitis C positivity of blood products varies, depending on the country of origin of plasma donation [15]. Donors that test antibody-positive are systematically excluded. In February 1994, Baxter Healthcare Corporation, Glendale, California, USA instituted a worldwide recall of Gammagard®, its brand of IVIG, because of reports of some ten cases of possible transmission of hepatitis C. The coming months should clarify this issue and its extent. The production process for this IVIG preparation includes a chromatography procedure without any further chemical step of inactivation. As of this writing, other IVIG products currently in use have not been incriminated in hepatitis C transmission. Additional steps used in the production process of most other IVIG preparations include adjustment to pH 4, or the use of propionic acid or solvent detergent. At present, it seems cautious to use only IVIG products that have been prepared with an additional inactivation procedure.

No case of human immunodeficiency virus (HIV) seroconversion has yet been ascribed to the administration of IVIG. Furthermore, experiments in which large amounts of HIV were added to plasma before fractionation indicate that HIV is successfully eliminated during IVIG preparation.

Hepatitis B virus has not been detected in IVIG batches and the risk of its transmission is also considered negligible.

Neurological complications

As noted previously, headache is commonly reported by patients receiving IVIG; this symptom is efficiently palliated by antalgic and/or anti-histaminic drugs. Acute aseptic meningitis has been reported as a cause of recurrent IVIG-associated headaches. A 7-year-old boy treated for ITP presented with severe headache, vomiting, fever and meningism a few hours after his second infusion of IVIG [16]. A similar episode has been reported in a 2-year-old Japanese girl also treated for ITP. Seven days after IVIG infusions she experienced the same symptoms as the child just described, which were also attributed to an aseptic meningitis [17]. Two other cases have been reported in the literature [18,19]. The mechanism of this reaction remains unclear; several cases of aseptic meningitis have been associated with the use of drugs such as isoniazid and sulphamethizole or in patients with systemic lupus erythematosus taking anti-inflammatory agents.

Recently, a case of recurrent migraine after IVIG therapy has been described, suggested by the typical symptoms at presentation and the efficient prevention by propanolol before subsequent IVIG infusions. Again, the mechanism is difficult to explain [20].

Stroke as a side-effect of IVIG treatment will be discussed later.

Renal complications

Renal failure related to IVIG treatment has been reported in eight cases [21–24]. When it occurred, the best evidence for a cause–effect relationship was the close temporal association between infusion of the drug and the onset of clinical (oliguria) and biological symptoms, as well as the patients' return to pretreatment creatinine levels after stopping the drug, with the exception of a young woman who was haemodialysed and subsequently received a transplant. Renal biopsy was performed in four patients and some pathological features in three of the cases suggested a high solute load-induced damage of the proximal tubule, similar to that associated with the use of dextran or mannitol. Immunoglobulins themselves (especially large aggregates), or more likely, some component of the preparations (such as sucrose) could be responsible for this injury. The fourth case was a 39-year-old woman with mixed cryoglobulinaemia associated with a lymphoma, who had been treated specifically for hypogammaglobulinaemia and recurrent infections. The mechanism of renal damage in this case differs from the previous cases: this patient developed acute, severe, mixed cryoglobulinaemic nephropathy with evidence of antigen–antibody complex deposition after a single infusion of IVIG [24]. However, most of these patients presented with impairment of their renal function before the episode of acute degradation; IVIG treatment probably just contributed to the deterioration in renal function. Support for this conclusion comes from observations that elevated serum creatinine levels occur in patients with glomerulonephritis who receive IVIG for nephrotic syndromes

[25]. This should draw attention to the importance of screening for impaired renal function before IVIG therapy is initiated. In addition, the report of the case of acute cryoglobulinaemic renal failure after IVIG can serve as a caution against this potential complication in patients with B cell neoplasm and demonstrable serum rheumatoid factor activity.

Thrombotic events

Woodruff *et al.* reported four cases of fatal stroke in elderly patients (62–83 years old), all receiving IVIG for ITP [26]. The authors postulated that IVIG infusion could be responsible for an enhancement of adenosine triphosphate release from platelets, favouring their aggregation, as suggested by *in vitro* aggregometry studies, but these data were not confirmed by another group [27]. In those cases with ITP, the rise in platelet count during IVIG treatment could have played a role in the thrombotic event.

Recently, Reinhart & Berchtold studied the effect of high-dose IVIG on blood rheology both *in vitro* and *in vivo* [28]. Their data show that the rise in viscosity occurring after IVIG therapy can significantly impair blood flow; for this reason IVIG infusions might be sufficient to generate myocardial infarction or stroke in predisposed patients, especially elderly patients at risk of cardiovascular and thromboembolic events. However, few severe thrombotic episodes have been observed with IVIG therapy and when mentioned in case reports, the aetiological link between the treatment and frequent events in old and severely ill patients is not obvious.

Contamination of IVIG batches

Immunologically active proteins. The levels of soluble class II molecules (sHLA-DR, -DQ and -DP) in IVIG preparations appear to exceed those found in the plasma of healthy individuals, suggesting a concentration process [29]; in contrast, HLA class I molecules (A,B,C) are not detectable. Based on the total dosage of IVIG per infusion, the contaminating sHLA class II molecules may become immunogenic.

Significant levels of soluble CD4 and CD8 molecules have been found in some commercial preparations [30]. Seventeen of these were tested by enzyme-linked immunosorbent assays for the presence of proteins and cytokines such as interferon-γ (IFN-γ), tumour necrosis factor, interleukin-1 (IL-1), sIL-2 and sIL-4. Of the substances studied, only IFN-γ was present at measurable concentrations [31]. The clinical relevance of these observations remains unclear.

Anticytoplasmic antigens (ANCA). One case of uveitis has been reported in a 9-year-old hypogammaglobulinaemic patient, which was attributed to a localized vasculitis [32]. Cytoplasmic ANCA activity was detected in IVIG batches and was proposed as the cause of the vasculitis. However, the causative role for ANCA in vasculitis remains unproven [33]. Attempts to transfer the disease to animals by the same mechanism have failed. Moreover, a transient peak in serum ANCA activity has been noted after IVIG infusion, attributed to displacement of ANCA from tissue sites [34]. The young patient in the case report might have had an underlying localized vasculitis.

Miscellaneous side-effects

Many side-effects of IVIG are in the literature as sporadic case reports. Generally, the assessment of a real cause–effect relationship is sustained by a temporal association to the infusion and the absence of other obvious aetiological agents. Most of the time, no clear physiopathogenic explanation can be given.

Alopecia. Three cases of alopecia developing after infusion of IVIG have been reported [35]. The three women (aged 19, 42 and 61) were being treated for ITP and complained of diffuse alopecia up to 4 weeks after treatment. Their hair regrew within the 4 weeks following the withdrawal of IVIG. Two more cases have been reported by the IVIG manufacturers. An immunological basis for alopecia is possible, despite the negativity of immunofluorescence studies performed on the scalp biopsies of two of these patients.

Hypothermia. We saw one case of transitory hypothermia (to 35°C) in a 59-year-old CLL patient after each IVIG infusion. The pathogenesis of this observation remains obscure.

MANAGEMENT AND PREVENTION OF IVIG SIDE-EFFECTS

The management of the side-effects of IVIG is symptomatic and, in view of their mildness, they do not necessitate any aggressive treatment in most cases. Depending on the particular manifestation, drugs palliating the symptoms are antalgic, anti-pyretic, or anti-histaminic drugs; non-steroidal, anti-inflammatory agents; and/or low-dose corticosteroids.

Most adverse reactions to IVIG treatment could be reduced in three main ways: assuring the maximal purification of the product, screening the patient for factors predisposing to complications and respecting some rules of administration.

Purification of IVIG

One batch of IVIG results from processing the plasma of 3000–15 000 donors, all of whom are currently screened for hepatitis B and C, undergo HIV serology and measurement of transaminase levels. Commercial IVIG products are prepared from pooled plasma by the cold-ethanol fractionation technique based on Cohn's procedure and now in world-wide use. Once the plasma fraction II has been obtained, the immunoglobulins are stabilized by substances such as β-propionolactone. This procedure of cold-ethanol fractionation contributes to inactivation of viruses which might be present in the plasma pool, despite meticulous donor selection and the use of sensitive screening procedures. Moreover, β-propionolactone also has virucidal properties.

In addition, some manufacturers currently include a step of inactivation of lipid-enveloped viruses by a solvent detergent technique in the processing. This, concurrent with such measures as lowering the pH, raising the temperature, and increasing the incubation time during the production of IVIG, renders these products free of any major viral transmission.

The composition of each IVIG speciality is not exactly the same: they may differ in IgG subclass levels and IgA contaminants. Preparations containing very low levels of IgA should be selected for patients who present with serum anti-IgA antibodies or in emergency situations where this information cannot be obtained before IVIG treatment.

Screening of the patient

Most of the severe reactions to IVIG have been observed in patients with anti-IgA antibodies. This eventuality should be

assessed by systematic screening before any instauration of treatment, particularly in patients with hypogammaglobulinaemia or autoimmune diseases [36].

As noted earlier, the presence of rheumatoid factor activity (especially in patients with B lymphoma) or renal impairment should be investigated in any candidate for IVIG treatment.

Drug administration

Rate of infusion. The rate of IVIG infusions should be low at the beginning and increased every 15–30 min, based on the patient's tolerance. Infusion of a standard dose (e.g. 400 mg/kg) may take up to 8 h in some patients. In most cases, symptoms such as chills, fever and headache during infusion may be alleviated by lowering the rate of infusion or briefly stopping it. A phase I rate-escalation study was conducted recently in patients undergoing bone marrow transplantation and receiving 500 mg/kg of IVIG per week prophylactically, to determine the minimal period of infusion of concentrated IVIG that was well tolerated [37]. After a first infusion over a 6-h period, the 40 patients were randomized to receive the same treatment over a period of 2, 3, 4 or 5 h. The conclusion was that IVIG could be infused over a 3-h period with good tolerance, but a faster rate of infusion was poorly tolerated. This rule should be respected, particularly in patients at risk of complications (those with multi-organ failure, previous severe reactions, etc.).

Premedication. For patients with repeated reactions unresponsive to reducing the infusion rate, premedication with hydrocortisone (100 mg intravenously) or an antihistaminic drug can be considered and is generally efficacious.

CONCLUSIONS

IVIG preparations are some of the safest biological products available. Although severe adverse experiences have been reported, they are all largely anecdotal. Besides, the aetiological role of IVIG in their pathogenesis is rarely unequivocal.

The benefits of IVIG have been described for a growing number of conditions where immunoregulatory disorders are suspected and for which satisfactory alternative treatment is lacking. This harmless drug has been 'tried' and isolated therapeutic responses that are occasionally dramatic and plausible have been reported, while failures are forgotten. In contrast to the preventive indications study, few randomized placebo-controlled trials have been conducted to assess the real therapeutic impact of IVIG in conditions such as rare vasculitis, demyelinating neuropathies or severe epilepsy, which require multicentre studies. Simultaneously, the specific side-effects attributed to IVIG in those special indications could be appreciated.

To date, and because patients can be screened for anti-IgA antibodies, IVIG can be administered very safely with minimal reactions. However, this currently very expensive form of therapy should still be restricted to adequately established indications.

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UnitedHealthcare

DRUG POLICY

IMMUNE GLOBULIN (IVIG and SCIG)

Policy Number: 2016D0035S
Effective Date: 2/1/2016

Related Medical or Drug Policies:
None

Related Coverage Determination Guidelines:
Immune Globulin Site of Care Review Guidelines for Medical Necessity of Hospital Outpatient Facility Infusion

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INSTRUCTIONS FOR USE

This Drug Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this Drug Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Drug Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COVERAGE RATIONALE

This policy refers to the following intravenous (IV) and subcutaneous (SC) immune globulin (IG) products (List not all inclusive):

Bivigam™ (IV)
Carimune® NF (IV)
Flebogamma® DIF (IV)
Gammagard® Liquid (IV, SC)
Gammagard® S/D (IV)
Gammaked™ (IV, SC)
Gammaplex® (IV)
Octagam® (IV)
Privigen® (IV)
Gamunex®-C (IV, SC)
Hizentra® (SC)
HyQvia® (SC)

In absence of a product listed, and in addition to applicable criteria outlined within the drug policy, prescribing and dosing information from the package insert is the clinical information used to determine benefit coverage.

The term "IVIG" will be used in this policy where prescribing and dosing information is specific to the intravenous formulation. At all other times, the term "immune globulin" will be used.

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Diagnoses addressed in this policy

Asthma (severe, persistent, high-dose steroid-dependent)	Autoimmune bullous diseases	Autoimmune uveitis
Bone marrow transplantation (BMT)	Chronic inflammatory demyelinating polyneuropathy	Chronic lymphocytic leukemia (CLL), prevention of infection in B-cell CLL
Cytomegalovirus (CMV) induced pneumonitis in solid organ transplants	Dermatomyositis or polymyositis	Diabetes mellitus
Enteroviral meningoencephalitis	Fetomaternal alloimmune thrombocytopenia	Graves' ophthalmopathy
Guillain-Barré syndrome (GBS)	HIV-infection, prevention of bacterial infection in pediatric HIV	Idiopathic thrombocytopenic purpura (ITP)
IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy	Kawasaki disease	Lambert-Eaton myasthenic syndrome (LEMS)
Lennox Gastaut syndrome	Lymphoproliferative disease, treatment of bacterial infections	Monoclonal gammopathy
Multifocal motor neuropathy (MMN)	Multiple sclerosis, relapsing remitting (RRMS)	Myasthenic exacerbation
Neuromyeltis optica	Paraproteinemic neuropathy	Posttransfusion purpura
Primary immunodeficiency syndromes	Rasmussen syndrome	Renal transplantation, prevention of acute humoral rejection
Rheumatoid arthritis, severe	Rotaviral enterocolitis	Staphylococcal toxic shock
Stiff-person syndrome	Thrombocytopenia, secondary to HCV, HIV, and	Toxic epidermal necrolysis or Stevens-Johnson syndrome
Urticaria, delayed pressure	Unproven Uses	

The following information pertains to medical necessity review:

A. **General Requirements** (applicable to **all** medical necessity requests):
   1. For **initial therapy**, **both** of the following:
      a. Diagnosis
      AND
      b. Medical records documenting **both** of the following:
         (1) History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
         AND
         (2) Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested
   2. For **continuation of therapy, all** of the following:
      a. Documentation of positive clinical response to immune globulin therapy
      AND
      b. Statement of expected frequency and duration of proposed immune globulin treatment
      AND
      c. For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response.

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B. Diagnosis-Specific Requirements
The information below indicates additional requirements for those indications having specific medical necessity criteria in the list of proven indications.

Immune globulin is **proven** for:

1. **Asthma (severe, persistent, high-dose steroid-dependent)**[71,98,122]

   Additional information to support medical necessity review where applicable:
   Immune globulin is **medically necessary** for the treatment of **severe, persistent, high-dose steroid-dependent asthma** when **all** of the following criteria are met:
   a. Patient is receiving optimal conventional asthma therapy (e.g., high-dose inhaled glucocorticoids, short- and long-acting inhaled β agonists).
      AND
   b. Patient has required continuous oral glucocorticoid therapy for a minimum of 2 months prior to the decision to initiate immune globulin therapy.
      AND
   c. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

2. **Autoimmune bullous diseases** [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis][3,6,94,116,122,169]

   Additional information to support medical necessity review where applicable:
   Immune globulin is **medically necessary** for the treatment of autoimmune bullous diseases when **all** of the following criteria are met:
   a. Diagnosis of an autoimmune bullous disease
      AND
   b. Extensive and debilitating disease
      AND
   c. History of failure, contraindication, or intolerance to systemic corticosteroids **with concurrent** immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil).
      AND
   d. IVIG dose does not exceed 1,000 to 2,000 mg/kg per month divided into 3 equal doses each given over 3 consecutive days or 400 mg/kg per day given over 5 consecutive days per month. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities.[3]
      AND
   e. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

3. **Autoimmune uveitis**[121,122]

4. **Bone marrow transplantation (BMT),** [47,57,122,152,158,177]
   Additional information to support medical necessity review where applicable:
   Immune globulin is **medically necessary** after allogeneic **BMT** when **all** of the following criteria are met:
   a. **One** of the following uses:
      (1) Prevention of acute graft vs. host disease (GVHD)
      OR
      (2) Prevention of infection
      AND

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b. Confirmed allogeneic bone marrow transplant within the last 100 days
AND
c. Documented severe hypogammaglobulinemia (IgG < 400 mg/dL)
AND
d. IVIG dose does not exceed 500 mg/kg once weekly for the first 90 days of therapy, then monthly up to 360 days after transplantation

5. **Chronic inflammatory demyelinating polyneuropathy**[41,60,62,63,99,122,125,141,144,146,158,161]

Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the treatment of **chronic inflammatory demyelinating polyneuropathy** when **all** of the following criteria are met:

a. **Initial treatment:**
(1) Diagnosis of chronic inflammatory demyelinating polyneuropathy as confirmed by **all** of the following:
(a) Progressive symptoms present for at least 2 months
AND
(b) Symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor or sensory impairment of more than one limb
AND
(c) Electrophysiologic findings when at least **three** of the following four criteria are present
i. Partial conduction block of ≥ 1 motor nerve
ii. Reduced conduction velocity of ≥ 2 motor nerves
iii. Prolonged distal latency of ≥ 2 motor nerves
iv. Prolonged F-wave latencies of ≥ 2 motor nerves or the absence of F waves
AND
(d) **Both** of the following findings following lumbar puncture:
i. White blood cell count <10/mm^3
ii. Elevated CSF protein
AND
(2) IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

b. **Continuation of treatment:**
(1) Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]
AND
(2) For long-term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect
AND
(3) IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities.

6. **Chronic lymphocytic leukemia (CLL), prevention of infection in B-cell CLL**[8,58,59,115,123,158]

Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the prevention of infection in **B-cell chronic lymphocytic leukemia** when **all** of the following criteria are met:

a. Diagnosis of B-cell chronic lymphocytic leukemia (CLL)
AND

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b. **One** of the following:
   (1) Documented hypogammaglobulinemia (IgG < 500 mg/dL)
   (2) History of bacterial infection(s) associated with B-cell CLL
   AND
c. IVIG dose does not exceed 400 mg/kg every 3 to 4 weeks

7. **Cytomegalovirus (CMV) induced pneumonitis in solid organ transplants**

8. **Dermatomyositis or polymyositis**[41,42,47,50,122,125,141]

   Additional information to support medical necessity review where applicable:
   Immune globulin is **medically necessary** for the treatment of **dermatomyositis or polymyositis** when **all** of the following criteria are met:
   a. Diagnosis of dermatomyositis or polymyositis
      AND
   b. History of failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate)
      AND
   c. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days administered as monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.
      AND
   d. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

9. **Diabetes mellitus**[73,122]

   Additional information to support medical necessity review where applicable:
   Immune globulin is **medically necessary** for the treatment of **autoimmune diabetes mellitus** when **both** of the following criteria are met:
   a. Patient is newly diagnosed with insulin dependent (type 1) diabetes mellitus
      AND
   b. Patient is not a candidate for or is refractory to insulin therapy.

10. **Enteroviral meningoencephalitis**[45,122,135]

11. **Fetomaternal alloimmune thrombocytopenia**[1,8,134]

    Additional information to support medical necessity review where applicable:
    Immune globulin is **medically necessary** for the treatment of **fetomaternal alloimmune thrombocytopenia** when **all** of the following criteria are met:
    a. For pregnant women:
       (1) Diagnosis of fetomaternal alloimmune thrombocytopenia
       AND
       (2) **One** or more of the following:
          (a) Previously affected pregnancy
          (b) Family history of the disease
          (c) Platelet alloantibodies found on screening
          AND
       (3) IVIG dose does not exceed 1,000 mg/kg once weekly until delivery
       OR
    b. For newborns:
       (1) Diagnosis of fetomaternal alloimmune thrombocytopenia
       AND
       (2) Thrombocytopenia that persists after transfusion of antigen-negative compatible platelets

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12. **Graves' ophthalmopathy**[14,122]

13. **Guillain-Barré syndrome (GBS)**[41,50,79,80,122,125,141,161]
    Additional information to support medical necessity review where applicable:
    Immune globulin is **medically necessary** for the treatment of **Guillain-Barré syndrome** when **all** of the following criteria are met:
    a. Diagnosis of Guillain-Barré Syndrome
       AND
    b. Severe disease requiring aid to walk
       AND
    c. Onset of neuropathic symptoms within the last four weeks
       AND
    d. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.
       AND
    e. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

14. **HIV-infection, prevention of bacterial infection in pediatric HIV**[57,89,111,158,178]

    Additional information to support medical necessity review where applicable:
    Immune globulin is **medically necessary** for the prevention of **bacterial infection in pediatric HIV** when **all** of the following criteria are met:
    a. Diagnosis of HIV disease[57,89,111,158,178]
       AND
    b. Patient age ≤ 13 years
       AND
    c. **One** of the following criteria:
       (1) Documented hypogammaglobulinemia (IgG < 400 mg/dL)
           OR
       (2) Functional antibody deficiency as demonstrated by either poor specific antibody titers or recurrent bacterial infections
       AND
    d. IVIG dose does not exceed 400 mg/kg every 28 days

15. **Idiopathic thrombocytopenic purpura (ITP)**[8,28,57,59,60,62,63,122,133,151,158]

    Additional information to support medical necessity review where applicable:
    Immune globulin is **medically necessary** for the treatment of **idiopathic thrombocytopenic purpura** when at least **one** of the following criteria is met:
    a. **All** of the following:
       (1) Diagnosis of **acute** thrombocytopenic purpura (ITP)
           AND
       (2) Documented platelet count < 50×10^9 / L (obtained within the past 30 days)[151]
           AND
       (3) IVIG dose does not exceed 1,000 mg/kg/day for 1 to 2 days.
       OR
    b. **All** of the following:
       (1) Diagnosis of **chronic** thrombocytopenic purpura (ITP)
           AND
       (2) **History of failure, contraindication, or intolerance to at least **one** of the following:
           (a) Corticosteroids

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(b) Splenectomy
AND

(3) IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval should be adjusted depending upon response and titrated to the minimum effective dose that can be given at maximum intervals to maintain safe platelet levels.

16. **IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy**[41,122]

17. **Kawasaki disease**[59,122,158,172]

Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the treatment of **Kawasaki disease** when **both** of the following criteria are met:

a. Diagnosis of Kawasaki disease
AND
b. IVIG dose does not exceed 400 mg/kg for five consecutive days or a single dose of 2,000 mg/kg

18. **Lambert-Eaton myasthenic syndrome (LEMS)**[41,47,50,122,125,141,181-2]

Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the treatment of **Lambert-Eaton myasthenic syndrome** when **all** of the following criteria are met:

a. Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)
AND
b. History of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids)
AND
c. Concomitant immunomodulator therapy (e.g., azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS
AND
d. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days.[50] IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities.
AND
e. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

19. **Lennox Gastaut syndrome**[47,50]

Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the treatment of **Lennox Gastaut syndrome** when **all** of the following criteria are met:

a. History of failure, contraindication or intolerance to initial treatment with traditional anti-epileptic pharmacotherapy (e.g., lamotrigine, phenytoin, valproic acid).
AND
b. IVIG dose does not exceed 400 mg/kg/day given for 4 to 5 consecutive days. IVIG administration may be repeated monthly as needed in patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities.
AND

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c. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

20. **Lymphoproliferative disease, treatment of bacterial infections**[122]

21. **Monoclonal gammopathy**[66,122]

22. **Multifocal motor neuropathy** (MMN)[41,47,50,58,122,125,183]

Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the treatment of **multifocal motor neuropathy** when **both** of the following criteria are met:

a. Initial treatment:
   (1) Diagnosis of multifocal motor neuropathy as confirmed by **all** of the following:[183]
      (a) Weakness with slowly progressive or stepwise progressive course over at least one month
      AND
      (b) Asymmetric involvement of two or more nerves
      AND
      (c) Absence of motor neuron signs and bulbar signs
      AND
   (2) IVIG dose does not exceed 2,400 mg/kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities.[41,47,50,183]
b. Continuation of treatment:
   (1) Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]
   AND
   (2) IVIG dose does not exceed 2,400 mg/kg per month given over 2 to 5 consecutive days. Dosing interval may need to be adjusted in patients with severe comorbidities.[41,47,50,183]
   AND
   (3) For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

23. **Multiple sclerosis, relapsing remitting (RRMS)**[47,49,50,67,77,122,149]
NOTE: Treatment of any other type of multiple sclerosis with immune globulin is not supported by clinical evidence.

Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the treatment of **relapsing remitting multiple sclerosis** when **all** of the following criteria are met:

a. **Initial treatment:**
   (1) Diagnosis of relapsing-remitting multiple sclerosis (RRMS)
   AND
   (2) Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy.
   AND
   (3) History of failure, contraindication, or intolerance to at least **two** of the following agents:
      (a) Aubagio (teriflunomide)
      (b) Avonex (interferon beta-1a)

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(c) Betaseron (interferon beta-1b)
(d) Extavia (interferon beta-1b)
(e) Copaxone (glatiramer acetate)
(f) Gilenya (fingolimod)
(g) Rebif (interferon beta-1a)
(h) Tecfidera (dimethyl fumarate)
(i) Tysabri (natalizumab)

AND

(4) Induction, when indicated, does not exceed a dose of 400 mg/kg daily for up to five days

b. Continuation of treatment:

(1) Medical records, including findings of interval examination including neurological deficits incurred and assessment of disability [e.g., Expanded Disability Status Scale (EDSS), Functional Systems Score (FSS), Multiple Sclerosis Functional Composite (MSFC), Disease Steps (DS)]

AND

(2) Stable or improved disability score (e.g., EDSS, FSS, MSFC, DS)

AND

(3) Documentation of decreased number of relapses since starting immune globulin therapy

AND

(4) Diagnosis continues to be the relapsing-remitting form of MS (RRMS)

AND

(5) IVIG dose does not exceed 1,000 mg/kg monthly

AND

(6) For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

24. **Myasthenic exacerbation**[41,47,50,56,72,122,125]

NOTE: Evidence does not support the use of immune globulin maintenance therapy for generalized myasthenia gravis or for ocular myasthenia.

Additional information to support medical necessity review where applicable:
Immune globulin is **medically necessary** for the treatment of **myasthenic exacerbation** when **all** of the following criteria are met:

a. Diagnosis of generalized myasthenia gravis

AND

b. Evidence of myasthenic exacerbation, defined by at least **one** of the following symptoms in the last month:
   (1) Difficulty swallowing
   (2) Acute respiratory failure
   (3) Major functional disability responsible for the discontinuation of physical activity

AND

c. **One** of the following:
   (1) History of failure, contraindication, or intolerance to immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine) for long-term management of myasthenia gravis.
   (2) Currently receiving immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine) for long-term management of myasthenia gravis.

AND

d. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 days administered in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

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25. **Neuromyeltis optica**[81,190-191]

Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the treatment of **neuromyelitis optica** when **all** of the following criteria are met:

a. Diagnosis of neuromyelitis optica
AND
b. History of failure, contraindication, or intolerance to at least **two** of the following:
(1) Azathioprine
(2) Corticosteroids
(3) Mycophenolate mofetil
(4) Rituximab
AND
c. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

26. **Paraproteinemic neuropathy**[66,122]

27. **Posttransfusion purpura**[8,122]

Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the treatment of **posttransfusion purpura** when **both** of the following criteria are met:

a. Diagnosis of posttransfusion purpura
AND
b. IVIG dose does not exceed 1,000 mg/kg for 2 days

28. **Primary immunodeficiency syndromes**[8,28,51,52,57-63,76,118,122,133,158,164,173,183-9] **(See disease list linked to below)**

Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the treatment of **primary immunodeficiency syndromes** when **all** of the following criteria are met:

a. Diagnosis of primary immunodeficiency
AND
b. Clinically significant functional deficiency of humoral immunity as evidenced by **one** of the following:
(1) Documented failure to produce antibodies to specific antigens
OR
(2) History of significant recurrent infections
AND
c. Initial IVIG dose is 300 to 600 mg/kg every 3 to 4 weeks and titrated based upon patient response.[28,51-2,57-61,63,76,118,133] (For SCIG products, FDA-labeled dosing and conversion guidelines will used to determine benefit coverage.)

29. **Rasmussen syndrome**[50,122]
Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the treatment of **Rasmussen syndrome** when **both** of the following criteria are met:

a. Documentation that short term amelioration of encephalitis is needed prior to definitive surgical therapy
AND

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b. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 days. IVIG is not recommended for long-term therapy for Rasmussen's encephalitis as surgical treatment is the current standard of care.[50]

30. **Renal transplantation, prevention or treatment of acute humoral rejection**[30,87,104,112,122]

31. **Rheumatoid arthritis, severe**[114,122,155]

32. **Rotaviral enterocolitis**[68,122]

33. **Staphylococcal toxic shock**[122]

34. **Stiff-person syndrome**[41,47,50,122,179-80]

Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the treatment of **stiff-person syndrome** when **all** of the following criteria are met:

a. Diagnosis of stiff-person syndrome
AND
b. History of failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines)[47,50,179-80]
AND
c. History of failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids)[179-80]
AND
d. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 days. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities.[50]
AND
e. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

35. **Thrombocytopenia, Secondary to Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), or pregnancy**[192]

Additional information to support medical necessity review where applicable: Immune globulin is **medically necessary** for the treatment of **thrombocytopenia** when **one** of the following criteria is met:

a. For initial therapy, **all** of the following:
(1) **One** of the following:
(a) **Both** of the following:
i. Diagnosis of thrombocytopenia secondary to HCV infection
ii. **Patient is receiving concurrent antiviral therapy, unless contraindicated.
OR
(b) **Both** of the following:
i. Diagnosis of thrombocytopenia secondary HIV infection
ii. **Patient is receiving concurrent antiviral therapy, unless contraindicated.
OR
(c) Diagnosis of thrombocytopenia secondary to pregnancy
AND

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(2) Documented platelet count < 50 x 10^9 / L (obtained within the past 30 days)[151]
AND
(3) IVIG dose does not exceed 1,000 mg/kg/day for 1 to 2 days
OR

b. For continuation of therapy, **both** of the following:
(1) **One** of the following:
(a) **Both** of the following:
i. Diagnosis of thrombocytopenia secondary to HCV infection
ii. **Patient is receiving concurrent antiviral therapy, unless contraindicated.
OR
(b) **Both** of the following:
i. Diagnosis of thrombocytopenia secondary to HIV infection
ii. **Patient is receiving concurrent antiviral therapy, unless contraindicated.
OR
(c) Diagnosis of thrombocytopenia secondary to pregnancy
AND
(2) IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval should be adjusted depending upon response and titrated to the minimum effective dose that can be given at maximum intervals to maintain safe platelet levels.

36. **Toxic epidermal necrolysis or Stevens-Johnson syndrome**[55,122]

37. **Urticaria, delayed pressure**[37,122]

Immune globulin is **unproven and not medically necessary** for:

1. Acquired hemophilia
2. Acute disseminated encephalomyelitis (ADEM)
3. Adrenoleukodystrophy
4. Alzheimer's disease
5. Amyotrophic lateral sclerosis (ALS)
6. Antiphospholipid antibody syndrome (APS) in pregnancy
7. Asthma, non-steroid dependent
8. Atopic dermatitis
9. Autism spectrum disorders
10. Autoimmune hemolytic anemia
11. Autoimmune liver disease
12. Autoimmune neutropenia
13. Bone marrow transplantation (BMT), prevention of acute graft vs. host disease (GVHD) after autologous BMT
14. Bone marrow transplantation (BMT), prevention of chronic graft vs. host disease (GVHD) after either allogeneic or autologous BMT
15. Bone marrow transplantation (BMT), prevention of infection after autologous BMT
16. *Campylobacter* species-induced enteritis
17. Cerebral infarctions with antiphospholipid antibodies
18. Chronic fatigue syndrome
19. Demyelinative brain stem encephalitis
20. Demyelinating neuropathy associated with monoclonal IgM
21. Dilated cardiomyopathy
22. HIV infection, to reduce viral load
23. HTLV-1-associated myelopathy
24. Idiopathic dysautonomia, acute

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25. Inclusion body myositis
26. Isolated IgA deficiency
27. Isolated IgG4 deficiency
28. Lumbosacral or brachial plexitis
29. Myocarditis, acute
30. Neonatal isoimmune hemolytic jaundice
31. Neonatal sepsis, prevention
32. Neonatal sepsis, treatment
33. Ocular myasthenia
34. Opsoclonus myoclonus
35. Paraneoplastic cerebellar degeneration, sensory neuropathy, or encephalopathy
36. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)
37. POEMS syndrome
38. Postinfectious cerebellar ataxia
39. Postoperative sepsis
40. Pseudomembranous colitis
41. Respiratory syncytial virus (RSV) lower respiratory tract infection
42. Rheumatic fever, acute
43. Sjogren's syndrome
44. Spontaneous recurrent abortions, prevention
45. Systemic lupus erythematosus
46. Urticaria, chronic
47. Vasculitides and antineutrophil antibody syndromes

Efficacy for these conditions has not been described in adequately designed studies. The available evidence is limited to case reports or case series, anecdotal reports, and open-label trials, or the available studies have failed to demonstrate a positive treatment effect. Further well-designed studies are needed to establish the role of immune globulin in these conditions.

Centers for Medicare and Medicaid Services (CMS):
Medicare covers Intravenous Immune Globulin when criteria are met. Refer to the National Coverage Determinations (NCDs) for Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases (250.3) and Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine) (260.7).

Local Coverage Determinations (LCDs) do exist. See the LCDs for Drugs and Biologicals: Immune Globulin Intravenous (IVIg), External Infusion Pumps, Immune Globulin Intravenous (IVIg), Immune Globulins, Intravenous Immune globulin and Intravenous Immune Globulin (IVIg).

Medicare does not have an NCD that specifically addresses the subcutaneous administration of immunoglobulins (Ig). Local Coverage Determinations (LCDs) do exist; refer to the LCDs for External Infusion Pumps.

In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

(Accessed September 23, 2015)

BENEFIT CONSIDERATIONS

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The enrollee-specific benefit document must be consulted to make coverage decisions for this service. Some states

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mandate benefit coverage for off-label use of medications when certain conditions are met. Regulations governing off-label use in the individual state must be consulted when deciding coverage. Benefit coverage for otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. See the Policy and Procedure addressing the treatment of serious rare diseases.

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

BACKGROUND

Immune globulin, whether intravenous (IV) or subcutaneous (SC), is a sterile, purified preparation of human immunoglobulin derived from pooled human plasma from thousands of donors. Consisting primarily of immunoglobulin G, one of 5 classes of immunoglobulin (Ig), each batch of immune globulin (typically referred to as IVIG) provides immunomodulating peptides and antibodies against most exogenous antigens, many normal human proteins, and Fab, the antigen-binding region of autoantibodies.[72] All currently available products contain high concentrations of IgG with subclass distribution corresponding to that of normal serum.[28,51,52,57-63,76,118,133,164]

IVIG is considered a mainstay of treatment for immunodeficiency conditions and bullous skin disorders. It has been prescribed off-label to treat a wide variety of autoimmune and inflammatory neurologic conditions.[72]

CLINICAL EVIDENCE

Proven

Autoimmune Diseases

IVIG is beneficial for treatment of a number of autoimmune diseases based upon US Food and Drug Administration (FDA) approval, published practice guidelines, professional society evidence reviews, and/or randomized, controlled clinical trials. These include immune thrombocytopenic purpura,[8,28,57,59,60,62,63,122,133,151,158] Graves' ophthalmopathy,[14,122] autoimmune uveitis,[121,122] dermatomyositis and polymyositis,[41,42,47,50,122,125,141] severe rheumatoid arthritis,[114,122,155] and autoimmune diabetes mellitus.[73,122]

IVIG is a first-line therapy for fetomaternal alloimmune thrombocytopenia.[1,8,134]

An article by Anderson et al. summarized the National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for hematologic conditions. Response rates in available reports of post-transfusion purpura, a rare and life-threatening condition were high.[8]

Infectious and Infection-related Diseases

IVIG is beneficial for a number of infectious and infection-related diseases based upon FDA approval, published practice guidelines, professional society evidence reviews, and/or randomized, controlled clinical trials. These include prevention of coronary artery aneurysms associated with Kawasaki syndrome,[59,122,158,172] treatment of CMV-induced pneumonitis in solid organ transplants,[93,122] treatment of rotaviral enterocolitis,[68,122] treatment of staphylococcal toxic

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shock,[122] treatment of enteroviral meningoencephalitis,[45,122,135] treatment of bacterial infections in lymphoproliferative diseases,[122] prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia (CLL).[8,59,115,123,158]

Neuroimmunologic Disorders
IVIG is beneficial for treatment of a number of neuroimmunologic diseases based upon FDA approval, published practice guidelines, professional society evidence reviews, and/or randomized, controlled clinical trials. These include chronic inflammatory demyelinating polyneuropathy,[41,60,62,63,99,122,125,141,144,146,158,161] Guillain-Barré syndrome,[41,50,79,80,122,125,141,162] multifocal motor neuropathy,[41,47,50,58,122,125] Lambert-Eaton myasthenic syndrome,[41,47,50,122,125,141] IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy,[122] paraproteinemic neuropathy,[66,122] stiff-person syndrome,[41,47,50,122] myasthenia gravis,[41,47,50,56,72,122,125] Lennox-Gastaut,[47,50] Rasmussen syndrome,[50,122] and monoclonal gammopathy.[66,122]

The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for neurologic conditions states that IVIG should be reserved as an option for patients with relapsing-remitting MS who fail, decline, or are not able to take standard immunomodulatory therapies. Based on consensus by the expert panel, IVIG is not recommended for treatment of primary or secondary progressive MS or for acute exacerbations of MS.[50]

In their Guidelines for the Use of Intravenous Immunoglobulin in the Treatment of Neurological Diseases, the European Federation of Neurological Societies (EFNS) states that IVIG could be considered as a second or third-line therapy in RRMS if conventional immunomodulatory therapies are not tolerated because of side effects or concomitant diseases, and in particular in pregnancy where other therapies may not be used. IVIG cannot be recommended for treatment in secondary progressive MS. IVIG does not seem to have any valuable effect as add-on therapy to methylprednisolone for acute exacerbations and cannot be recommended as treatment for chronic symptoms in MS. In clinically isolated syndromes and in primary progressive MS, the EFNS Task Force concluded that there is not sufficient evidence to make any recommendations.[47]

Similar findings were reported in a review of evidence by members of the Primary Immunodeficiency Committee of the AAAAI. The Committee concluded that IVIG might provide benefit for relapsing-remitting multiple sclerosis.[122] A meta-analysis and a review of multiple sclerosis clinical trials also found that evidence supports the use of IVIG for reduction of relapses in relapsing-remitting MS.[67,149] The use of IVIG in relapsing-remitting MS should only be considered when other established therapies have failed or cannot be utilized.

In their review of relapse therapy and intermittent long-term therapy, the Neuromyelitis Optica Study Group (NEMOS) suggests IVIG therapy as an alternative for patients with contraindication to one of the other treatments (azathioprine and rituximab) or, particularly, in children.[81]
The use of intravenous immunoglobulin (IVIG) as treatment for acute relapses in NMO was reported in a retrospective review of 10 patients.[190] In the majority of cases, IVIG was used due to lack of response to steroids with/without plasma exchange. Improvement was noted in five of 11 (45.5%) events; the remaining had no further worsening.
In a case series of eight Spanish patients with neuromyelitis optica (NMO), positive results were observed from bimonthly IVIG treatment (0.7 g/kg body weight/day for 3 days).[191] The primary outcome measure in the study was the occurrence of serious adverse effects. Secondary outcome measures were changes in the yearly rate of attacks and in the degree of neurological disability measured with the Expanded Disability Status Scale (EDSS). All 8 patients were treated with IVIG; 5 had relapsing optic neuritis with or without myelitis and 3 had recurrent longitudinally extensive transverse myelitis (LETM). The mean age of onset was 20.5 years (range, 7-31 years) and 87.5% were female. The mean duration of the disease before beginning treatment was 9.0

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years (range, 3-17 years). Following 83 infusions (range, 4-21 per patient) and a mean follow-up time of 19.3 months (range, 6-39 months), minor adverse events had occurred (headache in 3 patients and a mild cutaneous eruption in a single patient). The relapse rate decreased from 1.8 in the previous year to 0.006 during follow-up ($z = -2.5$, $p=0.01$). The EDSS score fell from 3.3 [SD 1.3] to 2.6 [SD 1.5] ($z = -2.0$, $p=0.04$). The investigators concluded that treatment with IVIG is safe and well-tolerated, and it may be used as a treatment alternative for NMO spectrum disorders.

Primary and Secondary Immune Deficiencies
IVIG is indicated as replacement therapy in primary immune deficiencies.[8,28,51,52,57-63,76,118,122,133,158,164,173]

IVIG is also beneficial in chronic lymphocytic leukemia with reduced IgG and history of infections[8,58,59,115,123,158] and prevention of bacterial infection in HIV-infected children.[57,89,111,158]

Miscellaneous Categories
Evidence supports IVIG for autoimmune bullous diseases;[3,6,94,116,122,172] toxic epidermal necrolysis and Stevens-Johnson syndrome;[55,122] severe, persistent, high-dose, steroid-dependent asthma;[71,98,122] delayed-pressure urticaria;[37,122] prevention of infection and acute GVHD after allogeneic bone marrow transplantation;[46,57,122,152,158,177] and prevention and treatment of acute humoral rejection in renal transplantation.[30,87,104,112,122]

Unproven
Acquired hemophilia: An article by Anderson et al. summarized the National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for hematologic conditions. In the opinion of the expert panel, there is no convincing evidence of clinical benefit of IVIG in this disorder, and routine use is not recommended.[8]

Acute disseminated encephalomyelitis (ADEM): This is a nonvasculitic inflammatory demyelinating condition of brain that usually occurs following a viral infection but may appear following vaccination, bacterial or parasitic infection, or even appear spontaneously. The widely accepted first-line treatment is high doses of intravenous corticosteroids. Several case reports, but no controlled trials, have provided evidence of IVIG's successful use in ADEM. The largest by Ravaglia et al. reported that in 10 of 19 ADEM patients who had failed steroids, IVIG was effective in improving motor dysfunction. Among an additional 5 patients who received IVIG first-line due to steroid contraindications, 3 were responsive to IVIG.[136]

Adrenoleukodystrophy (ALD): This is one of a group of genetic disorders called the leukodystrophies that cause damage to the myelin sheath surrounding nerve cells in the brain and progressive dysfunction of the adrenal gland. In one very small randomized trial 6 patients received IVIG in addition to the dietary therapy while 6 received dietary therapy alone. No treatment effect of IVIG was demonstrated in this study. MRI findings and clinical status deteriorated in both groups.[27] The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for neurologic conditions stated that IVIG should not be used for ALD.[50]

Alzheimer's disease: An open label dose-ranging study was conducted in 8 mild Alzheimer's disease (AD) patients. IVIG was added to approved AD therapies for 6 months, discontinued, and then resumed for another 9 months. Anti-Aβ antibodies in the serum from AD patients increased in proportion to IVIG dose and had a shorter half-life than anti-hepatitis antibodies and total IgG. Plasma Aβ levels increased transiently after each infusion. Cerebrospinal fluid Aβ decreased significantly at 6 months, returned to baseline after washout and decreased again after IVIG was re-administered for an additional 9 months. Mini-mental state scores increased an average of 2.5 points after 6 months, returned to baseline during washout and remained stable during

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subsequent IVIG treatment. This study did not include an adequate number of AD patients to establish whether IVIG altered cognitive status.[137]

Devi et al. reported on a retrospective investigation of patients (n=10) with Alzheimer's disease treated with IVIG. Eight of the patients completed 6 months of treatment; two completed 3.5 months of treatment. Two patients developed a pruritic, maculopapular, generalized rash, resolving with appropriate treatment, but both continued with IVIG. Patients showed stability on neurocognitive scores overall, with trends toward decline on their WAIS verbal scale and full-scale intelligence scores ($p<0.1$), as well as on the WAIS information ($p<0.1$) subtest and the BNT ($p=0.1$). Patients showed trends toward improvement on the WMS logical memory II recall ($p<0.1$), WMS verbal paired associates ($p=0.15$), and the WMS auditory delayed memory test ($p=0.1$). It was found that IVIG was well tolerated and effective in this sample, with patients showing stability on neurocognitive test scores and trends toward improvement in some areas.[40]

Further studies are needed to establish efficacy, to determine the optimal dosing regimen and to confirm the safety of IVIG in the general population of AD patients.

Amyotrophic lateral sclerosis (ALS): This is a disease characterized by progressive motor neuron degeneration, which manifests as weakness, spasticity, and muscle atrophy, usually beginning with the upper limbs. Two small-scale, uncontrolled studies (n=7,9) examined the use of IVIG for treatment of ALS; neither of these studies found a positive treatment effect. During and after treatment, all patients showed progressive deterioration at a pace similar to that observed before treatment or faster.[35,109] The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for neurologic conditions stated that there is no role for IVIG in the treatment of ALS.[50]

Antiphospholipid antibody syndrome (APS) in pregnancy: In their guideline for the treatment of recurrent first-trimester and second-trimester miscarriage, the Royal College of Obstetricians and Gynaecologists (RCOG) recommends against the use of IVIG.[142] There are several reports supporting a role for IVIG in the treatment of antiphospholipid antibody syndrome (APS), including in patients with APS undergoing in vitro fertilization. However, a meta-analysis of several modes of therapy (heparin, aspirin, glucocorticosteroids, and IVIG) in this clinical setting did not support any improved outcome with IVIG and a possible association with pregnancy loss or premature birth.[48] A small randomized controlled study (n=16) demonstrated no greater benefit from IVIG (plus heparin and aspirin) than from heparin and aspirin alone.[20] Because the efficacy of IVIG has not been proved in appropriately designed studies, its use is not recommended for APS in pregnancy.[2]

Asthma, non-steroid dependent: While there have been studies done on the effect of IVIG on steroid-dependent asthma patients with efficacy shown in a trial with a subgroup that required relatively high doses of daily oral steroids, there are no clinical trials or studies to support the effect on non-steroid dependent patients.[122]

Atopic dermatitis: IVIG treatment has shown success in small, open, uncontrolled trials of patients not responding to standard therapies.[122] A small, randomized, evaluator-blinded trial (n = 10) did not support the routine use of IVIG in patients with atopic dermatitis.[126]

Autism spectrum disorders: According to the review of evidence by members of the Primary Immunodeficiency Committee of the AAAAI, there are no formal randomized studies to evaluate the use of IVIG in autism.[122] They found that two small, open-trial reports of autistic children placed on IVIG for 6 months showed no benefit.[39,131] The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for neurologic conditions stated that the available evidence does not support the use of IVIG in the treatment of autism.[50]

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Autoimmune hemolytic anemia: Multiple anecdotal reports demonstrate benefit from the use of IVIG in the treatment of autoimmune hemolytic anemia (AIHA), but the use of IVIG should be considered only when other therapeutic modalities fail.[16,53,75,97,100] An article by Anderson et al. summarized the National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for hematologic conditions. They found "sparse evidence" on the use of IVIG in AIHA and despite a literal definition of response rates, those with IVIG were substantially less than accepted published response rates with other treatment alternatives. Therefore, they agreed the overall role of IVIG in AIHA is very limited.[8]

Autoimmune liver disease: In one case report of a patient with immuno-mediated chronic active hepatitis not eligible for steroids, IVIG treatment successfully normalized liver enzymes, led to undetectable circulating immune complexes, and disappearance of periportal mononuclear cell infiltrates.[29] Further studies evaluating the use of IVIG in autoimmune liver disease are needed, however, to determine the safety and efficacy of use.

Autoimmune neutropenia: Improvement in neutrophil counts has been described in several small series of patients with autoimmune neutropenia treated with IVIG,[23-25,97] and anecdotal reports also suggest utility for IVIG in post- bone marrow transplantation neutropenia, which might be autoimmune in nature.[91,95,108] It is unclear whether IVIG offers any advantage over corticosteroid therapy for the treatment of autoimmune neutropenia. The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts evidence-based practice guideline on the use of IVIG for hematologic conditions found that "the evidence to support treatment with IVIG is sparse and of poor quality. However, there was some discussion regarding its use in rare circumstances when other options (e.g. intravenous antibiotics and G-CSF) have failed.[8]

Bone marrow transplantation (BMT), prevention of acute graft-versus-host disease (GVHD) after autologous BMT: According to the Centers for Disease Control and Prevention, routine use of IVIG among autologous recipients is not recommended.[177]

Bone marrow transplantation (BMT), prevention of chronic graft-versus-host disease (GVHD) after either allogeneic or autologous BMT: The use of IVIG was studied in a randomized, double-blind, dose-effect, placebo-controlled, multicenter trial in related allogeneic marrow transplantation.[32] The trial included 200 patients receiving HLA-identical sibling marrow. IVIG-treated patients experienced no benefit versus placebo in reduction of incidence of infection, interstitial pneumonia, GVHD, transplantation-related mortality, or overall survival. There was a statistically higher incidence of grade 3 (severe) veno-occlusive disease associated with high-dose IVIG. The patients given higher doses of IVIG also had more side effects, such as fever and chills. The data does not support a recommendation for IVIG in HLA-identical sibling bone marrow transplants.[8]

Bone marrow transplantation (BMT), prevention of infection after autologous BMT: According to the Centers for Disease Control and Prevention, routine use of IVIG among autologous recipients is not recommended.[177]

***Campylobacter* species-induced enteritis:** The value of immunoglobulin therapy has been anecdotally described in *Campylobacter jejuni* infection when administered orally.[70] This uncontrolled report is insufficient to support the use for the treatment of this condition.

Cerebral infarctions with antiphospholipid antibodies: Only single case reports were found that reported successful treatment of patients with stroke associated with antiphospholipid syndrome. Horn et al. reported that a 32-year old woman with antiphospholipid antibody syndrome who developed progressive cerebral thrombosis rapid resolution of her neurological impairment after administration of IVIG.[78] Arabshahi et al. treated a child with trisomy 21, hypothyroidism, and insulin-dependent diabetes who developed acute hemiplegia due to the

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antiphospholipid antibody syndrome at age four. Antiphospholipid antibodies were no longer detectable within 6 months and have continued to be negative. There was no clinical deterioration or further changes on magnetic resonance arteriography over 7 years.[9]

Chronic fatigue syndrome: Numerous anecdotal reports have shown subjective benefits of IVIG for chronic fatigue syndrome. However, a double-blind, placebo-controlled trial demonstrated IVIG was not effective in the treatment of typical chronic fatigue syndrome.[122,165]

Demyelinative brain stem encephalitis: The disease is characterized by the acute onset of neurologic deficit days to weeks after a variety of viral and bacterial infections or vaccinations. The literature search identified one case series of 2 patients with acute demyelinating brainstem encephalitis who were treated with IVIG and improved rapidly, concomitant with the course of therapy.[13]

Demyelinating neuropathy associated with monoclonal IgM: Mariette et al. conducted a 12 month multicenter, prospective, randomized, open clinical trial to compare IVIG (n=10) and interferon alpha (n=10) in the treatment of 20 patients with polyneuropathy associated with monoclonal IgM. After six months of treatment 1 out of 10 patients treated with IVIG had an improvement of neurological symptoms versus eight out of 10 patients treated with interferon alpha. The mean functional score worsened in the IVIG group whereas it improved in the interferon group.[106]

Dilated cardiomyopathy: According to a review of evidence by the members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology, "Case reports suggest that patients with acute myocarditis benefit from high-dose IVIG. Placebo-controlled trials evaluating the benefit of IVIG use in recent-onset cardiomyopathy showed no benefit over placebo. High-dose IVIG might provide help to patients with acute myocarditis but has no therapeutic role in recent-onset dilated cardiomyopathy.[122]

HIV infection, to reduce viral load: Although IVIG is FDA-approved for reducing the incidence of secondary infection in HIV-infected children, its use in treating HIV infection per se has not been as widely evaluated. A study examining the effect of a 2 g/kg IVIG dose on viral load found that p24 antigen levels and numbers of HIV RNA copies were significantly increased after treatment.[31] Thus IVIG might be useful for preventing bacterial infections but should not be considered an antiviral therapy in the HIV-infected patient.[122]

Human T-Lymphotrophic Virus Type 1 (HTLV-1)-associated myelopathy: HTLV-1-associated myelopathy, also known as tropical spastic paresis, is a chronic inflammatory disease of the central nervous system (CNS). The one report of IVIG usage for HTLV-1-associated myelopathy was a very small case series study (n=14) that reported a positive response to IVIG therapy in 10 (71%) patients and included an increase of 30% to 280% in muscle strength. Effects were evident beginning from day 3 to day 7 after initial IVIG treatment and were sustained for over 3 weeks in 6 patients.[96]

Idiopathic dysautonomia, acute: This is a disorder characterized by severe sympathetic and parasympathetic failure with relative preservation of motor and sensory function. There is some anecdotal evidence that IVIG is effective in this disorder. Yoshimaru et al. described a case of a 32-year old man with acute idiopathic autonomic neuropathy (AIAN) in which IVIG proved effective.[170] Smit et al. reported that a 33-year-old woman with acute idiopathic postganglionic panautonomic neuropathy experienced prompt recovery of all dysautonomic symptoms after receiving high-dose intravenous immunoglobulin therapy.[148]

Inclusion body myositis: The treatment of inclusion body myositis (IBM) with IVIG has been studied in two randomized, double-blind, placebo controlled trials. In the first study (n=19), no statistically significant treatment differences were noted between IVIG and placebo.[34] In the second study (n=22), outcome measures showed a trend towards improvement with IVIG.[167]

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Based on these studies, IVIG is not recommended as routine therapy for IBM due to the variability of response and expense of therapy.[41]

In an additional placebo-controlled trial (n=36), no significant changes in primary outcomes were noted from baseline at each month after treatment.[36]

IVIG for inclusion body myositis was also assessed in open-label trials, but generalized conclusions or recommendations are not presently possible.[7,122,150]

The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for neurologic conditions stated that IVIG should not be used for the treatment of IBM.[50]

In their Guidelines for the Use of Intravenous Immunoglobulin in the Treatment of Neurological Diseases, the European Federation of Neurological Societies (EFNS) states that IVIG cannot be recommended for the treatment of sporadic IBM.[47]

In their evidence-based guideline on IVIG in the treatment of neuromuscular disorders, the American Academy of Neurology states that there is insufficient evidence to support the use of IVIG in IBM.[125]

Isolated IgA deficiency: This is the most common immunodeficiency disorder characterized by a deficiency of IgA with normal levels of other immunoglobulin classes. Isolated IgA deficiency is marked by recurrent sinusitis, bronchitis, and pneumonia, and recurrent diarrhea, although many patients have no symptoms. Management of selective IgA deficiency is limited to treating associated infections. Some advocate prophylactic daily doses of antibiotics for patients with multiple, recurrent infections. No intervention is available to either replace IgA via infusion or increase production of native IgA.[140] Selective IgA deficiency is not an indication for IVIG replacement therapy, although in some cases poor specific IgG antibody production, with or without IgG2 subclass deficiency, might coexist; in these patients IVIG might be required. Intravenous administration of IVIG can pose a risk of anaphylaxis for IgA-deficient patients who have IgE anti-IgA antibodies or reactions caused by complement activation if IgG anti-IgA antibodies are present.[122]

Isolated IgG4 deficiency: IgG4 deficiency may be found in 10-15% of the general population. The significance of isolated, or selective, IgG4 deficiency is unclear.[22,160]

Lumbosacral or brachial plexitis: Only anecdotal experience is available for assessing the treatment with IVIG for lumbar and brachial plexitis. The literature search revealed single case reports with mixed outcomes.[10,124,171]

Myocarditis, acute: According to a review of evidence by the members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology, "Case reports suggest that patients with acute myocarditis benefit from high-dose IVIG. Placebo-controlled trials evaluating the benefit of IVIG use in recent-onset cardiomyopathy showed no benefit over placebo. High-dose IVIG might provide help to patients with acute myocarditis but has no therapeutic role in recent-onset dilated cardiomyopathy.[122]

Neonatal isoimmune hemolytic jaundice: In a 2004 Cochrane review, seven studies were identified. Three of these fulfilled the inclusion criteria and included a total of 189 infants. Term and preterm infants and infants with rhesus and ABO incompatibility were included. The use of exchange transfusion decreased significantly in the IVIG treated group (typical RR 0.28, 95% CI 0.17, 0.47; typical RD -0.37, 95% CI -0.49, -0.26; NNT 2.7). The mean number of exchange transfusions per infant was also significantly lower in the IVIG treated group (WMD -0.52, 95% CI -0.70, -0.35). None of the studies assessed long term outcomes.

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Although the results show a significant reduction in the need for exchange transfusion in those treated with intravenous immunoglobulin, the applicability of the results is limited.
The number of studies and infants included is small and none of the three included studies was of high quality. The protocols of two of the studies mandated the use of early exchange transfusion, limiting the generalizability of the results. Further well designed studies are needed before routine use of intravenous immunoglobulin can be recommended for the treatment of isoimmune haemolytic jaundice.[4]

Neonatal sepsis, prevention: A recent meta-analysis found that there is insufficient evidence to support the routine administration of IVIG to prevent mortality in infants with suspected or subsequently proved neonatal infection.[120] Despite encouraging trials of IVIG as an adjunct to enhance the antibacterial defenses of premature newborn infants, there are substantial contradictory data and insufficient overall evidence to support the routine administration of IVIG in infants at risk for neonatal infection.[122]

Neonatal sepsis, treatment: In a multi-center, international, double-blind controlled trial of 3,493 infants receiving antibiotics for suspected or proven infection, subjects were randomly assigned to receive two infusions of either polyvalent IgG immune globulin (500 mg/kg) or placebo 48 hours apart. The investigators found that there was no significant between-group difference in the rates of primary outcome which was death or major disability at the age of 2 years. The primary outcome was observed in 686 of 1,759 infants (39.0%) in the intravenous immune globulin group and in 677 of 1,734 infants (39.0%) in the placebo group (relative risk, 1.00; 95% confidence interval, 0.92 to 1.08). No significant differences in the rates of seven pre-specified secondary outcomes were observed, including the incidence of subsequent sepsis episodes and causative organisms. In follow-up of survivors at 2 years, there were no significant differences in the rates of major or non-major disability or of adverse events. The authors concluded that the use of immune globulin was not associated with significant differences in the risk of major complications or other adverse outcomes in neonates with suspected or proven sepsis.[21]

A recent meta-analysis also found that there is insufficient evidence to support the routine administration of IVIG to prevent mortality in infants with suspected or subsequently proved neonatal infection.[120]

Ocular myasthenia: Myasthenia gravis is an autoimmune disorder in which the body's own antibodies block the transmission of nerve impulses to muscles, causing fluctuating weakness and muscles that tire easily. Approximately half of patients present with purely ocular symptoms (ptosis, diplopia), so-called ocular myasthenia. Between 50% and 60% of people who have ocular myasthenia will progress to develop generalized myasthenia gravis (GMG) and weakness affecting other muscles. The aims of treatment for ocular myasthenia are to return the person to a state of clear vision and to prevent the development, or limit the severity of GMG. Treatments proposed for ocular myasthenia include drugs that suppress the immune system including corticosteroids and azathioprine, thymectomy, and acetylcholinesterase inhibitors. There are retrospective, but no prospective, data, which indicate that immunosuppressive treatment of ocular myasthenia may decrease the likelihood of developing GMG. It is not clear from these studies whether treatment actually reduces the incidence of GMG, delays its onset, or just masks its symptoms. Plasmapheresis and intravenous immune globulin are used for the short-term management of severe GMG, but available evidence does not indicate that either therapy has a role in patients with ocular myasthenia.[174-5]

Opsoclonus myoclonus is a rare neurological disorder that may occur in association with tumors (paraneoplastic) or viral infections and is characterized by an unsteady, trembling gait, myoclonus and opsoclonus (irregular, rapid eye movements). It is more common in children. Published evidence consists of single case reports and case series that included patients with different etiology of opsoclonus-myoclonus and different treatment approaches. Bataller et al. analyzed neurological outcomes in adult patients with idiopathic (n=10) and paraneoplastic (n=14) opsoclonus-myoclonus following IVIG treatment. The authors found that most patients with

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idiopathic opsoclonus-myoclonus make a good recovery that seems to be accelerated by steroids or IVIG. Among the 14 patients with paraneoplastic opsoclonus-myoclonus, eight patients whose tumors were treated showed complete or partial neurological recovery. In contrast, five of the six patients whose tumors were not treated died of the neurological syndrome despite steroids, IVIG or plasma exchange.[15]

Russo et al. conducted a retrospective case series involving 29 children diagnosed with neuroblastoma and opsoclonus-myoclonus. Patients were treated with different treatment options including ACTH (n=14), prednisone (n=12), IVIG (n=6), Imuran (n=2), and other drugs (n=2) Eighteen of 29 children (62%) had resolution of opsoclonus-myoclonus symptoms. Twenty of 29 children (69%) had persistent neurologic deficits including speech delay, cognitive deficits, motor delay, and behavioral problems. Interestingly, 6/9 children with complete recovery received chemotherapy as part of their treatment[143] Based on this case series it is difficult to assess the effectiveness of IVIG compared to other treatment options.

Improvement following the administration of IVIG has been described in abundant single cases.[65,129,130,163]

Paraneoplastic cerebellar degeneration, sensory neuropathy, or encephalopathy: Paraneoplastic neurological syndromes are remote effects of cancer that are not caused by invasion of the tumor or its metastases. Immunologic factors appear important in their pathogenesis because antineuronal autoantibodies against nervous system antigens have been defined for many of these disorders.[38]

Uchuya et al. evaluated 22 patients with neurological paraneoplastic syndromes (paraneoplastic encephalomyelitis and sensory neuronopathy syndrome =18; paraneoplastic cerebellar degeneration =4) and found treatment with IVIG was not effective in paraneoplastic CNS syndromes associated with antineuronal antibodies. Of the 21 patients who were evaluable one patient with subacute sensory neuronopathy improved for at least 15 months, 10 remained stable, and 10 deteriorated.[157]

Keime-Guibert et al. evaluated 17 patients with paraneoplastic encephalomyelitis/sensory neuropathy (PEM/SN=10) or cerebellar degeneration (PCD=7) who received one to nine cycles of a combination of IVIG, cyclophosphamide and methylprednisolone. Of the seven patients with severe symptoms (bedridden), none improved. Of the nine patients who were still ambulatory, none improved but three stabilized.[90]

Blaes et al. reported that IVIG treatment was effective in two patients, one suffering from paraneoplastic cerebellar degeneration and the other from paraneoplastic brain stem encephalitis and polyneuropathy who started infusions within 3 weeks of the onset of neurological symptoms. However, two other patients, who had suffered from paraneoplastic neuropathy for 3 and 6 months showed no improvement with the intravenous immunoglobulin therapy.[17]

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS): Streptococcal infections induce exacerbation of symptoms in some children with obsessive-compulsive and tic disorders, possibly on an autoimmune basis. The syndrome of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection is referred to as pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS). According to a review of evidence by the members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology, IVIG might provide benefit for PANDAS. However, it should be noted that those children who do not have the autoimmune feature do not benefit from IVIG.[122] The review cited only one case-controlled, single-dose study which showed benefit from plasmapharesis and IVIG therapy.[128] Additional double-blind, placebo-controlled studies are needed before this becomes a standard of therapy.

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POEMS syndrome: Polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, and skin changes (POEMS) syndrome also known as Crow-Fukase syndrome or osteosclerotic myeloma is a unique multisystem disorder strongly associated with plasma cell dyscrasia. Only anecdotal experience is available for assessing IVIG as treatment for POEMS syndrome. The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for neurologic conditions stated there is no role for IVIG in the treatment of POEMS syndrome.[50]

Postinfectious cerebellar ataxia: Acute cerebellar ataxia in childhood is a usually a self-limited disease which occurs after viral infections.[117] Treatment with IVIG has not yet been established. Published evidence consists of isolated case reports. Daaboul et al. treated a 19 year-old man presented with acute cerebellar ataxia after a recent Epstein-Barr virus infection with IVIG. Progressive neurologic improvement occurred over two weeks.[33]

Postoperative sepsis: A meta-analysis identified six trials which enrolled surgical patients. The largest trial included 104 participants (50 received IVIG). In general, results favored IVIG versus control, although one trial did not favor IVIG for reduction in number of deaths. Use in this setting should be evaluated in large trials in patients receiving current standard-of-care therapies.[156]

Pseudomembranous colitis: The value of IVIG therapy has been anecdotally described in pseudomembranous colitis caused by *Clostridium difficile* (*C. difficile*).[101,145] A retrospective analysis of 79 hospital-admitted patients who had a positive *C. difficile* toxin titer and severe disease included 18 patients given IVIG treatment (200-300 mg/kg) along with standard therapy. These patients were pair matched by propensity scoring with 18 patients not receiving IVIG who had the most similar characteristics and severity. There were no statistical differences in clinical outcomes as measured by all-cause mortality, colectomies, and length of stay. The investigators concluded that the use of IVIG in severe *C. difficile*-associated diarrhea remains unsubstantiated.[88]

Rheumatic fever, acute: In a prospective, double-blind trial, 59 patients with first episode of rheumatic fever, stratified by presence and severity of carditis (39 with carditis and/or migratory polyarthritis), were randomized to receive IVIG (1 g/kg on days 1 and 2 and 0.4 g/kg on days 14 and 28) or placebo. No difference in erythrocyte sedimentation rate or acute-phase proteins was found between the groups at 6 weeks. After 1 year, no difference in cardiac outcomes was found between the groups.[166]

RSV lower respiratory tract infection: The use of IVIG combined with ribavirin in the treatment of RSV-induced pneumonitis was reported in small series of immunodeficient patients.[64,168] Survival rates were encouraging and suggested that IVIG might be of benefit as an adjunct therapy to ribavirin. In a double-blind, controlled study involving 35 RSV-infected, hospitalized infants and children, IVIG 2 grams/kilogram was given over 12 to 24 hours. Therapy resulted in significant reductions in nasal RSV shedding and in improvements in transcutaneous oximetry readings. However, the mean duration of hospitalization was not reduced by IVIG treatment.[74]

Sjogren's syndrome: IVIG has shown some efficacy in Sjogren's syndrome. Most of the reports have focused on associated dysautonomia or neuropathy although they have been very small case studies.[43,69,92,110,113,153,154] One case study was of a 41 year old man with severe sympathetic and parasympathetic autonomic dysfunction as a consequence of acetylcholine receptor antibodies and Sjogren's syndrome who failed to respond to IVIG.[19] Other published literature has described IVIG use for vasculitis of the skin and central nervous system.[26,44] Larger, blinded and controlled studies of IVIG are required regarding its efficacy for Sjogren's syndrome.

Spontaneous recurrent abortions, prevention: Results of treatment with IVIG have been conflicting. While prospective studies have suggested that the use of IVIG in pregnant women with a history of recurrent abortions imparted a protective benefit, other studies suggested no benefit. The members of the Primary Immunodeficiency Committee of the American Academy of

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Allergy, Asthma and Immunology assessed a review from a number of high-quality randomized, placebo-controlled, multicenter studies and found that, "Given the review of randomized trials, cumulative current evidence does not presently support the use of IVIG for the prevention of recurrent spontaneous abortions."[8]

In a Cochrane review by Porter et al., randomized trials of immunotherapies used to treat women with three or more prior miscarriages and no more than one live birth after were considered. Twenty trials of high quality were included. The various forms of immunotherapy investigated (paternal cell immunization, third party donor leukocytes, trophoblast membranes, and intravenous immune globulin) were found to provide no significant beneficial effect over placebo in improving the live birth rate.[132]

Systemic lupus erythematosus: The use of IVIG in the treatment of systemic lupus erythematosus (SLE) has been studied in a few open label trials. In the first trial, 20 patients with severe thrombocytopenia associated with SLE received IVIG 2 g/kg for 5 consecutive days each month and patients received between 1-8 treatment courses.[102] A beneficial response was noted in 17 out of 20 patients based on either the disappearance or marked clinical improvement of the main clinical manifestation. In 9 patients who had Systemic Lupus Activity Measure (SLAM) scores before and after IVIG, there was a significant reduction in SLAM scores (19.3 ± 4.7 to 4 ± 2.9; $p<0.0001$). The average daily dose of prednisolone was decreased (29.7 ± 18.2 mg/day to 13.8 ± 16.7 mg/day; $p=0.02$) and laboratory abnormalities improved after IVIG. Two other open label studies, with 12 patients each, showed similar results.[54,147] In another trial, 14 patients with progressive lupus nephritis who had received cyclophosphamide 1 g/m^2 monthly for 6 months with 0.5 mg/kg/d of prednisone were randomized to cyclophosphamide 1 g/m^2 every 2 months for 6 months and then every 3 months for 1 year or to IVIG 400 mg/kg monthly for 18 months. The two groups were similar after randomization and at the end of follow-up.[18] In a retrospective study of 59 SLE patients, 65% of the thirty-one subjects given IVIG had clinical improvement. However, responses were transient.[11] In other case reports high-dose IVIG led to disease resolution in patients with lupus affecting specific organs. However, there is limited anecdotal experience and concerns about potential prothromboembolic effects and possible IVIG-associated azotemia in SLE.[122]

Urticaria, chronic: A report of 5 patients with common variable immunodeficiency and chronic urticaria showed improvement of urticaria in response to IVIG therapy.[5] The efficacy of IVIG (0.15 g/kg, for a minimum of 6 months and a maximum of 51 months) was also assessed in 29 outpatients (F=20, M=9) with the diagnosis of autoimmune chronic urticaria.[127] All the patients had unsatisfactory response to conventional therapy and a positive intradermal autologous serum test (AST). A clinical improvement was observed in 26 patients, with reduction of urticaria or angioedema complaints ($p<0.0001$) and decreasing need for oral antihistamine medication ($p=0.002$). The number of infusions needed to achieve clinical control showed great range between patients. In a report of delayed-pressure urticaria, a difficult-to-treat variant, 9 of 10 patients with chronic urticaria were reported to benefit from IVIG therapy, whereas, in another delayed-pressure urticaria report, no benefit was observed.[12,119] The use of IVIG in patients with delayed-pressure urticaria was reported in another open trial.[37] One third of the enrolled patients underwent a remission, another third experienced some benefit, and the rest did not respond. Due to the conflicting evidence for IVIG in patients with chronic urticaria, additional studies are needed.

Vasculitides and antineutrophil antibody syndromes: The efficacy of IVIG in the treatment of anti-neutrophil cytoplasm antibody (ANCA)-associated systemic vasculitis (AASV) was assessed in a randomized, placebo-controlled trial.[86] Thirty four patients (24 diagnosed with Wegener's granulomatosis, 10 diagnosed with microscopic polyangiitis) were randomized to a single course of either 400 mg/kg/day IVIG or placebo for 5 days. A therapeutic response was defined as a 50% decrease in the Birmingham Vasculitis Activity Score (BVAS) at 3 months. A therapeutic response was found in 14/17 patients who received IVIG and 6/17 patients who received placebo (OR = 8.56, 95% CI = 1.74 - 42.2, $p=0.015$). The C-reactive protein (CRP) level decrease was

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significantly greater at 2 weeks and one month in the IVIG group compared to the placebo group. After 3 months, there was no difference in disease activity or CRP level between the IVIG and placebo groups. In addition, small open label trials of IVIG found some clinical benefit as an alternative therapeutic agent.[82-85,103,107,138,139] Results were reported as transient in several of these. Additional randomized controlled trials will need to be conducted to determine its place in therapy.

Professional Societies

Immune Deficiency Foundation (IDF)

There are more than 250 primary immunodeficiency diseases (PIDs) recognized by the World Health Organization. The following diseases are PIDs are thus are proven indications for immune globulin (list not all inclusive). Additional PID information can be found at the IDF website: primaryimmune.org. Back to criteria

1. Autosomal recessive agammaglobulinemia
2. Autosomal recessive hyperimmunoglobulin M syndrome (HIM)
3. Bruton's disease
4. Chronic mucocutaneous moniliasis (CMC or APCED),
5. Combined immunodeficiency disorders
    a. Ataxia-telangiectasia
    b. DiGeorge syndrome
    c. Nijmegan breakage syndrome
    d. WHIM (warts, hypogammaglobulinemia, immunodeficiency, and myelokathexis) syndrome
    e. Wiskott Aldrich syndrome
6. Common variable immunodeficiency (CVID)
7. Congenital hypogammaglobulinemia late onset, ICOS impaired
8. Congenital / X-linked agammaglobulinemia
9. Good syndrome (immunodeficiency with thymoma)
10. Hyperimmunoglobulinemia E syndrome
11. Hypogammaglobulinemia
12. ICF syndrome
13. Polyendocrinopathy and enteropathy (IPEX)
14. Selective IgG subclass deficiencies (persistent absence of IgG1, IgG2, and/or IgG3)
15. Selective IgM deficiency
16. Severe combined immunodeficiency
17. Specific antibody deficiency
18. Transient hypogammaglobulinemia of infancy, short-term treatment of recurrent severe bacterial infections
19. X-linked immunodeficiency with hyperimmunoglobulin M

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

There are currently eight clinical indications for which IVIG has been licensed by the United States Food and Drug Administration (FDA).[158] The indications can be summarized as follows:

1) treatment of primary immunodeficiencies such as common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies[28,51,52,57-63,76,118,133,164,173]
2) prevention of bacterial infections in patients with hypogammaglobulinemia and recurrent bacterial infection caused by B-cell chronic lymphocytic leukemia[59]
3) prevention of coronary artery aneurysms in Kawasaki disease (KD)[59]
4) prevention of infections, pneumonitis, and acute graft-versus-host disease (GVHD) after bone marrow transplantation[57]
5) reduction of serious bacterial infection in children with human immunodeficiency virus (HIV)[57]

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6) increase of platelet counts in idiopathic thrombocytopenic purpura to prevent or control bleeding[28,57,58,60,62,63,133]
7) to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse in chronic inflammatory demyelinating polyneuropathy (CIDP)[60,62,63]
8) as a maintenance therapy to improve muscle strength and disability in adult patients with multifocal motor neuropathy[58]

Subcutaneous human immune globulin products are FDA approved for the treatment of patients with primary immune deficiency.[60,63,76,164,193]

The FDA issued a Safety Communication dated November 13, 2012 to provide an update to their August 2002 interim statement regarding thrombotic events as a potential risk following the administration of human immunoglobulin.[159] The updated safety communication also addressed hemolysis, another risk potentially associated with the administration of human immune globulin.

In their update, the FDA issued the following recommendations regarding thrombosis:

- Care should be used when immune globulin products are given to individuals determined to be at increased risk of thrombosis.
- Patients at increased risk of thrombosis include those with acquired or hereditary hypercoagulable states, prolonged immobilization, in-dwelling vascular catheters, advanced age, estrogen use, a history of venous or arterial thrombosis, cardiovascular risk factors (including history of atherosclerosis and/or impaired cardiac output), and hyperviscosity (including cryoglobulins, fasting chylomicronemia and/or high triglyceride levels, and monoclonal gammopathies).
- Patients at risk for thrombosis should receive immune globulin products at the slowest infusion rate practicable, and should be monitored for thrombotic complications.
- Consideration should also be given to measurement of baseline blood viscosity in individuals at risk for hyperviscosity.

The FDA also issued the following recommendations regarding hemolysis:

- Patients at increased risk for hemolysis following treatment with immune globulins include those with non-O blood group types, those who have underlying associated inflammatory conditions, and those receiving high cumulative doses of immune globulins over the course of several days.
- Clinical symptoms and signs of hemolysis include fever, chills and dark urine. If these occur, appropriate laboratory testing should be obtained.

The FDA issued a Safety Communication dated June 10, 2013 to report that a recent data analysis that has strengthened the association between the use of intravenous, subcutaneous and intramuscular human immune globulin products and the risk of thrombosis.[176] Because additional caution regarding the use of these products is warranted, the FDA is requiring manufacturers to add information on thrombosis to the current boxed warning in the labels of all intravenous human immune globulin products and to add a boxed warning to the labels of all subcutaneous and intramuscular human immune globulin products to highlight the risk of thrombosis and to add information on its mitigation.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and/or Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

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CPT Code	Description
90283	Immune globulin (IgIV), human, for intravenous use
90284	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each

HCPCS Code	Description
J1459	Injection, immune globulin (Privigen), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1561	Injection, immune globulin, (Gamunex-C/Gammaked), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin, (Octagam), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), intravenous, nonlyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase, (Hyqvia), 100 mg immuneglobulin
J1599	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg

ICD-9 Codes (Discontinued 10/1/15)
The following list of codes is provided for reference purposes only. Effective October 1, 2015, the Centers for Medicare & Medicaid Services (CMS) implemented ICD-10-CM (diagnoses) and ICD-10-PCS (inpatient procedures), replacing the ICD-9-CM diagnosis and procedure code sets.
ICD-9 codes will not be accepted for services provided on or after October 1, 2015.

ICD-9 Code (Discontinued 10/1/2015)	Description
008.61	Intestinal infection, enteritis due to rotavirus
040.82	Toxic shock syndrome
042	Human immunodeficiency virus [HIV]
047.0	Meningitis due to enterovirus; Coxsackie virus
047.1	Meningitis due to enterovirus; ECHO virus
047.8	Meningitis due to enterovirus; other specifiec viral meningitis
047.9	Meningitis due to enterovirus; unspecifird viral meningitis
048	Other enterovirus diseases of central nervous system
204.10	Chronic lymphoid leukemia, without mention of having achieved remission
204.11	Chronic lymphoid leukemia in remission
204.12	Chronic lymphoid leukemia, in relapse
238.79	Neoplasm of uncertain behavior of other and unspecified sites and tissues; other lymphatic and hematopoietic tissues
242.00	Toxic diffuse goiter without mention of thyrotoxic crisis or storm
242.01	Toxic diffuse goiter with mention of thyrotoxic crisis or storm
250.01	Diabetes mellitus without mention of complication, type I [juvenile type], not stated as uncontrolled
250.03	Diabetes mellitus without mention of complication, type I [juvenile type], uncontrolled
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled
250.21	Diabetes with hyperosmolarity, type I [juvenile type], not stated as uncontrolled
250.23	Diabetes with hyperosmolarity, type I [juvenile type], uncontrolled
250.31	Diabetes with other coma, type I [juvenile type], not stated as uncontrolled

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250.33	Diabetes with other coma, type I [juvenile type], uncontrolled
250.41	Diabetes with renal manifestations, type I [juvenile type], not stated as uncontrolled
250.43	Diabetes with renal manifestations, type I [juvenile type], uncontrolled
250.51	Diabetes with ophthalmic manifestations, type I [juvenile type], not stated as uncontrolled
250.53	Diabetes with ophthalmic manifestations, type I [juvenile type], uncontrolled
250.61	Diabetes with neurological manifestations, type I [juvenile type], not stated as uncontrolled
250.63	Diabetes with neurological manifestations, type I [juvenile type], uncontrolled
250.71	Diabetes with peripheral circulatory disorders, type I [juvenile type], not stated as uncontrolled
250.73	Diabetes with peripheral circulatory disorders, type I [juvenile type], uncontrolled
250.81	Diabetes with other specified manifestations, type I [juvenile type], not stated as uncontrolled
250.83	Diabetes with other specified manifestations, type I [juvenile type], uncontrolled
250.91	Diabetes with unspecified complication, type I [juvenile type], not stated as uncontrolled
250.93	Diabetes with unspecified complication, type I [juvenile type], uncontrolled
258.1	Other combinations of endocrine dysfunction
273.1	Monoclonal paraproteinemia
279.00	Unspecified hypogammaglobulinemia
279.02	Selective IgM immunodeficiency
279.03	Other selective immunoglobulin deficiencies
279.04	Congenital hypogammaglobulinemia
279.05	Immunodeficiency with increased IgM
279.06	Common variable immunodeficiency
279.09	Other deficiency of humoral immunity
279.10	Immunodeficiency with predominant T-cell defect, unspecified
279.11	DiGeorge's syndrome
279.12	Wiskott-Aldrich syndrome
279.2	Combined immunity deficiency
279.3	Unspecified immunity deficiency
279.41	Autoimmune lymphoproliferative syndrome
279.51	Acute graft-versus-host disease
279.53	Acute on chronic graft-versus-host disease
279.8	Other specified disorders involving the immune mechanism
279.9	Unspecified disorder of immune mechanism
287.31	Immune thrombocytopenic purpura
287.41	Posttransfusion purpura
287.49	Other secondary thrombocytopenia
323.01	Encephalitis and encephalomyelitis in viral diseases classified elsewhere
323.02	Myelitis in viral diseases classified elsewhere
323.81	Other causes of encephalitis and encephalomylitis
323.9	Unspecified cause of encephalitis, myelitis, and encephalomyelitis
333.91	Stiff-man syndrome
334.8	Other spinocerebellar diseases
340	Multiple sclerosis
341.0	Neuromyelitis optica
345.80	Other forms of epilepsy and recurrent seizures, without mention of intractable epilepsy
345.81	Other forms of epilepsy and recurrent seizures, with intractable epilepsy
357.0	Acute infective polyneuritis
357.4	Polyneuropathy in other diseases classified elsewhere
357.81	Chronic inflammatory demyelinating polyneuritis
357.89	Other inflammatory and toxic neuropathy
357.9	Inflammatory and toxic neuropathy; Unspecified
358.01	Myasthenia gravis with (acute) exacerbation
358.30	Lambert-Eaton syndrome, unspecified

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358.31	Lambert-Eaton syndrome in neoplastic disease
358.39	Lambert-Eaton syndrome in other diseases classified elsewhere
364.00	Unspecified acute and subacute iridocyclitis
364.01	Primary iridocyclitis
364.02	Recurrent iridocyclitis
364.04	Secondary iridocyclitis, noninfectious
446.1	Acute febrile mucocutaneous lymph node syndrome (MCLS)
484.1	Pneumonia in cytomegalic inclusion disease
493.01	Extrinsic asthma with status asthmaticus
493.02	Extrinsic asthma, with (acute) exacerbation
493.11	Intrinsic asthma with status asthmaticus
493.12	Intrinsic asthma, with (acute) exacerbation
646.80	Other specified complication of pregnancy, unspecified as to episode of care
646.81	Other specified complication of pregnancy, with delivery
646.83	Other specified complication, antepartum
694.4	Pemphigus
694.5	Pemphigoid
694.60	Benign mucous membrane pemphigoid without mention of ocular involvement
694.61	Benign mucous membrane pemphigoid with ocular involvement
694.8	Other specified bullous dermatosis
695.13	Stevens-Johnson syndrome
695.14	Stevens-Johnson syndrome-toxic epidermal necrolysis overlap syndrome
695.15	Toxic epidermal necrolysis
708.8	Other specified urticaria
710.3	Dermatomyositis
710.4	Polymyositis
714.0	Rheumatoid arthritis
714.1	Felty's syndrome
714.2	Other rheumatoid arthritis with visceral or systemic involvement
714.30	Polyarticular juvenile rheumatoid arthritis, chronic or unspecified
714.31	Polyarticular juvenile rheumatoid arthritis, acute
714.32	Pauciarticular juvenile rheumatoid arthritis
714.33	Monoarticular juvenile rheumatoid arthritis
776.1	Transient neonatal thrombocytopenia
996.81	Complications of transplanted organ; kidney
996.85	Complications of transplanted organ; bone marrow
V42.81	Bone marrow replaced by transplant
V42.82	Peripheral stem cells replaced by transplant

ICD-10 Codes (Effective 10/1/15)
ICD-10-CM (diagnoses) and ICD-10-PCS (inpatient procedures) must be used to report diagnoses for services provided on or after October 1, 2015.

ICD-10 codes will not be accepted for services provided prior to October 1, 2015.

ICD-10 Diagnosis Code (Effective 10/1/15)	Description
A08.0	Rotaviral enteritis
A48.3	Toxic shock syndrome
A87.0	Enteroviral meningitis
A87.8	Other viral meningitis
A87.9	Viral meningitis, unspecified

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A88.0	Enteroviral exanthematous fever [Boston □xanthema]
A88.8	Other specified viral infections of central nervous system
B20	Human immunodeficiency virus [HIV] disease
B25.0	Cytomegaloviral pneumonitis
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
D47.2	Monoclonal gammopathy
D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
D69.3	Immune thrombocytopenic purpura
D69.51	Posttransfusion purpura
D69.59	Other secondary thrombocytopenia
D80.0	Hereditary hypogammaglobulinemia
D80.1	Nonfamilial hypogammaglobulinemia
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.7	Transient hypogammaglobulinemia of infancy
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
D84.8	Other specified immunodeficiencies
D89.2	Hypergammaglobulinemia, unspecified
D89.810	Acute graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.82	Autoimmune lymphoproliferative syndrome [ALPS]
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm
E05.01	Thyrotoxicosis with diffuse goiter with thyrotoxic crisis or storm
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma
E10.21	Type 1 diabetes mellitus with diabetic nephropathy
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E10.321	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E10.329	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E10.331	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema

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E10.339	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E10.341	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.349	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema
E10.351	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E10.359	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E10.36	Type 1 diabetes mellitus with diabetic cataract
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E10.44	Type 1 diabetes mellitus with diabetic amyotrophy
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication
E10.51	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.59	Type 1 diabetes mellitus with other circulatory complications
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E10.618	Type 1 diabetes mellitus with other diabetic arthropathy
E10.620	Type 1 diabetes mellitus with diabetic dermatitis
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E10.628	Type 1 diabetes mellitus with other skin complications
E10.630	Type 1 diabetes mellitus with periodontal disease
E10.638	Type 1 diabetes mellitus with other oral complications
E10.641	Type 1 diabetes mellitus with hypoglycemia with coma
E10.649	Type 1 diabetes mellitus with hypoglycemia without coma
E10.65	Type 1 diabetes mellitus with hyperglycemia
E10.69	Type 1 diabetes mellitus with other specified complication
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications
E31.0	Autoimmune polyglandular failure
G04.81	Other encephalitis and encephalomyelitis
G04.90	Encephalitis and encephalomyelitis, unspecified
G05.3	Encephalitis and encephalomyelitis in diseases classified elsewhere
G05.4	Myelitis in diseases classified elsewhere
G11.3	Cerebellar ataxia with defective DNA repair
G25.82	Stiff-man syndrome
G35	Multiple sclerosis
G36.0	Neuromyelitis optica [Devic]
G40.811	Lennox-Gastaut syndrome, not intractable, with status epilepticus
G40.812	Lennox-Gastaut syndrome, not intractable, without status epilepticus
G40.813	Lennox-Gastaut syndrome, intractable, with status epilepticus
G40.814	Lennox-Gastaut syndrome, intractable, without status epilepticus
G61.0	Guillain-Barré syndrome
G61.81	Chronic inflammatory demyelinating polyneuritis
G61.89	Other inflammatory polyneuropathies
G61.9	Inflammatory polyneuropathy, unspecified
G62.89	Other specified polyneuropathies
G62.9	Polyneuropathy, unspecified
G65.0	Sequelae of Guillain-Barré syndrome
G70.01	Myasthenia gravis with (acute) exacerbation

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G70.80	Lambert-Eaton syndrome, unspecified
G70.81	Lambert-Eaton syndrome in disease classified elsewhere
G73.1	Lambert-Eaton syndrome in neoplastic disease
H20.00	Unspecified acute and subacute iridocyclitis
H20.011	Primary iridocyclitis, right eye
H20.012	Primary iridocyclitis, left eye
H20.013	Primary iridocyclitis, bilateral
H20.019	Primary iridocyclitis, unspecified eye
H20.021	Recurrent acute iridocyclitis, right eye
H20.022	Recurrent acute iridocyclitis, left eye
H20.023	Recurrent acute iridocyclitis, bilateral
H20.029	Recurrent acute iridocyclitis, unspecified eye
H20.041	Secondary noninfectious iridocyclitis, right eye
H20.042	Secondary noninfectious iridocyclitis, left eye
H20.043	Secondary noninfectious iridocyclitis, bilateral
H20.049	Secondary noninfectious iridocyclitis, unspecified eye
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
L10.0	Pemphigus vulgaris
L10.2	Pemphigus foliaceous
L12.0	Bullous pemphigoid
L12.1	Cicatricial pemphigoid
L12.30	Acquired epidermolysis bullosa, unspecified
L12.35	Other acquired epidermolysis bullosa
L13.8	Other specified bullous disorders
L50.8	Other urticaria
L51.1	Stevens-Johnson syndrome
L51.2	Toxic epidermal necrolysis [Lyell]
L51.3	Stevens-Johnson syndrome-toxic epidermal necrolysis overlap syndrome
M05.00	Felty's syndrome, unspecified site
M05.011	Felty's syndrome, right shoulder
M05.012	Felty's syndrome, left shoulder
M05.019	Felty's syndrome, unspecified shoulder
M05.021	Felty's syndrome, right elbow
M05.022	Felty's syndrome, left elbow
M05.029	Felty's syndrome, unspecified elbow
M05.031	Felty's syndrome, right wrist
M05.032	Felty's syndrome, left wrist
M05.039	Felty's syndrome, unspecified wrist
M05.041	Felty's syndrome, right hand
M05.042	Felty's syndrome, left hand
M05.049	Felty's syndrome, unspecified hand
M05.051	Felty's syndrome, right hip
M05.052	Felty's syndrome, left hip
M05.059	Felty's syndrome, unspecified hip
M05.061	Felty's syndrome, right knee
M05.062	Felty's syndrome, left knee
M05.069	Felty's syndrome, unspecified knee
M05.071	Felty's syndrome, right ankle and foot
M05.072	Felty's syndrome, left ankle and foot
M05.079	Felty's syndrome, unspecified ankle and foot
M05.09	Felty's syndrome, multiple sites
M05.20	Rheumatoid vasculitis with rheumatoid arthritis of unspecified site

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M05.211	Rheumatoid vasculitis with rheumatoid arthritis of right shoulder
M05.212	Rheumatoid vasculitis with rheumatoid arthritis of left shoulder
M05.219	Rheumatoid vasculitis with rheumatoid arthritis of unspecified shoulder
M05.221	Rheumatoid vasculitis with rheumatoid arthritis of right elbow
M05.222	Rheumatoid vasculitis with rheumatoid arthritis of left elbow
M05.229	Rheumatoid vasculitis with rheumatoid arthritis of unspecified elbow
M05.231	Rheumatoid vasculitis with rheumatoid arthritis of right wrist
M05.232	Rheumatoid vasculitis with rheumatoid arthritis of left wrist
M05.239	Rheumatoid vasculitis with rheumatoid arthritis of unspecified wrist
M05.241	Rheumatoid vasculitis with rheumatoid arthritis of right hand
M05.242	Rheumatoid vasculitis with rheumatoid arthritis of left hand
M05.249	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hand
M05.251	Rheumatoid vasculitis with rheumatoid arthritis of right hip
M05.252	Rheumatoid vasculitis with rheumatoid arthritis of left hip
M05.259	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hip
M05.261	Rheumatoid vasculitis with rheumatoid arthritis of right knee
M05.262	Rheumatoid vasculitis with rheumatoid arthritis of left knee
M05.269	Rheumatoid vasculitis with rheumatoid arthritis of unspecified knee
M05.271	Rheumatoid vasculitis with rheumatoid arthritis of right ankle and foot
M05.272	Rheumatoid vasculitis with rheumatoid arthritis of left ankle and foot
M05.279	Rheumatoid vasculitis with rheumatoid arthritis of unspecified ankle and foot
M05.29	Rheumatoid vasculitis with rheumatoid arthritis of multiple sites
M05.30	Rheumatoid heart disease with rheumatoid arthritis of unspecified site
M05.311	Rheumatoid heart disease with rheumatoid arthritis of right shoulder
M05.312	Rheumatoid heart disease with rheumatoid arthritis of left shoulder
M05.319	Rheumatoid heart disease with rheumatoid arthritis of unspecified shoulder
M05.321	Rheumatoid heart disease with rheumatoid arthritis of right elbow
M05.322	Rheumatoid heart disease with rheumatoid arthritis of left elbow
M05.329	Rheumatoid heart disease with rheumatoid arthritis of unspecified elbow
M05.331	Rheumatoid heart disease with rheumatoid arthritis of right wrist
M05.332	Rheumatoid heart disease with rheumatoid arthritis of left wrist
M05.339	Rheumatoid heart disease with rheumatoid arthritis of unspecified wrist
M05.341	Rheumatoid heart disease with rheumatoid arthritis of right hand
M05.342	Rheumatoid heart disease with rheumatoid arthritis of left hand
M05.349	Rheumatoid heart disease with rheumatoid arthritis of unspecified hand
M05.351	Rheumatoid heart disease with rheumatoid arthritis of right hip
M05.352	Rheumatoid heart disease with rheumatoid arthritis of left hip
M05.359	Rheumatoid heart disease with rheumatoid arthritis of unspecified hip
M05.361	Rheumatoid heart disease with rheumatoid arthritis of right knee
M05.362	Rheumatoid heart disease with rheumatoid arthritis of left knee
M05.369	Rheumatoid heart disease with rheumatoid arthritis of unspecified knee
M05.371	Rheumatoid heart disease with rheumatoid arthritis of right ankle and foot
M05.372	Rheumatoid heart disease with rheumatoid arthritis of left ankle and foot
M05.379	Rheumatoid heart disease with rheumatoid arthritis of unspecified ankle and foot
M05.39	Rheumatoid heart disease with rheumatoid arthritis of multiple sites
M05.40	Rheumatoid myopathy with rheumatoid arthritis of unspecified site
M05.411	Rheumatoid myopathy with rheumatoid arthritis of right shoulder
M05.412	Rheumatoid myopathy with rheumatoid arthritis of left shoulder
M05.419	Rheumatoid myopathy with rheumatoid arthritis of unspecified shoulder
M05.421	Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.422	Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.429	Rheumatoid myopathy with rheumatoid arthritis of unspecified elbow
M05.431	Rheumatoid myopathy with rheumatoid arthritis of right wrist

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M05.432	Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.439	Rheumatoid myopathy with rheumatoid arthritis of unspecified wrist
M05.441	Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442	Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.449	Rheumatoid myopathy with rheumatoid arthritis of unspecified hand
M05.451	Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452	Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.459	Rheumatoid myopathy with rheumatoid arthritis of unspecified hip
M05.461	Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462	Rheumatoid myopathy with rheumatoid arthritis of left knee
M05.469	Rheumatoid myopathy with rheumatoid arthritis of unspecified knee
M05.471	Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot
M05.472	Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot
M05.479	Rheumatoid myopathy with rheumatoid arthritis of unspecified ankle and foot
M05.49	Rheumatoid myopathy with rheumatoid arthritis of multiple sites
M05.50	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site
M05.511	Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512	Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.519	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified shoulder
M05.521	Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow
M05.522	Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.529	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified elbow
M05.531	Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532	Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.539	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified wrist
M05.541	Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542	Rheumatoid polyneuropathy with rheumatoid arthritis of left hand
M05.549	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hand
M05.551	Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552	Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.559	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hip
M05.561	Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562	Rheumatoid polyneuropathy with rheumatoid arthritis of left knee
M05.569	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified knee
M05.571	Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot
M05.572	Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot
M05.579	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified ankle and foot
M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites
M05.60	Rheumatoid arthritis of unspecified site with involvement of other organs and systems
M05.611	Rheumatoid arthritis of right shoulder with involvement of other organs and systems
M05.612	Rheumatoid arthritis of left shoulder with involvement of other organs and systems
M05.619	Rheumatoid arthritis of unspecified shoulder with involvement of other organs and systems
M05.621	Rheumatoid arthritis of right elbow with involvement of other organs and systems
M05.622	Rheumatoid arthritis of left elbow with involvement of other organs and systems
M05.629	Rheumatoid arthritis of unspecified elbow with involvement of other organs and systems
M05.631	Rheumatoid arthritis of right wrist with involvement of other organs and systems
M05.632	Rheumatoid arthritis of left wrist with involvement of other organs and systems
M05.639	Rheumatoid arthritis of unspecified wrist with involvement of other organs and systems
M05.641	Rheumatoid arthritis of right hand with involvement of other organs and systems
M05.642	Rheumatoid arthritis of left hand with involvement of other organs and systems
M05.649	Rheumatoid arthritis of unspecified hand with involvement of other organs and systems
M05.651	Rheumatoid arthritis of right hip with involvement of other organs and systems
M05.652	Rheumatoid arthritis of left hip with involvement of other organs and systems

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M05.659	Rheumatoid arthritis of unspecified hip with involvement of other organs and systems
M05.661	Rheumatoid arthritis of right knee with involvement of other organs and systems
M05.662	Rheumatoid arthritis of left knee with involvement of other organs and systems
M05.669	Rheumatoid arthritis of unspecified knee with involvement of other organs and systems
M05.671	Rheumatoid arthritis of right ankle and foot with involvement of other organs and systems
M05.672	Rheumatoid arthritis of left ankle and foot with involvement of other organs and systems
M05.679	Rheumatoid arthritis of unspecified ankle and foot with involvement of other organs and systems
M05.69	Rheumatoid arthritis of multiple sites with involvement of other organs and systems
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement
M05.711	Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement
M05.712	Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement
M05.719	Rheumatoid arthritis with rheumatoid factor of unspecified shoulder without organ or systems involvement
M06.1	Adult-onset Still's disease
M08.00	Unspecified juvenile rheumatoid arthritis of unspecified site
M08.011	Unspecified juvenile rheumatoid arthritis, right shoulder
M08.012	Unspecified juvenile rheumatoid arthritis, left shoulder
M08.019	Unspecified juvenile rheumatoid arthritis, unspecified shoulder
M08.021	Unspecified juvenile rheumatoid arthritis, right elbow
M08.022	Unspecified juvenile rheumatoid arthritis, left elbow
M08.029	Unspecified juvenile rheumatoid arthritis, unspecified elbow
M08.031	Unspecified juvenile rheumatoid arthritis, right wrist
M08.032	Unspecified juvenile rheumatoid arthritis, left wrist
M08.039	Unspecified juvenile rheumatoid arthritis, unspecified wrist
M08.041	Unspecified juvenile rheumatoid arthritis, right hand
M08.042	Unspecified juvenile rheumatoid arthritis, left hand
M08.049	Unspecified juvenile rheumatoid arthritis, unspecified hand
M08.051	Unspecified juvenile rheumatoid arthritis, right hip
M08.052	Unspecified juvenile rheumatoid arthritis, left hip
M08.059	Unspecified juvenile rheumatoid arthritis, unspecified hip
M08.061	Unspecified juvenile rheumatoid arthritis, right knee
M08.062	Unspecified juvenile rheumatoid arthritis, left knee
M08.069	Unspecified juvenile rheumatoid arthritis, unspecified knee
M08.071	Unspecified juvenile rheumatoid arthritis, right ankle and foot
M08.072	Unspecified juvenile rheumatoid arthritis, left ankle and foot
M08.079	Unspecified juvenile rheumatoid arthritis, unspecified ankle and foot
M08.08	Unspecified juvenile rheumatoid arthritis, vertebrae
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites
M08.20	Juvenile rheumatoid arthritis with systemic onset, unspecified site
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder
M08.219	Juvenile rheumatoid arthritis with systemic onset, unspecified shoulder
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow
M08.229	Juvenile rheumatoid arthritis with systemic onset, unspecified elbow
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist
M08.239	Juvenile rheumatoid arthritis with systemic onset, unspecified wrist
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand

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M08.249	Juvenile rheumatoid arthritis with systemic onset, unspecified hand
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip
M08.259	Juvenile rheumatoid arthritis with systemic onset, unspecified hip
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee
M08.269	Juvenile rheumatoid arthritis with systemic onset, unspecified knee
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot
M08.279	Juvenile rheumatoid arthritis with systemic onset, unspecified ankle and foot
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.40	Pauciarticular juvenile rheumatoid arthritis, unspecified site
M08.411	Pauciarticular juvenile rheumatoid arthritis, right shoulder
M08.412	Pauciarticular juvenile rheumatoid arthritis, left shoulder
M08.419	Pauciarticular juvenile rheumatoid arthritis, unspecified shoulder
M08.421	Pauciarticular juvenile rheumatoid arthritis, right elbow
M08.422	Pauciarticular juvenile rheumatoid arthritis, left elbow
M08.429	Pauciarticular juvenile rheumatoid arthritis, unspecified elbow
M08.431	Pauciarticular juvenile rheumatoid arthritis, right wrist
M08.432	Pauciarticular juvenile rheumatoid arthritis, left wrist
M08.439	Pauciarticular juvenile rheumatoid arthritis, unspecified wrist
M08.441	Pauciarticular juvenile rheumatoid arthritis, right hand
M08.442	Pauciarticular juvenile rheumatoid arthritis, left hand
M08.449	Pauciarticular juvenile rheumatoid arthritis, unspecified hand
M08.451	Pauciarticular juvenile rheumatoid arthritis, right hip
M08.452	Pauciarticular juvenile rheumatoid arthritis, left hip
M08.459	Pauciarticular juvenile rheumatoid arthritis, unspecified hip
M08.461	Pauciarticular juvenile rheumatoid arthritis, right knee
M08.462	Pauciarticular juvenile rheumatoid arthritis, left knee
M08.469	Pauciarticular juvenile rheumatoid arthritis, unspecified knee
M08.471	Pauciarticular juvenile rheumatoid arthritis, right ankle and foot
M08.472	Pauciarticular juvenile rheumatoid arthritis, left ankle and foot
M08.479	Pauciarticular juvenile rheumatoid arthritis, unspecified ankle and foot
M08.48	Pauciarticular juvenile rheumatoid arthritis, vertebrae
M08.80	Other juvenile arthritis, unspecified site
M08.811	Other juvenile arthritis, right shoulder
M08.812	Other juvenile arthritis, left shoulder
M08.819	Other juvenile arthritis, unspecified shoulder
M08.821	Other juvenile arthritis, right elbow
M08.822	Other juvenile arthritis, left elbow
M08.829	Other juvenile arthritis, unspecified elbow
M08.831	Other juvenile arthritis, right wrist
M08.832	Other juvenile arthritis, left wrist
M08.839	Other juvenile arthritis, unspecified wrist
M08.841	Other juvenile arthritis, right hand
M08.842	Other juvenile arthritis, left hand
M08.849	Other juvenile arthritis, unspecified hand
M08.851	Other juvenile arthritis, right hip
M08.852	Other juvenile arthritis, left hip
M08.859	Other juvenile arthritis, unspecified hip
M08.861	Other juvenile arthritis, right knee

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M08.862	Other juvenile arthritis, left knee
M08.869	Other juvenile arthritis, unspecified knee
M08.871	Other juvenile arthritis, right ankle and foot
M08.872	Other juvenile arthritis, left ankle and foot
M08.879	Other juvenile arthritis, unspecified ankle and foot
M08.88	Other juvenile arthritis, vertebrae
M08.89	Other juvenile arthritis, multiple sites
M08.90	Juvenile arthritis, unspecified, unspecified site
M08.911	Juvenile arthritis, unspecified, right shoulder
M08.912	Juvenile arthritis, unspecified, left shoulder
M08.919	Juvenile arthritis, unspecified, unspecified shoulder
M08.921	Juvenile arthritis, unspecified, right elbow
M08.922	Juvenile arthritis, unspecified, left elbow
M08.929	Juvenile arthritis, unspecified, unspecified elbow
M08.931	Juvenile arthritis, unspecified, right wrist
M08.932	Juvenile arthritis, unspecified, left wrist
M08.939	Juvenile arthritis, unspecified, unspecified wrist
M08.941	Juvenile arthritis, unspecified, right hand
M08.942	Juvenile arthritis, unspecified, left hand
M08.949	Juvenile arthritis, unspecified, unspecified hand
M08.951	Juvenile arthritis, unspecified, right hip
M08.952	Juvenile arthritis, unspecified, left hip
M08.959	Juvenile arthritis, unspecified, unspecified hip
M08.961	Juvenile arthritis, unspecified, right knee
M08.962	Juvenile arthritis, unspecified, left knee
M08.969	Juvenile arthritis, unspecified, unspecified knee
M08.971	Juvenile arthritis, unspecified, right ankle and foot
M08.972	Juvenile arthritis, unspecified, left ankle and foot
M08.979	Juvenile arthritis, unspecified, unspecified ankle and foot
M08.98	Juvenile arthritis, unspecified, vertebrae
M08.99	Juvenile arthritis, unspecified, multiple sites
M30.3	Mucocutaneous lymph node syndrome [Kawasaki]
M33.00	Juvenile dermatopolymyositis, organ involvement unspecified
M33.01	Juvenile dermatopolymyositis with respiratory involvement
M33.02	Juvenile dermatopolymyositis with myopathy
M33.09	Juvenile dermatopolymyositis with other organ involvement
M33.10	Other dermatopolymyositis, organ involvement unspecified
M33.11	Other dermatopolymyositis with respiratory involvement
M33.12	Other dermatopolymyositis with myopathy
M33.19	Other dermatopolymyositis with other organ involvement
M33.20	Polymyositis, organ involvement unspecified
M33.21	Polymyositis with respiratory involvement
M33.22	Polymyositis with myopathy
M33.29	Polymyositis with other organ involvement
M33.90	Dermatopolymyositis, unspecified, organ involvement unspecified
M33.91	Dermatopolymyositis, unspecified with respiratory involvement
M33.92	Dermatopolymyositis, unspecified with myopathy
M33.99	Dermatopolymyositis, unspecified with other organ involvement
M36.0	Dermato(poly)myositis in neoplastic disease
O26.40	Herpes gestationis, unspecified trimester
O26.41	Herpes gestationis, first trimester
O26.42	Herpes gestationis, second trimester
O26.43	Herpes gestationis, third trimester

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P61.0	Transient neonatal thrombocytopenia
T86.00	Unspecified complication of bone marrow transplant
T86.01	Bone marrow transplant rejection
T86.02	Bone marrow transplant failure
T86.03	Bone marrow transplant infection
T86.09	Other complications of bone marrow transplant
T86.10	Unspecified complication of kidney transplant
T86.11	Kidney transplant rejection
T86.12	Kidney transplant failure
T86.13	Kidney transplant infection
T86.19	Other complication of kidney transplant
Z48.290	Encounter for aftercare following bone marrow transplant
Z94.81	Bone marrow transplant status
Z94.84	Stem cells transplant status

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
2/1/2016	Annual Review. Added titration to minimum effective dose to general requirements. Consolidated clinical criteria for bone marrow transplantation, renal transplantation, and secondary thrombocytopenia, Added J1575. Updated ICD9 & ICD10 codes. Approved by the National Pharmacy & Therapeutics Committee on 11/18/2015. Policy 2015D0035R archived.
10/1/2015	Updated Applicable Codes for ICD-10 transition. Policy 2015D0035Q archived.
3/1/2015	Policy updated to include trial/failure language to myasthenia gravis. Updated Benefits Consideration. Removed J1562. Added codes 279.02 and D80.4. Approved by the National Pharmacy & Therapeutics Committee on 2/18/2015. Policy 2015D0035P archived.
1/1/2015	Policy updated to include HyQvia and additional language supporting new products and SCIG dosing. Removed NJ language. Approved by the National Pharmacy & Therapeutics Committee on 11/19/2014. Policy 2014D0035O archived.
9/1/2014	Added NMO and secondary thrombocytopenia as proven uses. Updated medical necessity criteria for ITP. Clarified examples of PID subtypes. Updated clinical evidence and references. Updated list of ICD-9 codes (added 204.11, 287.49, 341.0, 647.60, 647.61, 647.63, and 647.64) and associated ICD-10 codes. Approved by the National Pharmacy & Therapeutics Committee on 7/8/2014. Policy 2014D0035N archived.
4/1/2014	Clarified General Criteria for Medical Necessity Review. Revised dosing criteria for ITP and PID. Added dose titration criterion to asthma, autoimmune bullous diseases, CIDP, dermatomyositis, polymyositis, Guillain-Barré syndrome, LEMS, Lennox Gastaut syndrome, MMN, MS, and stiff person syndrome. Removed concomitant immunomodulator requirement from continuation of therapy criteria for CIDP and MMN. Updated clinical evidence and references. Updated list of ICD-9 codes (added 334.8 and 448.0) and associated ICD-10 codes. Approved by the National Pharmacy & Therapeutics Committee on 2/18/2014. Policy 2013D0035M archived.
1/1/2014	Policy updated with code J1556, effective on 1/1/2014.
N/A	Added product selection criteria. Approved by the National Pharmacy & Therapeutics Committee on 11/12/2013.
12/1/2013	Full policy review. Removed Gamunex from list of products. Changed "myasthenia gravis, acute exacerbation" to "myasthenic exacerbation," and revised medical necessity criteria for this indication. Revised medical necessity criteria for CIDP, dermatomyositis and polymyositis, GBS, LEMS, MMN, MS, and stiff-person syndrome. Specified that IVIG is proven in allogeneic BMT. Added treatment of acute GVHD after autologous BMT, prevention of infection after autologous BMT, and ocular myasthenia to the list of unproven uses. Added FDA Safety Communication. Updated clinical evidence and references. Updated list of ICD-9 codes (added 355.9) and associated ICD-10 codes. Approved by the National Pharmacy & Therapeutics Committee on 10/8/2013. Policy 2013D0035L archived.
6/1/2013	Revised dosing for prevention of infection and prevention of GVHD after BMT and for fetomaternal alloimmune thrombocytopenia. Approved by the National Pharmacy & Therapeutics Committee on 4/9/2013. Policy 2013D0035K archived.
4/1/2013	Policy updated. Added Bivigam to list of products. Updated list of ICD-9 codes (added 242.00 and 242.01, and removed 242.0, 287.33, 337.00, 337.09, 356.9, 358.00, 714.4, and 776.7) and associated ICD-10 codes. Approved by the National Pharmacy & Therapeutics Committee on 2/19/2013.
4/1/2013	Annual policy review. Removed Vivaglobin from list of products. Added Alzheimer's

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	disease to the list of unproven uses. Revised paraproteinemic neuropathy from unproven to proven use. Reformatted list of proven and unproven uses to appear in alphabetical order. Added medical necessity criteria. Updated clinical evidence and references. Added FDA Safety Communication. Added CPT codes 90283 and 90284 to the policy. Updated list of ICD-9 codes (added 204.12, 279.11, 279.8, 279.9, 288.09, 288.1, 323.01, 323.02, 323.9, 357.9, 484.1, 646.80, 646.81, 646.82, 646.83, 646.84, 678.00, 678.03, 757.39, 776.8, and 776.9, and removed 038.10, 041.01, 279.02, 337.01, 694.0, 772.10, 772.11, 772.12, 772.13, 772.14, 995.91, and 995.92) and applicable ICD-10 codes. Approved by the National Pharmacy & Therapeutics Committee on 11/13/2012. Modifications to policy based upon societal input approved by the National Pharmacy & Therapeutics Committee on 12/14/2012. Policy 2012D0035J archived.
11/1/2012	Policy updated. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS) revised to unproven use. Updated FDA section to list multifocal motor neuropathy as a new indication for Gammagard. Updated clinical evidence and references. Updated list of ICD-9 codes (added 337.00, 337.01, 337.09, 772.10, 772.11, 772.12, 772.13, 772.14, and 773.2, and removed 337.0, 493, 772.1, and 996.8). Added list of applicable ICD-10 codes (preview draft) in preparation for the transition from ICD-9 to ICD-10 medical coding on 10/01/14. Approved by the National Pharmacy & Therapeutics Committee on 7/10/2012. Policy 2012D0035I archived.
3/1/2012	Policy updated. Added Gammaked to list of products. Approved by the National Pharmacy & Therapeutics Committee on 1/10/2012. Policy 2012D0035H archived.
2/1/2012	Policy updated. Gammagard Liquid added to list of subcutaneous products. Prevention and treatment of neonatal sepsis revised to unproven status. Addition of Clinical Evidence related to treatment and prevention of neonatal sepsis. Updated list of proven ICD-9 codes (removed 771.81). Added code J1557, which became effective on 1/1/2012. Approved by the National Pharmacy & Therapeutics Committee on 11/8/2011. Policy 2012D0035G archived.
1/1/2012	Policy updated with code J1557, effective on 1/1/2012. Policy 2011D0035F archived.
10/1/2011	Policy updated with addition of ICD-9 codes 358.30, 358.31, and 358.39, which became effective on 10/1/2011. Incomplete ICD-9 code 041.0 updated to 041.01. Policy 2011D0035E archived.
9/1/2011	Annual policy review. Added Flebogamma DIF and Gamunex-C to list of products. Autoimmune blistering skin diseases revised to proven use. Revised proven status and evidence for intractable childhood epilepsy to be specific to Lennox Gastaut syndrome. Updated list of proven ICD-9 codes (added 041.0, 238.79, 242.0, 273.1 279.51, 279.53, 323.81, 337.0, 345.00, 345.01, 345.10, 345.11, 493, 493.01, 493.11, 493.21, 694.0, 694.4, 694.5, 694.60, 694.61, 694.8, 695.13, 695.14, 695.15, 708.5, 708.8, 772.1, 776.7, 995.91, 995.92, 996.8, 996.81, and 996.85, and removed 204.00 and 446.6). Removed all unproven ICD-9 codes from the policy because standard policy format is to list only proven ICD-9 codes. Approved by the National Pharmacy & Therapeutics Committee on 7/12/2011. Policy 2010D0035D archived.
1/5/2011	Policy updated with addition of codes J1559 and J1599, which became effective on 1/1/2011.
11/14/2010	Removed 287.4 from and added 287.41 to list of proven ICD-9 codes.
8/16/2010	Policy revised per annual review. Posttransfusion purpura revised to proven use. Clinical evidence and references revised. Switched ICD-9 287.4 to proven. Approved by the National Pharmacy & Therapeutics Committee on 5/11/2010. Added Gammaplex to list of products and information to Background section regarding product IgG content. Approved by the National Pharmacy & Therapeutics Committee on 8/11/2010. Policy 2009D0035C archived.
11/16/2009	Updated list of proven indications for immune globulin (IVIG) to add fetomaternal alloimmune thrombocytopenia; enteroviral meningoencephalitis; staphylococcal toxic shock; treatment of acute humoral rejection in renal transplantation; and primary immune defects with normogammaglobulinemia and impaired specific antibody production. Revised coverage rationale to indicate the use of IVIG for the treatment of diabetes

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	mellitus is proven for autoimmune, type 1 diabetes mellitus only and the use of IVIG for the treatment of multiple sclerosis (MS) is proven for relapsing-remitting multiple sclerosis only. Updated the list of unproven indications to include Sjogren's syndrome. Updated list of proven ICD-9 codes (added 038.10, 040.82, 048, 279.12, and 776.1 and removed 249.00-249.91, 250.00, 250.02, 250.10, 250.12, 250.20, 250.22, 250.30, 250.32, 250.40, 250.42, 250.50, 250.52, 250.60, 250.62, 250.70, 250.72, 250.80, 250.82, 250.90, 250.92, 279.01 and 694.60). Approved by National Pharmacy & Therapeutics Committee on 6/9/2009. Policy 2008D0035B archived.
7/7/2009	Policy updated with separation of monoclonal gammopathy and multiple sclerosis (MS) diagnoses in neuroimmunologic disorders section.
1/2/2009	Policy updated with deletion of codes G0332 and Q4097 and addition of code J1459. Policy 2008D0035A archived.
11/7/2008	New ICD9 code added 90283.
9/17/2008	New ICD9 Codes for Diabetes added as Proven.
9/16/2008	Diagnosis codes 279.01 and 279.02 added as Proven.
8/18/2008	Diagnosis codes 279.00 and 279.03 added to Proven Diagnosis Code list per National Pharmacy & Therapeutics Committee.
6/30/2008	Proven diagnosis code list updated per Manager, Coding and Integrity.
6/30/2008	Diagnosis code 279.00 removed and 358.1 added to Proven Diagnosis Code list per Manger, Coding and Integrity.
4/22/2008	Diagnosis codes 279.05 and 279.06 removed from Unproven Diagnosis Codes per Manager, Coding and Integrity.
4/10/2008	Immune Globulin (IVIG)2008D0035A replaces the previous policies, Intravenous Immune Serum Globulin (IVIG) for Recurrent Spontaneous Abortion 2006D0009B; Intravenous Immune Globulin (IVIg) Use in Rheumatological Disorders 2005D0015C; Intravenous Immune Globulin (IVIg) Use in Neurological and Neuromuscular Disorders 2005D0014C; Intravenous Immune Globulin (IVIg) Use in Infectious Disease 2005D2019C; Intravenous Immune Globulin (IVIg) Use in Miscellaneous Disorders 2007D0020D; Intravenous Immune Globulin (IVIg) Use in Hematological Disorders 2005D0018C. Previous policies were archived.

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REPORT 6

REPORT FOR HOME HEALTH AGENCIES 2015

HOME HEALTH AGENCIES LICENSED IN TENNESSEE

PATIENT ORIGIN BY BASE COUNTY

Resident County: Anderson

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	2,537	100.0
Anderson	267	10.5
Clinch River Home Health	190	
Professional Case Management of Tennessee	77	
Campbell	3	0.1
Sunbelt Homecare	3	
Davidson	17	0.7
Elk Valley Health Services, LLC	1	
Home Care Solutions	16	
Fentress	107	4.2
All Care Plus, Inc. dba Quality Home Health	107	
Hamblen	1	0.0
Premier Support Services	1	
Knox	2,102	82.9
Amedisys Home Health Care	703	
Camellia Home Health of East Tennessee, LLC	102	
Covenant Homecare	722	
East Tennessee Children's Hospital Home Health Care	48	
Gentiva Health Services, dba Kindred at Home	112	
Maxim Healthcare Services, Inc.	22	
NHC Homecare	175	
Tennova Home Health	149	
University of TN Medical Center Home Care Services - Home He	69	
Monroe	40	1.6
Intrepid USA Healthcare Services	40	

Resident County: Bedford

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,183	100.0
Bedford	401	33.9
Heritage Home Health	401	

Resident County: Bedford (Continued)

Facility Location/Name	Patients	Percent
Coffee	293	24.8
Gentiva Health Services, dba Kindred at Home	35	
Suncrest Home Health	258	
Davidson	40	3.4
Alere Women's and Children's Health, LLC	6	
Elk Valley Health Services, LLC	5	
Friendship Home Healthcare, Inc.	3	
Home Care Solutions	4	
VIP Home Nursing & Rehabilitation Service, LLC DBA Careall	4	
Willowbrook Home Health Care Agency, Inc.	18	
Franklin	42	3.6
Caresouth HHA Holdings of Winchester, LLC	42	
Lincoln	105	8.9
Deaconess Homecare	105	
Maury	134	11.3
NHC Homecare	134	
Rutherford	111	9.4
Amedisys Home Health	86	
NHC Homecare	25	
Warren	51	4.3
Intrepid USA Healthcare Services	51	
Williamson	6	0.5
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	6	

Resident County: Benton

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	684	100.0
Benton	145	21.2
Tennessee Quality Homecare - Northwest	145	
Carroll	15	2.2
Baptist Memorial Home Care	15	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Benton (Continued)

Facility Location/Name	Patients	Percent
Davidson	4	0.6
Elk Valley Health Services, LLC	4	
Gibson	249	36.4
NHC Homecare	34	
Volunteer Home Care, Inc.	215	
Henderson	25	3.7
Regional Home Care, Lexington	25	
Henry	53	7.7
Henry County Medical Center Home Health	53	
Hickman	1	0.1
Saint Thomas Home Health	1	
Madison	166	24.3
Amedisys Home Health Care	105	
Extendicare Home Health of West Tennessee	61	
Weakley	26	3.8
Careall Homecare Services	26	

Resident County: Bledsoe

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	425	100.0
Bradley	21	4.9
Home Health Care of East Tennessee, Inc.	21	
Davidson	2	0.5
Elk Valley Health Services, LLC	1	
Home Care Solutions	1	
Hamilton	152	35.8
Amedisys Home Health	92	
Continucare Healthservices, Inc. - I	10	
Home Care Solutions	2	
Memorial Hospital Home Health	45	
NHC Homecare	3	

Resident County: Bledsoe (Continued)

Facility Location/Name	Patients	Percent
Warren	250	58.8
JW Carell Enterprises, LLC DBA Careall Home Care Services	250	

Resident County: Blount

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	3,027	100.0
Anderson	9	0.3
Professional Case Management of Tennessee	9	
Blount	1,409	46.5
Blount Memorial Hospital Home Health Services	1,409	
Davidson	10	0.3
Elk Valley Health Services, LLC	6	
Home Care Solutions	4	
Fentress	269	8.9
All Care Plus, Inc. dba Quality Home Health	267	
Quality Private Duty Care	2	
Hamilton	2	0.1
Amedisys Home Health	2	
Knox	1,326	43.8
Amedisys Home Health Care	222	
Camellia Home Health of East Tennessee, LLC	49	
Covenant Homecare	189	
East Tennessee Children's Hospital Home Health Care	46	
Gentiva Health Services, dba Kindred at Home	167	
Maxim Healthcare Services, Inc.	18	
NHC Homecare	51	
Tennova Home Health	168	
University of TN Medical Center Home Care Services - Home He	416	
Monroe	2	0.1
Intrepid USA Healthcare Services	2	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Bradley

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	2,501	100.0
Bradley	945	37.8
Family Home Care, Cleveland	814	
Home Health Care of East Tennessee, Inc.	131	
Davidson	1	0.0
Elk Valley Health Services, LLC	1	
Franklin	192	7.7
Caresouth HHA Holdings of Winchester, LLC	192	
Hamilton	1,271	50.8
Alere Women's and Children's Health, LLC	11	
Amedisys Home Health	274	
Continucare Healthservices, Inc. - I	100	
Gentiva Health Services	10	
Guardian Home Care, LLC	455	
Home Care Solutions	15	
Life Care at Home of Tennessee	207	
Maxim Healthcare Services	9	
Memorial Hospital Home Health	179	
NHC Homecare	11	
Knox	81	3.2
Camellia Home Health of East Tennessee, LLC	81	
McMinn	6	0.2
NHC Homecare	6	
Monroe	5	0.2
Intrepid USA Healthcare Services	5	

Resident County: Campbell

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,726	100.0
Anderson	52	3.0
Clinch River Home Health	40	
Professional Case Management of Tennessee	12	

Resident County: Campbell (Continued)

Facility Location/Name	Patients	Percent
Campbell	239	13.8
Sunbelt Homecare	239	
Claiborne	486	28.2
Amedisys Home Health of Tennessee	473	
Suncrest Home Health	13	
Davidson	4	0.2
Elk Valley Health Services, LLC	3	
Gentiva Health Services, dba Kindred at Home	1	
Hamblen	3	0.2
Amedisys Home Health Care	3	
Knox	880	51.0
Camellia Home Health of East Tennessee, LLC	45	
Covenant Homecare	101	
East Tennessee Children's Hospital Home Health Care	22	
Gentiva Health Services, dba Kindred at Home	54	
Maxim Healthcare Services, Inc.	24	
NHC Homecare	2	
Tennova Home Health	563	
University of TN Medical Center Home Care Services - Home He	69	
Monroe	2	0.1
Intrepid USA Healthcare Services	2	
Scott	56	3.2
Deaconess Homecare	56	
Out-of-State	4	0.2
Professional Home Health Care Agency, Inc.	4	

Resident County: Cannon

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	472	100.0
Coffee	5	1.1
Suncrest Home Health	5	

Resident County: Cannon (Continued)

Facility Location/Name	Patients	Percent
Davidson	24	5.1
Home Health Care of Middle Tennessee, LLC	20	
Willowbrook Home Health Care Agency, Inc.	4	
DeKalb	299	63.3
Suncrest Home Health	299	
Franklin	6	1.3
Amedisys Home Care	1	
Caresouth HHA Holdings of Winchester, LLC	5	
Rutherford	61	12.9
Amedisys Home Health	13	
NHC Homecare	48	
Warren	67	14.2
Friendship Home Health, Inc.	6	
Intrepid USA Healthcare Services	19	
JW Carell Enterprises, LLC DBA Careall Home Care Services	42	
Williamson	1	0.2
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	1	
Wilson	9	1.9
Deaconess Homecare	1	
Gentiva Health Services, dba Kindred at Home	8	

Resident County: Carroll

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,465	100.0
Benton	101	6.9
Tennessee Quality Homecare - Northwest	101	
Carroll	207	14.1
Baptist Memorial Home Care	207	
Davidson	7	0.5
Elk Valley Health Services, LLC	7	
Gibson	338	23.1
NHC Homecare	64	

Resident County: Carroll (Continued)

Facility Location/Name	Patients	Percent
Gibson (Continued)		
Volunteer Home Care, Inc.	274	
Henderson	482	32.9
Regional Home Care, Lexington	482	
Henry	35	2.4
Henry County Medical Center Home Health	35	
Madison	198	13.5
Amedisys Home Health Care	74	
Extendicare Home Health of West Tennessee	76	
F.C of Tennessee	13	
Medical Center Home Health, LLC	28	
Regional Home Care, Jackson	7	
Weakley	97	6.6
Careall Homecare Services	97	

Resident County: Carter

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,942	100.0
Carter	574	29.6
Amedisys Home Health Care	574	
Davidson	5	0.3
Elk Valley Health Services, LLC	5	
Greene	84	4.3
Procare Home Health Services	84	
Hamblen	6	0.3
Premier Support Services	6	
Johnson	7	0.4
Johnson County Home Health	7	
Sullivan	30	1.5
Gentiva Health Services, dba Kindred at Home	30	
Washington	1,236	63.6
Amedysis Home Health	6	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: **Carter** (Continued)

Facility Location/Name	Patients	Percent
Washington (Continued)		
Medical Center Homecare Services	1,101	
Medical Center Homecare, Kingsport	89	
NHC Homecare	40	

Resident County: **Cheatham**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	737	100.0
Davidson	415	56.3
Alere Women's and Children's Health, LLC	5	
Amedisys Home Health	36	
Continuous Care Services, LLC	8	
Elk Valley Health Services, LLC	2	
Friendship Home Healthcare, Inc.	4	
Gentiva Health Services, dba Kindred at Home	18	
Home Care Solutions	9	
Home Health Care of Middle Tennessee, LLC	103	
Innovative Senior Care Home Health of Nashville, LLC	1	
Intrepid USA Healthcare Services	119	
Maxim Healthcare Services, Inc.	3	
Suncrest Home Health	1	
Vanderbilt Community and Home Services	43	
Vanderbilt Home Care Services	27	
VIP Home Nursing & Rehabilitation Service, LLC DBA Careall	2	
Willowbrook Home Health Care Agency, Inc.	34	
Franklin	28	3.8
Caresouth HHA Holdings of Winchester, LLC	28	
Maury	31	4.2
NHC Homecare	31	
Montgomery	100	13.6
Gateway Home Health, Clarksville	6	
Suncrest Home Health of Nashville, Inc.	94	

Resident County: **Cheatham** (Continued)

Facility Location/Name	Patients	Percent
Robertson	123	16.7
Lifeline Home Health Care	11	
NHC Homecare	112	
Williamson	40	5.4
Guardian Home Care of Nashville	32	
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	8	

Resident County: **Chester**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	545	100.0
Carroll	1	0.2
Baptist Memorial Home Care	1	
Decatur	221	40.6
Tennessee Quality Homecare-Southwest	119	
Volunteer Homecare of West Tennessee, Inc.	102	
Gibson	8	1.5
NHC Homecare	8	
Hardin	58	10.6
Deaconess Homecare	57	
HMC Home Health, LLC	1	
Haywood	50	9.2
Professional Home Health Care, LLC DBA CareAll Homecare Se	50	
Henderson	14	2.6
Regional Home Care, Lexington	14	
Madison	193	35.4
Amedisys Home Health Care	32	
Extendicare Home Health of West Tennessee	16	
F.C of Tennessee	28	
Medical Center Home Health, LLC	65	
Regional Home Care, Jackson	52	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Claiborne

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,800	100.0
Anderson	2	0.1
Professional Case Management of Tennessee	2	
Campbell	11	0.6
Sunbelt Homecare	11	
Claiborne	981	54.5
Amedisys Home Health of Tennessee	797	
Suncrest Home Health	184	
Cocke	52	2.9
Smoky Mountain Home Health and Hospice, Inc.	52	
Davidson	2	0.1
Elk Valley Health Services, LLC	2	
Hamblen	492	27.3
Amedisys Home Health Care	489	
Premier Support Services	3	
Hancock	89	4.9
Hancock County Home Health Agency	89	
Knox	166	9.2
Camellia Home Health of East Tennessee, LLC	12	
Covenant Homecare	38	
East Tennessee Children's Hospital Home Health Care	15	
Gentiva Health Services, dba Kindred at Home	2	
Maxim Healthcare Services, Inc.	6	
Tennova Home Health	63	
University of TN Medical Center Home Care Services - Home He	30	
Monroe	4	0.2
Intrepid USA Healthcare Services	4	
Out-of-State	1	0.1
Professional Home Health Care Agency, Inc.	1	

Resident County: Clay

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	235	100.0
Clay	137	58.3
Cumberland River Homecare	137	
Davidson	33	14.0
Elk Valley Health Services, LLC	1	
Home Care Solutions	1	
VIP Home Nursing & Rehabilitation Service, LLC DBA Careall	31	
Overton	45	19.1
Amedisys	45	
Rutherford	10	4.3
NHC Homecare	10	
Wilson	10	4.3
Deaconess Homecare	10	

Resident County: Cocke

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,272	100.0
Claiborne	28	2.2
Suncrest Home Health	28	
Cocke	356	28.0
Smoky Mountain Home Health and Hospice, Inc.	356	
Davidson	1	0.1
Elk Valley Health Services, LLC	1	
Greene	22	1.7
Advanced Home Care, Inc.	3	
Laughlin Home Health Agency	19	
Hamblen	283	22.2
Premier Support Services	110	
University of TN Medical Center Home Health Services	173	
Knox	582	45.8
Amedisys Home Health Care	426	
Camellia Home Health of East Tennessee, LLC	13	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: **Cocke** (Continued)

Facility Location/Name	Patients	Percent
Knox (Continued)		
Covenant Homecare	55	
East Tennessee Children's Hospital Home Health Care	22	
Gentiva Health Services, dba Kindred at Home	59	
Maxim Healthcare Services, Inc.	5	
University of TN Medical Center Home Care Services - Home He	2	

Resident County: **Coffee**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,701	100.0
Bedford	40	2.4
Heritage Home Health	40	
Bradley	11	0.6
Home Health Care of East Tennessee, Inc.	11	
Coffee	734	43.2
Gentiva Health Services, dba Kindred at Home	195	
Suncrest Home Health	539	
Davidson	12	0.7
Angel Private Duty and Home Health, Inc.	2	
Elk Valley Health Services, LLC	6	
Home Care Solutions	4	
Franklin	313	18.4
Amedisys Home Care	154	
Caresouth HHA Holdings of Winchester, LLC	159	
Hamilton	4	0.2
Alere Women's and Children's Health, LLC	3	
Gentiva Health Services	1	
Lincoln	65	3.8
Deaconess Homecare	65	
Rutherford	161	9.5
Amedisys Home Health	1	
NHC Homecare	160	

Resident County: **Coffee** (Continued)

Facility Location/Name	Patients	Percent
Warren	358	21.0
Friendship Home Health, Inc.	73	
Intrepid USA Healthcare Services	256	
JW Carell Enterprises, LLC DBA Careall Home Care Services	29	
Williamson	3	0.2
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	3	

Resident County: **Crockett**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	567	100.0
Davidson	4	0.7
Elk Valley Health Services, LLC	4	
Dyer	30	5.3
Regional Home Care, Dyersburg	30	
Gibson	109	19.2
NHC Homecare	16	
Volunteer Home Care, Inc.	93	
Haywood	62	10.9
Professional Home Health Care, LLC DBA CareAll Homecare Se	62	
Madison	360	63.5
Amedisys Home Health Care	140	
Extendicare Home Health of West Tennessee	71	
F.C of Tennessee	28	
Medical Center Home Health, LLC	58	
Regional Home Care, Jackson	63	
Weakley	2	0.4
Careall Homecare Services	2	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Cumberland

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,838	100.0
Anderson	1	0.1
Professional Case Management of Tennessee	1	
Clay	38	2.1
Cumberland River Homecare	38	
Davidson	120	6.5
Elk Valley Health Services, LLC	3	
Home Care Solutions	1	
VIP Home Nursing & Rehabilitation Service, LLC DBA Careall	116	
Fentress	928	50.5
All Care Plus, Inc. dba Quality Home Health	745	
Quality Private Duty Care	183	
Hamilton	5	0.3
Amedisys Home Health	5	
Knox	455	24.8
Amedisys Home Health Care	1	
Camellia Home Health of East Tennessee, LLC	202	
Covenant Homecare	252	
Overton	117	6.4
Amedisys	117	
Putnam	47	2.6
Highland Rim Home Health Agency	1	
Intrepid USA Healthcare Services	46	
Rutherford	74	4.0
NHC Homecare	74	
Wilson	53	2.9
Deaconess Homecare	53	

Resident County: Davidson

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	13,563	100.0
Davidson	10,443	77.0
Alere Women's and Children's Health, LLC	70	
Amedisys Home Health	1,200	
Amedisys Home Health Services	113	
Angel Private Duty and Home Health, Inc.	15	
Continuous Care Services, LLC	111	
Elk Valley Health Services, LLC	38	
Friendship Home Healthcare, Inc.	448	
Gentiva Health Services, dba Kindred at Home	586	
Home Care Solutions	180	
Home Health Care of Middle Tennessee, LLC	1,104	
Innovative Senior Care Home Health of Nashville, LLC	426	
Intrepid USA Healthcare Services	582	
Maxim Healthcare Services, Inc.	23	
Premiere Home Health, Inc.	79	
Suncrest Home Health	2,449	
Vanderbilt Community and Home Services	1,104	
Vanderbilt Home Care Services	1,112	
VIP Home Nursing & Rehabilitation Service, LLC DBA Careall	218	
Willowbrook Home Health Care Agency, Inc.	585	
Franklin	549	4.0
Caresouth HHA Holdings of Winchester, LLC	549	
Putnam	1	0.0
Intrepid USA Healthcare Services	1	
Robertson	568	4.2
Lifeline Home Health Care	11	
NHC Homecare	557	
Rutherford	720	5.3
Amedisys Home Health Care	3	
NHC Homecare	717	
Sumner	223	1.6
Highpoint Homecare	223	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Franklin (Continued)

Facility Location/Name	Patients	Percent
Rutherford	28	2.1
NHC Homecare	28	
Warren	18	1.3
Friendship Home Health, Inc.	18	
Williamson	4	0.3
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	4	

Resident County: Gibson

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,870	100.0
Benton	65	3.5
Tennessee Quality Homecare - Northwest	65	
Carroll	11	0.6
Baptist Memorial Home Care	11	
Davidson	14	0.7
Elk Valley Health Services, LLC	14	
Dyer	49	2.6
Regional Home Care, Dyersburg	49	
Gibson	704	37.6
NHC Homecare	279	
Volunteer Home Care, Inc.	425	
Haywood	51	2.7
Professional Home Health Care, LLC DBA CareAll Homecare Se	51	
Madison	822	44.0
Amedisys Home Health Care	172	
Extendicare Home Health of West Tennessee	33	
F.C of Tennessee	77	
Medical Center Home Health, LLC	350	
Regional Home Care, Jackson	190	
Obion	9	0.5
Extendicare Home Health of Western Tennessee	9	

Resident County: Gibson (Continued)

Facility Location/Name	Patients	Percent
Weakley	145	7.8
Careall Homecare Services	145	

Resident County: Giles

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	921	100.0
Davidson	7	0.8
Elk Valley Health Services, LLC	7	
Lincoln	73	7.9
Deaconess Homecare	68	
Lincoln Medical Home Health and Hospice	5	
Maury	687	74.6
Maury Regional Home Services	93	
Maxlife at Home of Tennessee, LLC DBA CareAll Homecare Ser	52	
NHC Homecare	425	
Quality First Home Care	117	
Rutherford	154	16.7
Amedisys Home Health Care	154	

Resident County: Grainger

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	846	100.0
Anderson	1	0.1
Professional Case Management of Tennessee	1	
Claiborne	134	15.8
Amedisys Home Health of Tennessee	79	
Suncrest Home Health	55	
Cocke	24	2.8
Smoky Mountain Home Health and Hospice, Inc.	24	
Hamblen	276	32.6
Amedisys Home Health Care	98	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Grainger (Continued)

Facility Location/Name	Patients	Percent
Hamblen (Continued)		
Premier Support Services	76	
University of TN Medical Center Home Health Services	102	
Hancock	117	13.8
Hancock County Home Health Agency	117	
Hawkins	6	0.7
Hometown Home Health Care, Inc.	6	
Knox	288	34.0
Amedisys Home Health Care	62	
Camellia Home Health of East Tennessee, LLC	14	
Covenant Homecare	83	
East Tennessee Children's Hospital Home Health Care	14	
Gentiva Health Services, dba Kindred at Home	20	
Maxim Healthcare Services, Inc.	4	
NHC Homecare	4	
Tennova Home Health	87	

Resident County: Greene

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	2,291	100.0
Claiborne	5	0.2
Suncrest Home Health	5	
Cocke	122	5.3
Smoky Mountain Home Health and Hospice, Inc.	122	
Davidson	7	0.3
Elk Valley Health Services, LLC	7	
Greene	1,145	50.0
Advanced Home Care, Inc.	397	
Laughlin Home Health Agency	678	
Procare Home Health Services	70	
Hamblen	727	31.7
Amedisys Home Health Care	610	

Resident County: Greene (Continued)

Facility Location/Name	Patients	Percent
Hamblen (Continued)		
Premier Support Services	30	
University of TN Medical Center Home Health Services	87	
Knox	50	2.2
Gentiva Health Services, dba Kindred at Home	20	
Maxim Healthcare Services, Inc.	30	
Sullivan	64	2.8
Advanced Home Care, Inc.	2	
Gentiva Health Services, dba Kindred at Home	62	
Washington	171	7.5
Medical Center Homecare Services	154	
Medical Center Homecare, Kingsport	13	
NHC Homecare	4	

Resident County: Grundy

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	500	100.0
Bradley	87	17.4
Home Health Care of East Tennessee, Inc.	87	
Coffee	64	12.8
Gentiva Health Services, dba Kindred at Home	3	
Suncrest Home Health	61	
Franklin	229	45.8
Amedisys Home Care	146	
Caresouth HHA Holdings of Winchester, LLC	83	
Hamilton	13	2.6
Amedisys Home Health	1	
Guardian Home Care, LLC	3	
Home Care Solutions	8	
Memorial Hospital Home Health	1	
Knox	2	0.4
Camellia Home Health of East Tennessee, LLC	2	

Resident County: Grundy (Continued)

Facility Location/Name	Patients	Percent
Lincoln	1	0.2
Deaconess Homecare	1	
Rutherford	41	8.2
NHC Homecare	41	
Warren	61	12.2
Friendship Home Health, Inc.	23	
JW Carell Enterprises, LLC DBA Careall Home Care Services	38	
Williamson	2	0.4
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	2	

Resident County: Hamblen

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	2,606	100.0
Anderson	1	0.0
Professional Case Management of Tennessee	1	
Claiborne	70	2.7
Suncrest Home Health	70	
Cocke	217	8.3
Smoky Mountain Home Health and Hospice, Inc.	217	
Davidson	3	0.1
Elk Valley Health Services, LLC	3	
Greene	2	0.1
Advanced Home Care, Inc.	1	
Laughlin Home Health Agency	1	
Hamblen	1,683	64.6
Amedisys Home Health Care	914	
Premier Support Services	491	
University of TN Medical Center Home Health Services	278	
Knox	630	24.2
Amedisys Home Health Care	4	
Camellia Home Health of East Tennessee, LLC	117	
Covenant Homecare	230	

Resident County: Hamblen (Continued)

Facility Location/Name	Patients	Percent
Knox (Continued)		
East Tennessee Children's Hospital Home Health Care	46	
Gentiva Health Services, dba Kindred at Home	68	
Maxim Healthcare Services, Inc.	8	
NHC Homecare	1	
Tennova Home Health	156	

Resident County: Hamilton

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	8,287	100.0
Bradley	673	8.1
Family Home Care, Cleveland	396	
Home Health Care of East Tennessee, Inc.	277	
Davidson	3	0.0
Elk Valley Health Services, LLC	3	
Franklin	466	5.6
Caresouth HHA Holdings of Winchester, LLC	466	
Hamilton	6,874	82.9
Alere Women's and Children's Health, LLC	14	
Amedisys Home Health	1,064	
Continucare Healthservices, Inc. - I	1,120	
Continucare Healthservices, Inc. - II	7	
Gentiva Health Services	390	
Guardian Home Care, LLC	1,160	
Home Care Solutions	352	
Life Care at Home of Tennessee	181	
Maxim Healthcare Services	36	
Memorial Hospital Home Health	2,316	
NHC Homecare	234	
Knox	271	3.3
Camellia Home Health of East Tennessee, LLC	271	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Hancock

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	643	100.0
Claiborne	12	1.9
Amedisys Home Health of Tennessee	6	
Suncrest Home Health	6	
Hamblen	349	54.3
Amedisys Home Health Care	339	
Premier Support Services	7	
University of TN Medical Center Home Health Services	3	
Hancock	275	42.8
Hancock County Home Health Agency	275	
Hawkins	1	0.2
Hometown Home Health Care, Inc.	1	
Knox	5	0.8
Camellia Home Health of East Tennessee, LLC	3	
Maxim Healthcare Services, Inc.	2	
Sullivan	1	0.2
Gentiva Health Services, dba Kindred at Home	1	

Resident County: Hardeman

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	920	100.0
Davidson	2	0.2
Elk Valley Health Services, LLC	2	
Decatur	157	17.1
Volunteer Homecare of West Tennessee, Inc.	157	
Fayette	69	7.5
NHC Homecare	69	
Hardin	55	6.0
Deaconess Homecare	55	
Haywood	71	7.7
Professional Home Health Care, LLC DBA CareAll Homecare Se	71	

Resident County: Hardeman (Continued)

Facility Location/Name	Patients	Percent
Madison	371	40.3
Amedisys Home Health Care	78	
Extendicare Home Health of West Tennessee	8	
F.C of Tennessee	10	
Medical Center Home Health, LLC	194	
Regional Home Care, Jackson	81	
Shelby	195	21.2
Alere Women's and Children's Health	6	
Homechoice Health Services	155	
Maxim Healthcare Services, Inc.	17	
Willowbrook Visiting Nurse Association, Inc.	17	

Resident County: Hardin

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,101	100.0
Anderson	1	0.1
Professional Case Management of Tennessee	1	
Davidson	17	1.5
Elk Valley Health Services, LLC	17	
Decatur	141	12.8
Tennessee Quality Homecare-Southwest	66	
Volunteer Homecare of West Tennessee, Inc.	75	
Hardin	530	48.1
Deaconess Homecare	280	
HMC Home Health, LLC	250	
Haywood	8	0.7
Professional Home Health Care, LLC DBA CareAll Homecare Se	8	
Henderson	11	1.0
Regional Home Care, Lexington	11	
Madison	274	24.9
Amedisys Home Health Care	197	
Extendicare Home Health of West Tennessee	1	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Hardin (Continued)

Facility Location/Name	Patients	Percent
Madison (Continued)		
F.C of Tennessee	15	
Medical Center Home Health, LLC	22	
Regional Home Care, Jackson	39	
Maury	107	9.7
Maxlife at Home of Tennessee, LLC DBA CareAll Homecare Ser	107	
Out-of-State	12	1.1
Magnolia Regional Health Center Home Health and Hospice Age	12	

Resident County: Hawkins

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	2,236	100.0
Anderson	1	0.0
Professional Case Management of Tennessee	1	
Claiborne	51	2.3
Suncrest Home Health	51	
Cocke	49	2.2
Smoky Mountain Home Health and Hospice, Inc.	49	
Davidson	2	0.1
Elk Valley Health Services, LLC	2	
Greene	278	12.4
Advanced Home Care, Inc.	275	
Laughlin Home Health Agency	3	
Hamblen	1,149	51.4
Amedisys Home Health Care	638	
Premier Support Services	233	
University of TN Medical Center Home Health Services	278	
Hancock	167	7.5
Hancock County Home Health Agency	167	
Hawkins	101	4.5
Hometown Home Health Care, Inc.	101	

Resident County: Hawkins (Continued)

Facility Location/Name	Patients	Percent
Knox	27	1.2
Camellia Home Health of East Tennessee, LLC	14	
Gentiva Health Services, dba Kindred at Home	3	
Maxim Healthcare Services, Inc.	10	
Sullivan	310	13.9
Advanced Home Care, Inc.	271	
Gentiva Health Services, dba Kindred at Home	39	
Washington	101	4.5
Amedysis Home Health	12	
Medical Center Homecare, Kingsport	86	
NHC Homecare	3	

Resident County: Haywood

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	649	100.0
Davidson	5	0.8
Elk Valley Health Services, LLC	5	
Fayette	19	2.9
NHC Homecare	19	
Haywood	109	16.8
Professional Home Health Care, LLC DBA CareAll Homecare Se	109	
Madison	323	49.8
Amedisys Home Health Care	52	
Extendicare Home Health of West Tennessee	9	
F.C of Tennessee	52	
Medical Center Home Health, LLC	70	
Regional Home Care, Jackson	140	
Shelby	193	29.7
Alere Women's and Children's Health	2	
Amedisys Home Health	1	
Homechoice Health Services	175	
Maxim Healthcare Services, Inc.	11	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Jackson

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	372	100.0
Clay	43	11.6
Cumberland River Homecare	43	
Davidson	36	9.7
Elk Valley Health Services, LLC	4	
Home Care Solutions	3	
VIP Home Nursing & Rehabilitation Service, LLC DBA Careall	29	
Hamblen	5	1.3
Amedisys Home Health Care	5	
Overton	70	18.8
Amedisys	70	
Putnam	67	18.0
Highland Rim Home Health Agency	46	
Intrepid USA Healthcare Services	21	
Rutherford	86	23.1
NHC Homecare	86	
Sumner	8	2.2
Highpoint Homecare	8	
Wilson	57	15.3
Deaconess Homecare	57	

Resident County: Jefferson

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,583	100.0
Anderson	2	0.1
Professional Case Management of Tennessee	2	
Claiborne	48	3.0
Suncrest Home Health	48	
Cocke	119	7.5
Smoky Mountain Home Health and Hospice, Inc.	119	
Davidson	3	0.2
Elk Valley Health Services, LLC	2	

Resident County: Jefferson (Continued)

Facility Location/Name	Patients	Percent
Davidson (Continued)		
Home Care Solutions	1	
Hamblen	359	22.7
Premier Support Services	137	
University of TN Medical Center Home Health Services	222	
Knox	1,052	66.5
Amedisys Home Health Care	487	
Camellia Home Health of East Tennessee, LLC	50	
Covenant Homecare	145	
East Tennessee Children's Hospital Home Health Care	22	
Gentiva Health Services, dba Kindred at Home	81	
Maxim Healthcare Services, Inc.	5	
NHC Homecare	9	
Tennova Home Health	250	
University of TN Medical Center Home Care Services - Home He	3	

Resident County: Johnson

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	787	100.0
Carter	297	37.7
Amedisys Home Health Care	297	
Greene	5	0.6
Procare Home Health Services	5	
Johnson	437	55.5
Johnson County Home Health	437	
Washington	48	6.1
Amedysis Home Health	1	
Medical Center Homecare Services	8	
Medical Center Homecare, Kingsport	39	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Knox

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	9,255	100.0
Anderson	222	2.4
Clinch River Home Health	162	
Professional Case Management of Tennessee	60	
Blount	15	0.2
Blount Memorial Hospital Home Health Services	15	
Davidson	124	1.3
Elk Valley Health Services, LLC	27	
Gentiva Health Services, dba Kindred at Home	1	
Home Care Solutions	96	
Fentress	550	5.9
All Care Plus, Inc. dba Quality Home Health	548	
Quality Private Duty Care	2	
Hamblen	8	0.1
Premier Support Services	6	
University of TN Medical Center Home Health Services	2	
Knox	8,042	86.9
Amedisys Home Health Care	1,556	
Camellia Home Health of East Tennessee, LLC	474	
Covenant Homecare	1,670	
East Tennessee Children's Hospital Home Health Care	177	
Gentiva Health Services, dba Kindred at Home	669	
Maxim Healthcare Services, Inc.	46	
NHC Homecare	514	
Tennova Home Health	2,057	
University of TN Medical Center Home Care Services - Home He	879	
Monroe	294	3.2
Intrepid USA Healthcare Services	294	

Resident County: **Lake**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	357	100.0
Davidson	1	0.3
Elk Valley Health Services, LLC	1	
Dyer	137	38.4
Regional Home Care, Dyersburg	137	
Gibson	90	25.2
Volunteer Home Care, Inc.	90	
Madison	9	2.5
Extendicare Home Health of West Tennessee	9	
Obion	46	12.9
Extendicare Home Health of Western Tennessee	46	
Weakley	74	20.7
Careall Homecare Services	74	

Resident County: **Lauderdale**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	907	100.0
Davidson	1	0.1
Elk Valley Health Services, LLC	1	
Dyer	225	24.8
Regional Home Care, Dyersburg	225	
Fayette	1	0.1
NHC Homecare	1	
Haywood	155	17.1
Professional Home Health Care, LLC DBA CareAll Homecare Se	155	
Madison	392	43.2
Amedisys Home Health Care	253	
Extendicare Home Health of West Tennessee	120	
F.C of Tennessee	10	
Regional Home Care, Jackson	9	
Shelby	133	14.7
Accredo Health Group, Inc.	1	

Resident County: Lincoln (Continued)

Facility Location/Name	Patients	Percent
Rutherford	4	0.3
Amedisys Home Health Care	4	
Warren	5	0.4
Intrepid USA Healthcare Services	5	
Williamson	2	0.2
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	2	

Resident County: Loudon

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,525	100.0
Anderson	17	1.1
Professional Case Management of Tennessee	17	
Blount	46	3.0
Blount Memorial Hospital Home Health Services	46	
Bradley	117	7.7
Home Health Care of East Tennessee, Inc.	117	
Davidson	78	5.1
Elk Valley Health Services, LLC	1	
Home Care Solutions	77	
Fentress	183	12.0
All Care Plus, Inc. dba Quality Home Health	127	
Quality Private Duty Care	56	
Hamilton	158	10.4
Amedisys Home Health	158	
Knox	807	52.9
Amedisys Home Health Care	2	
Camellia Home Health of East Tennessee, LLC	109	
Covenant Homecare	379	
East Tennessee Children's Hospital Home Health Care	29	
Gentiva Health Services, dba Kindred at Home	87	
Maxim Healthcare Services, Inc.	6	
NHC Homecare	30	

Resident County: Loudon (Continued)

Facility Location/Name	Patients	Percent
Knox (Continued)		
Tennova Home Health	71	
University of TN Medical Center Home Care Services - Home He	94	
McMinn	22	1.4
NHC Homecare	22	
Monroe	97	6.4
Intrepid USA Healthcare Services	36	
Sweetwater Hospital Home Health	61	

Resident County: McMinn

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,501	100.0
Bradley	201	13.4
Family Home Care, Cleveland	103	
Home Health Care of East Tennessee, Inc.	98	
Davidson	8	0.5
Elk Valley Health Services, LLC	2	
Home Care Solutions	6	
Franklin	60	4.0
Caresouth HHA Holdings of Winchester, LLC	60	
Hamilton	589	39.2
Alere Women's and Children's Health, LLC	1	
Amedisys Home Health	367	
Continucare Healthservices, Inc. - I	10	
Guardian Home Care, LLC	149	
Home Care Solutions	27	
Life Care at Home of Tennessee	18	
Maxim Healthcare Services	4	
Memorial Hospital Home Health	13	
Knox	206	13.7
Camellia Home Health of East Tennessee, LLC	204	
Gentiva Health Services, dba Kindred at Home	2	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: **McMinn** (Continued)

Facility Location/Name	Patients	Percent
McMinn	250	16.7
NHC Homecare	250	
Monroe	187	12.5
Intrepid USA Healthcare Services	91	
Sweetwater Hospital Home Health	96	

Resident County: **McNairy**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,138	100.0
Davidson	2	0.2
Elk Valley Health Services, LLC	2	
Decatur	298	26.2
Tennessee Quality Homecare-Southwest	85	
Volunteer Homecare of West Tennessee, Inc.	213	
Fayette	6	0.5
NHC Homecare	6	
Hardin	333	29.3
Deaconess Homecare	257	
HMC Home Health, LLC	76	
Haywood	19	1.7
Professional Home Health Care, LLC DBA CareAll Homecare Se	19	
Madison	418	36.7
Amedisys Home Health Care	117	
Extendicare Home Health of West Tennessee	16	
F.C of Tennessee	16	
Medical Center Home Health, LLC	52	
Regional Home Care, Jackson	217	
Maury	14	1.2
Maxlife at Home of Tennessee, LLC DBA CareAll Homecare Ser	14	
Out-of-State	48	4.2
Magnolia Regional Health Center Home Health and Hospice Age	48	

Resident County: **Macon**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	707	100.0
Clay	19	2.7
Cumberland River Homecare	19	
Davidson	420	59.4
Amedisys Home Health	39	
Angel Private Duty and Home Health, Inc.	1	
Home Care Solutions	29	
Home Health Care of Middle Tennessee, LLC	3	
Suncrest Home Health	304	
VIP Home Nursing & Rehabilitation Service, LLC DBA Careall	44	
Robertson	21	3.0
NHC Homecare	21	
Rutherford	6	0.8
NHC Homecare	6	
Sumner	32	4.5
Highpoint Homecare	32	
Warren	152	21.5
Friendship Home Health, Inc.	152	
Wilson	57	8.1
American National Home Health	11	
Deaconess Homecare	5	
Gentiva Health Services, dba Kindred at Home	41	

Resident County: **Madison**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	3,220	100.0
Benton	1	0.0
Tennessee Quality Homecare - Northwest	1	
Carroll	11	0.3
Baptist Memorial Home Care	11	
Davidson	7	0.2
Elk Valley Health Services, LLC	7	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Madison (Continued)

Facility Location/Name	Patients	Percent
Decatur	262	8.1
Tennessee Quality Homecare-Southwest	260	
Volunteer Homecare of West Tennessee, Inc.	2	
Gibson	881	27.4
NHC Homecare	164	
Volunteer Home Care, Inc.	717	
Hardin	24	0.7
Deaconess Homecare	24	
Haywood	125	3.9
Professional Home Health Care, LLC DBA CareAll Homecare Se	125	
Henderson	9	0.3
Regional Home Care, Lexington	9	
Madison	1,798	55.8
Amedisys Home Health Care	409	
Extendicare Home Health of West Tennessee	147	
F.C of Tennessee	131	
Medical Center Home Health, LLC	588	
Regional Home Care, Jackson	523	
Shelby	102	3.2
Alere Women's and Children's Health	28	
Maxim Healthcare Services, Inc.	74	

Resident County: Marion

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	679	100.0
Bradley	279	41.1
Home Health Care of East Tennessee, Inc.	279	
Coffee	30	4.4
Gentiva Health Services, dba Kindred at Home	1	
Suncrest Home Health	29	
Davidson	2	0.3
Elk Valley Health Services, LLC	2	

Resident County: Marion (Continued)

Facility Location/Name	Patients	Percent
Franklin	15	2.2
Amedisys Home Care	3	
Caresouth HHA Holdings of Winchester, LLC	12	
Hamilton	346	51.0
Alere Women's and Children's Health, LLC	1	
Amedisys Home Health	106	
Continucare Healthservices, Inc. - I	46	
Gentiva Health Services	13	
Home Care Solutions	37	
Life Care at Home of Tennessee	2	
Maxim Healthcare Services	1	
Memorial Hospital Home Health	122	
NHC Homecare	18	
Knox	7	1.0
Camellia Home Health of East Tennessee, LLC	7	

Resident County: Marshall

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	808	100.0
Bedford	16	2.0
Heritage Home Health	16	
Coffee	23	2.8
Suncrest Home Health	23	
Davidson	20	2.5
Alere Women's and Children's Health, LLC	6	
Elk Valley Health Services, LLC	2	
Friendship Home Healthcare, Inc.	2	
Home Care Solutions	2	
Willowbrook Home Health Care Agency, Inc.	8	
Franklin	9	1.1
Caresouth HHA Holdings of Winchester, LLC	9	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Marshall (Continued)

Facility Location/Name	Patients	Percent
Lincoln	41	5.1
Deaconess Homecare	39	
Lincoln Medical Home Health and Hospice	2	
Maury	549	67.9
Maury Regional Home Services	187	
NHC Homecare	313	
Quality First Home Care	49	
Rutherford	147	18.2
Amedisys Home Health Care	147	
Warren	1	0.1
Intrepid USA Healthcare Services	1	
Williamson	2	0.2
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	2	

Resident County: Maury

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	2,691	100.0
Davidson	292	10.9
Alere Women's and Children's Health, LLC	6	
Elk Valley Health Services, LLC	7	
Friendship Home Healthcare, Inc.	3	
Gentiva Health Services, dba Kindred at Home	18	
Home Care Solutions	3	
Home Health Care of Middle Tennessee, LLC	233	
Intrepid USA Healthcare Services	2	
Willowbrook Home Health Care Agency, Inc.	20	
Decatur	30	1.1
Tennessee Quality Homecare-Southwest	30	
Franklin	52	1.9
Caresouth HHA Holdings of Winchester, LLC	52	
Hickman	36	1.3
Saint Thomas Home Health	36	

Resident County: Maury (Continued)

Facility Location/Name	Patients	Percent
Maury	1,827	67.9
Maury Regional Home Services	896	
Maxlife at Home of Tennessee, LLC DBA CareAll Homecare Ser	184	
NHC Homecare	459	
Quality First Home Care	288	
Rutherford	438	16.3
Amedisys Home Health Care	438	
Williamson	16	0.6
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	16	

Resident County: Meigs

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	371	100.0
Anderson	2	0.5
Professional Case Management of Tennessee	2	
Bradley	76	20.5
Family Home Care, Cleveland	59	
Home Health Care of East Tennessee, Inc.	17	
Franklin	13	3.5
Caresouth HHA Holdings of Winchester, LLC	13	
Hamilton	161	43.4
Alere Women's and Children's Health, LLC	1	
Amedisys Home Health	57	
Continucare Healthservices, Inc. - I	11	
Gentiva Health Services	1	
Guardian Home Care, LLC	65	
Home Care Solutions	6	
Life Care at Home of Tennessee	8	
Maxim Healthcare Services	1	
Memorial Hospital Home Health	11	
Knox	48	12.9
Camellia Home Health of East Tennessee, LLC	45	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Meigs (Continued)

Facility Location/Name	Patients	Percent
Knox (Continued)		
Gentiva Health Services, dba Kindred at Home	3	
McMinn	28	7.5
NHC Homecare	28	
Monroe	43	11.6
Intrepid USA Healthcare Services	8	
Sweetwater Hospital Home Health	35	

Resident County: Monroe

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,203	100.0
Anderson	7	0.6
Professional Case Management of Tennessee	7	
Blount	108	9.0
Blount Memorial Hospital Home Health Services	108	
Bradley	217	18.0
Home Health Care of East Tennessee, Inc.	217	
Davidson	12	1.0
Gentiva Health Services, dba Kindred at Home	1	
Home Care Solutions	11	
Hamilton	83	6.9
Alere Women's and Children's Health, LLC	2	
Amedisys Home Health	81	
Knox	210	17.5
Camellia Home Health of East Tennessee, LLC	51	
Covenant Homecare	68	
East Tennessee Children's Hospital Home Health Care	14	
Gentiva Health Services, dba Kindred at Home	22	
University of TN Medical Center Home Care Services - Home He	55	
McMinn	88	7.3
NHC Homecare	88	

Resident County: Monroe (Continued)

Facility Location/Name	Patients	Percent
Monroe	478	39.7
Intrepid USA Healthcare Services	26	
Sweetwater Hospital Home Health	452	

Resident County: Montgomery

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	3,067	100.0
Benton	347	11.3
Tennessee Quality Homecare - Northwest	347	
Davidson	820	26.7
Alere Women's and Children's Health, LLC	17	
Amedisys Home Health	537	
Angel Private Duty and Home Health, Inc.	1	
Elk Valley Health Services, LLC	15	
Friendship Home Healthcare, Inc.	2	
Gentiva Health Services, dba Kindred at Home	26	
Intrepid USA Healthcare Services	177	
Maxim Healthcare Services, Inc.	43	
Suncrest Home Health	1	
Willowbrook Home Health Care Agency, Inc.	1	
Madison	1	0.0
F.C of Tennessee	1	
Maury	8	0.3
NHC Homecare	8	
Montgomery	1,328	43.3
Gateway Home Health, Clarksville	976	
Suncrest Home Health of Nashville, Inc.	352	
Robertson	236	7.7
Lifeline Home Health Care	67	
NHC Homecare	169	
Williamson	327	10.7
Guardian Home Care of Nashville	305	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Montgomery (Continued)

Facility Location/Name	Patients	Percent
Williamson (Continued)		
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	22	

Resident County: Moore

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	93	100.0
Bedford	7	7.5
Heritage Home Health	7	
Coffee	17	18.3
Gentiva Health Services, dba Kindred at Home	10	
Suncrest Home Health	7	
Davidson	2	2.2
Elk Valley Health Services, LLC	1	
Home Care Solutions	1	
Franklin	31	33.3
Amedisys Home Care	11	
Caresouth HHA Holdings of Winchester, LLC	20	
Lincoln	16	17.2
Deaconess Homecare	12	
Lincoln Medical Home Health and Hospice	4	
Maury	11	11.8
NHC Homecare	11	
Warren	9	9.7
Intrepid USA Healthcare Services	9	

Resident County: Morgan

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	526	100.0
Anderson	16	3.0
Clinch River Home Health	11	
Professional Case Management of Tennessee	5	

Resident County: Morgan (Continued)

Facility Location/Name	Patients	Percent
Bradley	4	0.8
Home Health Care of East Tennessee, Inc.	4	
Davidson	8	1.5
Elk Valley Health Services, LLC	3	
Home Care Solutions	5	
Fentress	253	48.1
All Care Plus, Inc. dba Quality Home Health	210	
Quality Private Duty Care	43	
Knox	200	38.0
Amedisys Home Health Care	40	
Camellia Home Health of East Tennessee, LLC	3	
Covenant Homecare	131	
East Tennessee Children's Hospital Home Health Care	13	
Gentiva Health Services, dba Kindred at Home	8	
Maxim Healthcare Services, Inc.	5	
Overton	21	4.0
Amedisys	21	
Scott	24	4.6
Deaconess Homecare	24	

Resident County: Obion

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,314	100.0
Benton	68	5.2
Tennessee Quality Homecare - Northwest	68	
Davidson	12	0.9
Elk Valley Health Services, LLC	12	
Dyer	25	1.9
Regional Home Care, Dyersburg	25	
Gibson	241	18.3
NHC Homecare	10	
Volunteer Home Care, Inc.	231	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Polk

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	419	100.0
Bradley	179	42.7
Family Home Care, Cleveland	122	
Home Health Care of East Tennessee, Inc.	57	
Hamilton	207	49.4
Amedisys Home Health	46	
Guardian Home Care, LLC	63	
Home Care Solutions	8	
Life Care at Home of Tennessee	83	
Memorial Hospital Home Health	7	
Knox	22	5.3
Camellia Home Health of East Tennessee, LLC	22	
McMinn	11	2.6
NHC Homecare	11	

Resident County: Putnam

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	2,563	100.0
Clay	19	0.7
Cumberland River Homecare	19	
Davidson	180	7.0
Elk Valley Health Services, LLC	8	
Home Care Solutions	7	
VIP Home Nursing & Rehabilitation Service, LLC DBA Careall	165	
DeKalb	296	11.5
Suncrest Home Health	296	
Fentress	347	13.5
All Care Plus, Inc. dba Quality Home Health	340	
Quality Private Duty Care	7	
Lincoln	2	0.1
Deaconess Homecare	2	

Resident County: Putnam (Continued)

Facility Location/Name	Patients	Percent
Overton	277	10.8
Amedisys	277	
Putnam	672	26.2
Highland Rim Home Health Agency	451	
Intrepid USA Healthcare Services	221	
Rutherford	541	21.1
NHC Homecare	541	
Sumner	1	0.0
Highpoint Homecare	1	
Warren	1	0.0
Intrepid USA Healthcare Services	1	
Williamson	3	0.1
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	3	
Wilson	224	8.7
American National Home Health	1	
Deaconess Homecare	223	

Resident County: Rhea

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	809	100.0
Anderson	1	0.1
Professional Case Management of Tennessee	1	
Bradley	111	13.7
Home Health Care of East Tennessee, Inc.	111	
Fentress	107	13.2
All Care Plus, Inc. dba Quality Home Health	107	
Hamilton	512	63.3
Alere Women's and Children's Health, LLC	2	
Amedisys Home Health	309	
Continucare Healthservices, Inc. - I	42	
Gentiva Health Services	7	
Home Care Solutions	7	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Rhea (Continued)

Facility Location/Name	Patients	Percent
Hamilton (Continued)		
Life Care at Home of Tennessee	21	
Maxim Healthcare Services	2	
Memorial Hospital Home Health	121	
NHC Homecare	1	
Knox	62	7.7
Camellia Home Health of East Tennessee, LLC	62	
McMinn	13	1.6
NHC Homecare	13	
Monroe	2	0.2
Intrepid USA Healthcare Services	2	
Putnam	1	0.1
Intrepid USA Healthcare Services	1	

Resident County: Roane

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	2,041	100.0
Anderson	84	4.1
Clinch River Home Health	43	
Professional Case Management of Tennessee	41	
Bradley	78	3.8
Home Health Care of East Tennessee, Inc.	78	
Davidson	52	2.5
Home Care Solutions	52	
Fentress	237	11.6
All Care Plus, Inc. dba Quality Home Health	219	
Quality Private Duty Care	18	
Knox	1,542	75.6
Amedisys Home Health Care	618	
Camellia Home Health of East Tennessee, LLC	152	
Covenant Homecare	593	
East Tennessee Children's Hospital Home Health Care	48	

Resident County: Roane (Continued)

Facility Location/Name	Patients	Percent
Knox (Continued)		
Gentiva Health Services, dba Kindred at Home	26	
Maxim Healthcare Services, Inc.	3	
NHC Homecare	38	
Tennova Home Health	35	
University of TN Medical Center Home Care Services - Home He	29	
McMinn	3	0.1
NHC Homecare	3	
Monroe	44	2.2
Intrepid USA Healthcare Services	37	
Sweetwater Hospital Home Health	7	
Overton	1	0.0
Amedisys	1	

Resident County: Robertson

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,757	100.0
Davidson	684	38.9
Alere Women's and Children's Health, LLC	4	
Amedisys Home Health	6	
Amedisys Home Health Services	80	
Angel Private Duty and Home Health, Inc.	3	
Elk Valley Health Services, LLC	4	
Friendship Home Healthcare, Inc.	9	
Gentiva Health Services, dba Kindred at Home	20	
Home Care Solutions	12	
Home Health Care of Middle Tennessee, LLC	156	
Innovative Senior Care Home Health of Nashville, LLC	1	
Intrepid USA Healthcare Services	72	
Maxim Healthcare Services, Inc.	16	
Suncrest Home Health	78	
Vanderbilt Community and Home Services	77	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Scott

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	828	100.0
Anderson	2	0.2
Clinch River Home Health	1	
Professional Case Management of Tennessee	1	
Davidson	5	0.6
Elk Valley Health Services, LLC	5	
Fentress	484	58.5
All Care Plus, Inc. dba Quality Home Health	448	
Quality Private Duty Care	36	
Greene	1	0.1
Advanced Home Care, Inc.	1	
Knox	58	7.0
Camellia Home Health of East Tennessee, LLC	2	
Covenant Homecare	32	
East Tennessee Children's Hospital Home Health Care	8	
Gentiva Health Services, dba Kindred at Home	4	
Maxim Healthcare Services, Inc.	8	
Tennova Home Health	1	
University of TN Medical Center Home Care Services - Home He	3	
Overton	37	4.5
Amedisys	37	
Scott	236	28.5
Deaconess Homecare	236	
Sullivan	4	0.5
Advanced Home Care, Inc.	4	
Out-of-State	1	0.1
Professional Home Health Care Agency, Inc.	1	

Resident County: Sequatchie

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	435	100.0
Bradley	47	10.8
Home Health Care of East Tennessee, Inc.	47	
Coffee	20	4.6
Suncrest Home Health	20	
Franklin	2	0.5
Caresouth HHA Holdings of Winchester, LLC	2	
Hamilton	155	35.6
Amedisys Home Health	38	
Continucare Healthservices, Inc. - I	17	
Gentiva Health Services	3	
Guardian Home Care, LLC	34	
Home Care Solutions	11	
Maxim Healthcare Services	4	
Memorial Hospital Home Health	37	
NHC Homecare	11	
Knox	5	1.1
Camellia Home Health of East Tennessee, LLC	5	
Warren	206	47.4
JW Carell Enterprises, LLC DBA Careall Home Care Services	206	

Resident County: Sevier

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	2,306	100.0
Anderson	1	0.0
Professional Case Management of Tennessee	1	
Blount	11	0.5
Blount Memorial Hospital Home Health Services	11	
Cocke	4	0.2
Smoky Mountain Home Health and Hospice, Inc.	4	
Davidson	8	0.3
Elk Valley Health Services, LLC	5	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: **Sevier** (Continued)

Facility Location/Name	Patients	Percent
Davidson (Continued)		
Home Care Solutions	3	
Hamblen	5	0.2
Premier Support Services	5	
Knox	2,277	98.7
Amedisys Home Health Care	425	
Camellia Home Health of East Tennessee, LLC	98	
Covenant Homecare	664	
East Tennessee Children's Hospital Home Health Care	29	
Gentiva Health Services, dba Kindred at Home	334	
Maxim Healthcare Services, Inc.	10	
NHC Homecare	42	
Tennova Home Health	234	
University of TN Medical Center Home Care Services - Home He	441	

Resident County: **Shelby**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	16,266	100.0
Davidson	19	0.1
Elk Valley Health Services, LLC	19	
Fayette	1,186	7.3
NHC Homecare	171	
Where The Heart Is, Inc.	1,015	
Madison	338	2.1
Extendicare Home Health of West Tennessee	338	
Shelby	14,723	90.5
Accredo Health Group, Inc.	21	
Alere Women's and Children's Health	332	
Amedisys Home Care	947	
Amedisys Home Health	140	
Amedisys Home Health Care	686	
Americare Home Health Agency, Inc.	807	

Resident County: **Shelby** (Continued)

Facility Location/Name	Patients	Percent
Shelby (Continued)		
Baptist Trinity Home Care	2,871	
Baptist Trinity Home Care - Private Pay Division	1	
Best Nurses, Inc.	9	
Extended Health Care, Inc.	284	
Family Home Health Agency	504	
Functional Independence Home Care, Inc.	1,775	
Home Health Care of West Tennessee, Inc.	468	
Homechoice Health Services	977	
Intrepid USA Healthcare Services	565	
Maritan, Inc.	652	
Maxim Healthcare Services, Inc.	162	
Methodist Alliance Home Care	2,952	
No Place Like Home, Inc.	79	
Still Waters Home Health Agency	58	
Willowbrook Visiting Nurse Association, Inc.	433	

Resident County: **Smith**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	479	100.0
Davidson	74	15.4
Amedisys Home Health	54	
Amedisys Home Health Services	1	
Angel Private Duty and Home Health, Inc.	2	
Elk Valley Health Services, LLC	1	
Home Care Solutions	5	
Suncrest Home Health	2	
VIP Home Nursing & Rehabilitation Service, LLC DBA Careall	9	
DeKalb	88	18.4
Suncrest Home Health	88	
Putnam	5	1.0
Highland Rim Home Health Agency	2	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Smith (Continued)

Facility Location/Name	Patients	Percent
Putnam (Continued)		
Intrepid USA Healthcare Services	3	
Rutherford	42	8.8
NHC Homecare	42	
Sumner	83	17.3
Highpoint Homecare	83	
Warren	85	17.7
Friendship Home Health, Inc.	85	
Williamson	1	0.2
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	1	
Wilson	101	21.1
American National Home Health	45	
Deaconess Homecare	12	
Gentiva Health Services, dba Kindred at Home	44	

Resident County: Stewart

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	372	100.0
Benton	223	59.9
Tennessee Quality Homecare - Northwest	223	
Davidson	40	10.8
Amedisys Home Health	31	
Elk Valley Health Services, LLC	2	
Home Care Solutions	7	
Henry	10	2.7
Henry County Medical Center Home Health	10	
Montgomery	70	18.8
Gateway Home Health, Clarksville	44	
Suncrest Home Health of Nashville, Inc.	26	
Weakley	8	2.2
Careall Homecare Services	8	

Resident County: Stewart (Continued)

Facility Location/Name	Patients	Percent
Williamson	21	5.6
Guardian Home Care of Nashville	21	

Resident County: Sullivan

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	5,685	100.0
Carter	10	0.2
Amedisys Home Health Care	10	
Claiborne	174	3.1
Suncrest Home Health	174	
Cocke	145	2.6
Smoky Mountain Home Health and Hospice, Inc.	145	
Davidson	15	0.3
Elk Valley Health Services, LLC	15	
Greene	192	3.4
Advanced Home Care, Inc.	24	
Procare Home Health Services	168	
Hamblen	12	0.2
Premier Support Services	12	
Knox	1	0.0
Gentiva Health Services, dba Kindred at Home	1	
Sullivan	2,495	43.9
Advanced Home Care, Inc.	2,286	
Gentiva Health Services, dba Kindred at Home	209	
Washington	2,641	46.5
Amedysis Home Health	851	
Medical Center Homecare Services	10	
Medical Center Homecare, Kingsport	1,539	
NHC Homecare	241	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Trousdale

Facility Location/Name	Patients	Percent
Davidson (Continued)		
Home Health Care of Middle Tennessee, LLC	4	
Suncrest Home Health	65	
VIP Home Nursing & Rehabilitation Service, LLC DBA Careall	4	
Willowbrook Home Health Care Agency, Inc.	1	
Rutherford	8	3.1
NHC Homecare	8	
Sumner	25	9.7
Highpoint Homecare	25	
Warren	30	11.6
Friendship Home Health, Inc.	30	
Williamson	4	1.6
Guardian Home Care of Nashville	3	
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	1	
Wilson	25	9.7
American National Home Health	10	
Deaconess Homecare	3	
Gentiva Health Services, dba Kindred at Home	12	

Resident County: Unicoi

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	486	100.0
Carter	1	0.2
Amedisys Home Health Care	1	
Cocke	3	0.6
Smoky Mountain Home Health and Hospice, Inc.	3	
Davidson	2	0.4
Elk Valley Health Services, LLC	2	
Greene	16	3.3
Procare Home Health Services	16	
Sullivan	102	21.0
Gentiva Health Services, dba Kindred at Home	102	

Resident County: Unicoi (Continued)

Facility Location/Name	Patients	Percent
Washington	362	74.5
Amedysis Home Health	92	
Medical Center Homecare Services	228	
Medical Center Homecare, Kingsport	10	
NHC Homecare	32	

Resident County: Union

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	528	100.0
Anderson	4	0.8
Clinch River Home Health	3	
Professional Case Management of Tennessee	1	
Claiborne	225	42.6
Amedisys Home Health of Tennessee	196	
Suncrest Home Health	29	
Hamblen	3	0.6
Amedisys Home Health Care	3	
Knox	278	52.7
Amedisys Home Health Care	2	
Camellia Home Health of East Tennessee, LLC	6	
Covenant Homecare	37	
East Tennessee Children's Hospital Home Health Care	7	
Gentiva Health Services, dba Kindred at Home	11	
Maxim Healthcare Services, Inc.	2	
NHC Homecare	4	
Tennova Home Health	195	
University of TN Medical Center Home Care Services - Home He	14	
Monroe	18	3.4
Intrepid USA Healthcare Services	18	

Resident County: Van Buren

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	155	100.0
Bradley	2	1.3
Home Health Care of East Tennessee, Inc.	2	
Coffee	20	12.9
Suncrest Home Health	20	
Davidson	3	1.9
Elk Valley Health Services, LLC	2	
VIP Home Nursing & Rehabilitation Service, LLC DBA Careall	1	
Fentress	11	7.1
All Care Plus, Inc. dba Quality Home Health	11	
Hamilton	10	6.5
Amedisys Home Health	10	
Rutherford	49	31.6
NHC Homecare	49	
Warren	60	38.7
Friendship Home Health, Inc.	35	
Intrepid USA Healthcare Services	4	
JW Carell Enterprises, LLC DBA Careall Home Care Services	21	

Resident County: Warren

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,896	100.0
Coffee	26	1.4
Gentiva Health Services, dba Kindred at Home	1	
Suncrest Home Health	25	
Davidson	11	0.6
Angel Private Duty and Home Health, Inc.	2	
Elk Valley Health Services, LLC	3	
Home Care Solutions	3	
Intrepid USA Healthcare Services	1	
VIP Home Nursing & Rehabilitation Service, LLC DBA Careall	2	

Resident County: Warren (Continued)

Facility Location/Name	Patients	Percent
DeKalb	433	22.8
Suncrest Home Health	433	
Fentress	7	0.4
All Care Plus, Inc. dba Quality Home Health	7	
Franklin	53	2.8
Amedisys Home Care	44	
Caresouth HHA Holdings of Winchester, LLC	9	
Lincoln	12	0.6
Deaconess Homecare	12	
Putnam	1	0.1
Highland Rim Home Health Agency	1	
Rutherford	439	23.2
NHC Homecare	439	
Warren	914	48.2
Friendship Home Health, Inc.	659	
Intrepid USA Healthcare Services	140	
JW Carell Enterprises, LLC DBA Careall Home Care Services	115	

Resident County: Washington

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	3,967	100.0
Carter	19	0.5
Amedisys Home Health Care	19	
Cocke	37	0.9
Smoky Mountain Home Health and Hospice, Inc.	37	
Davidson	13	0.3
Elk Valley Health Services, LLC	13	
Greene	385	9.7
Advanced Home Care, Inc.	144	
Laughlin Home Health Agency	10	
Procare Home Health Services	231	

Resident County: **Washington** (Continued)

Facility Location/Name	Patients	Percent
Hamblen	9	0.2
Premier Support Services	9	
Johnson	3	0.1
Johnson County Home Health	3	
Sullivan	225	5.7
Advanced Home Care, Inc.	71	
Gentiva Health Services, dba Kindred at Home	154	
Washington	3,276	82.6
Amedysis Home Health	714	
Medical Center Homecare Services	2,124	
Medical Center Homecare, Kingsport	147	
NHC Homecare	291	

Resident County: **Wayne**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	739	100.0
Davidson	35	4.7
Elk Valley Health Services, LLC	35	
Decatur	326	44.1
Tennessee Quality Homecare-Southwest	143	
Volunteer Homecare of West Tennessee, Inc.	183	
Hardin	297	40.2
Deaconess Homecare	276	
HMC Home Health, LLC	21	
Maury	80	10.8
Maury Regional Home Services	17	
Maxlife at Home of Tennessee, LLC DBA CareAll Homecare Ser	39	
NHC Homecare	24	
Williamson	1	0.1
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	1	

Resident County: **Weakley**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,203	100.0
Benton	93	7.7
Tennessee Quality Homecare - Northwest	93	
Carroll	2	0.2
Baptist Memorial Home Care	2	
Davidson	3	0.2
Elk Valley Health Services, LLC	3	
Gibson	100	8.3
NHC Homecare	29	
Volunteer Home Care, Inc.	71	
Henderson	19	1.6
Regional Home Care, Lexington	19	
Henry	11	0.9
Henry County Medical Center Home Health	11	
Madison	439	36.5
Amedisys Home Health Care	98	
Extendicare Home Health of West Tennessee	2	
F.C of Tennessee	3	
Medical Center Home Health, LLC	6	
Regional Home Care, Jackson	330	
Obion	46	3.8
Extendicare Home Health of Western Tennessee	46	
Weakley	484	40.2
Careall Homecare Services	484	
Out-of-State	6	0.5
Regional Home Care Purchase Parkway	6	

Resident County: **White**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	953	100.0
Anderson	2	0.2
Professional Case Management of Tennessee	2	

Pharmacy Quality Management

Accreditation & Measurement

Accreditation Programs

Health and Dental Plan Programs

Healthcare Management Programs

Pharmacy Quality Management® Programs

Specialty Pharmacy Accreditation

Mail Service Pharmacy Accreditation

Community Pharmacy Accreditation

Pharmacy Benefit Management Accreditation

Workers Compensation Property and Casualty Pharmacy Benefit Management Accreditation

Drug Therapy Management Accreditation

Provider Integration & Coordination Programs

All Programs

Measurement

AccreditNet

Pharmacy Quality Management® Programs

URAC's Pharmacy Quality Management Accreditation programs offer unmatched prestige for organizations that achieve the URAC accreditation seal – recognized by health plans, employers, regulators and providers, as the gold standard in accreditation.

URAC's accreditation standards provide key performance benchmarks, raise the bar on quality improvement efforts, and support consumer protection and empowerment. URAC's facilitative approach to the accreditation process encourages learning in the organization, leading to improved operations and regulatory compliance activities.

Our Pharmacy Quality Management Accreditation programs include:

- Specialty Pharmacy Accreditation
- Mail Service Pharmacy Accreditation
- Community Pharmacy Accreditation
- Pharmacy Benefit Management Accreditation
- Workers Compensation and Property & Casualty Pharmacy Benefit Management Accreditation
- Drug Therapy Management Accreditation

Follow our Pharmacy Resources page on Linkedin for news, articles, updates, and more.

Accreditation & Measurement

What is Accreditation?

Accreditation is an evaluative, rigorous, transparent, and comprehensive process in which a health care organization undergoes an examination of its systems, processes, and performance by an impartial external organization (accrediting body) to ensure that it is conducting business in a manner that meets predetermined criteria and is consistent with national standards.

What is Measurement?

Measurement facilitates quality improvement and enables more meaningful comparisons among accredited organizations. Beginning with measures concepts familiar to the industry, URAC is adding quantitative measures to our accreditation programs. URAC is committed to aligning and harmonizing its performance measures with the national quality endeavors of the federal, state, and local governments to address key health issues of the population.

Measurement

Through its performance measurement program, URAC promotes continuous improvement in the quality and efficiency of health care. Quality improvement initiatives cannot be realized without performance measures that are "coherent, robust, and integrated" into a system that is "purposeful, comprehensive, efficient, and transparent" (IOM, 2005: 4)

Performance measures selected for use by URAC provide a more comprehensive view of quality in broad topic areas while being sensitive to the administrative burden associated with the data collection required to report performance to the public. The measures add and incorporate "state-of-the-art" scientific evidence to assess health care quality and safety. Through its unique approach to measurement, URAC selects measures harmonized with other federal, state, and local quality measurement and reporting initiatives.

Reporting Measures Data

In an attempt to harmonize measure requirements, URAC's Measures Advisory and Research Group has recommended that beginning with the 2017 reporting period, health plans will be required to report the Quality Rating System Measure Set (QRS) to fulfill their accreditation requirement. These measures can be submitted via a selected web-based survey platform and an administrative fee will be assessed prior to the measure submission period that begins in July. Beginning in 2018, URAC will require health plans to have their submitted data validated by an approved independent third party to fulfill the accreditation requirement for reporting measures.

Clients with other URAC accreditation programs that require measure submission will also use the web-based survey platform as designated by URAC. Beginning in 2017, URAC will charge an administrative fee will be assessed to submit measures using this tool.

As with health plans, some other URAC programs are additionally required to have their data audited and validated (e.g., the Pharmacy Quality Management® programs). Data validation services are currently being offered by four URAC-approved vendors. Click here to download information on these vendors in PDF format.

URAC clients may select and contract with any of these URAC-approved data validation vendors:

Advent Advisory Group
Attest Health Care Advisors
HealthcareData Company, LLC
MetaStar

If you have questions, please contact your URAC account manager.

Support Letters

From Maryann Reilly,

To whom it may concern,
I have recently moved from California to Tennessee. In California I had Axelacare Nursing for my much needed IVIG infusions in my home. Since moving to Tennessee it has taken a month to get contracted nursing to agree to take on my case. I am now almost a month behind in my infusions. Luckily I have tolerated the delay fairly well, but as a retired nurse I know that this is not always the case and I might have become very ill.
I know that if Axelacare had a CON and License in the state my care would not have been delayed putting me at risk.
Please grant Axelacare the License they request so care can be delivered to the IVIG community in a timely manner.
Thanks for your consideration, Maryann Reilly RN.

From Patient - Maryann Reilly
new patient in Murfreesboro TN

FEB 13 '17 PM2:05

From Patient - David Haynes
active from Cookeville TN

Hey Dennis, here is the letter to assist with the license you asked for.

I am a current patient with Axelacare and get my nursing from a local Home Care Company. It took along time to get me started on my infusions due to lack of nursing in Cookeville TN. Finally I did get started and my nurse does fine, but it took along time to get set up and caused me a lot of worry and time. If Axelacare had their own nurses all of this would not have happened. Also I get confused some times about who to call when. I have 2 companies to call and keeping them straight is hard some times. It would be much easier on all patients if Axelacare could provide the care needed.

Sincerely David Haynes

State of Tennessee
Health Services and Development Agency
Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

March 1, 2017

John Wellborn
Development Support Group
4219 Hillsboro Road, Suite 210
Nashville, TN 37215

RE: Certificate of Need Application -- AxelaCare Health Solutions, LLC., (East Tennessee) - CN1702-008
The addition of 34 East Tennessee Counties to an established home care organization limited to the home infusion of immune globulin pharmaceuticals. The principal office will be located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis (Shelby County) Tennessee. The service area includes Anderson, Bledsoe, Blount, Bradley, Campbell, Carter, Claiborne, Cocke, Cumberland, Grainger, Greene, Hamblen, Hamilton, Hancock, Hawkins, Jefferson, Johnson, Knox, Loudon, McMinn, Marion, Meigs, Monroe, Morgan, Polk, Rhea, Roane, Scott, Sequatchie, Sevier, Sullivan, Unicoi, Union, and Washington Counties. The estimated project cost is $70,000.

Dear Mr. Wellborn:

This is to acknowledge the receipt of supplemental information to your application for a Certificate of Need. Please be advised that your application is now considered to be complete by this office.

Your application is being forwarded to Trent Sansing at the Tennessee Department of Health for Certificate of Need review by the Division of Policy, Planning and Assessment. You may be contacted by Mr. Sansing or someone from his office for additional clarification while the application is under review by the Department. Mr. Sansing's contact information is Trent.Sansing@tn.gov or 615-253-4702.

In accordance with Tennessee Code Annotated, §68-11-1607, et seq., as amended by Public Chapter 780, the 60-day review cycle for this project will begin on March 1, 2017. The first 60 days of the cycle are assigned to the Department of Health, during which time a public hearing may be held on your application. You will be contacted by a representative from this Agency to establish the date, time and place of the hearing should one be requested. At the end of the 60-day period, a written report from the Department of Health or its representative will be forwarded to this office for Agency review. You will receive a copy of their findings. The Health Services and Development Agency will review your application on June 28, 2017.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

(1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the Certificate of Need file.

(2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the Certificate of Need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have questions or require additional information, please contact me.

Sincerely,

Melanie M. Hill /NF

Melanie M. Hill
Executive Director

cc: Trent Sansing, TDH/Health Statistics, PPA

State of Tennessee
Health Services and Development Agency
Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

MEMORANDUM

TO: Trent Sansing, CON Director
Office of Policy, Planning and Assessment
Division of Health Statistics
Andrew Johnson Tower, 2nd Floor
710 James Robertson Parkway
Nashville, Tennessee 37243

FROM: Melanie M. Hill MMH/MF
Executive Director

DATE: March 1, 2017

RE: Certificate of Need Application
AxelaCare Health Solutions, LLC., (East Tennessee) - CN1702-008

Please find enclosed an application for a Certificate of Need for the above-referenced project.

This application has undergone initial review by this office and has been deemed complete. It is being forwarded to your agency for a sixty (60) day review period to begin on March 1, 2017 and end on May 1, 2017.

Should there be any questions regarding this application or the review cycle, please contact this office.

Enclosure

cc: John Wellborn

FEB 8 '17 AM11:20

LETTER OF INTENT -- HEALTH SERVICES & DEVELOPMENT AGENCY

The Publication of Intent is to be published on or before February 8, 2017, for one day, in the following newspapers:

(a) The *Knoxville News Sentinel*, which is a newspaper of general circulation in Anderson, Blount, Campbell, Claiborne, Cocke, Cumberland, Grainger, Hamblen, Jefferson, Knox, Loudon, McMinn, Monroe, Morgan, Roane, Scott, Sevier and Union Counties;

(b) The *Chattanooga Times Free Press*, which is a newspaper of general circulation in Bledsoe, Bradley, Hamilton, Marion, McMinn, Meigs, Polk, Rhea and Sequatchie Counties;

(c) The *Greeneville Sun*, which is a newspaper of general circulation in Greene County;

(d) The *Johnson City Press*, which is a newspaper of general circulation in Carter, Johnson, Unicoi and Washington Counties;

(e) The *Kingsport Times-News*, which is a newspaper of general circulation in Hawkins and Sullivan Counties; and

(f) The *Rogersville Review*, which is a newspaper of general circulation in Hancock and Hawkins Counties.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that AxelaCare Health Solutions, LLC (a home health agency with its principal office in Shelby County), owned and managed by AxelaCare Health Solutions, LLC (a limited liability company), intends to file an application for a Certificate of Need to expand its authorized service area to include 34 East Tennessee counties, which are Anderson, Bledsoe, Blount, Bradley, Campbell, Carter, Claiborne, Cocke, Cumberland, Grainger, Greene, Hamblen, Hamilton, Hancock, Hawkins, Jefferson, Johnson, Knox, Loudon, McMinn, Marion, Meigs, Monroe, Morgan, Polk, Rhea, Roane, Scott, Sequatchie, Sevier, Sullivan, Unicoi, Union, and Washington Counties. The project cost is estimated at $70,000. The agency's principal office is located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis, TN 38137. The project will not expand the agency's authorized scope of service, which is exclusively limited to the home infusion of immune globulin pharmaceuticals and related nursing services.

The applicant's initial licensure as a Home Health Agency (limited as described above) is pending before the Board for Licensing Health Care facilities. The project does not contain major medical equipment or initiate or discontinue any other health service, and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before February 13, 2017. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

(Signature)	16 FEB. 2017 (Date)	bphillips@bassberry.com (E-mail Address)

21268148.2

FEB 8'17 AM11:21

SUPPLEMENTAL 1

ORIGINAL

AxelaCare Health Solutions LLC (East TN)

CN1702-008

DSG Development Support Group

SUPPLEMENTAL #1
February 21, 2017
9:37 am
FEB 21 2017 AM 8:38

February 20, 2017

Phillip M. Earhart, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN 1702-008
AxelaCare Health Solutions, LLC--East Tennessee Expansion

Dear Mr. Earhart:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

1. **Section A: Executive Summary, A. Overview**
   In the middle of page 3 the applicant refers to two East Tennessee applications. If incorrect, please revise and submit a replacement page 3.

   The corrected page 3R is attached following this page.

2. **Section A, Project Details, Item 6.A**
   As required for all projects, a Plot Plan must provide the size of the site (in acres), location of the structure on the site, the location of the proposed construction, and the names of streets, roads, highways that cross or border the site. Please provide a new Plot Plan with all the required information.

   See the response to question #3 below.

3. **Section A, Project Details, Item 6.B**
   Please provide a floor plan of the principal office located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis (Shelby County) Tennessee.

   The requested plot plan and floor plan of the principal office are provided following this page.

4219 Hillsboro Road, Suite 203
Nashville, TN 37215
jwdsg@comcast.net
Tel 615.665.2022
Fax 615.665.2042

3. SECTION A: EXECUTIVE SUMMARY

A. Overview

Please provide an overview not to exceed three pages in total, explaining each numbered point.

(1) Description (Address the establishment of a health care institution, initiation of health services, bed complement changes, and/or how this project relates to any other outstanding but unimplemented certificates of need held by the applicant.)

Specialty home infusion is the process of providing very specialized medications intravenously in a patient's home, with the presence and support of a skilled registered nurse (R.N.) who works under the direction of the patient's referring physician. This is a very specialized therapy needed by a small group of seriously ill patients. It requires prolonged hours of onsite, in-home skilled nursing care, often on several consecutive days each month. Almost no nursing agencies are willing or able to staff for this type of therapy routinely -- especially since patient demand is small due to lack of Medicare reimbursement except when the infusion patient is totally homebound and, therefore, qualifies for Medicare reimbursement.

In 2016, AxelaCare Health Solutions, the applicant, requested CON approval to establish a home health agency to serve 21 West Tennessee counties. Its scope of service was to be limited to the home infusion of specialized immune globulin pharmaceuticals and nursing services necessary to provide for that specific type of infusion therapy.

The CON Board unanimously approved the application.

The approved application stated that, in two subsequent applications, AxelaCare would propose extending this limited home health service to all other Tennessee counties. This present application is to expand AxelaCare's authorized service area to cover 34 additional East Tennessee counties. A companion application has been filed simultaneously to serve 40 counties of Middle Tennessee. If both are approved, AxelaCare's specialized home health nurses will be able to meet specialized patient needs for immune globulin infusions in all 95 Tennessee counties.

As in the approved West Tennessee project, this service will be provided only to a very small number of patients whose physicians have prescribed infusion of specialized immune globulin medications. The non-homebound patients served by the project will not be eligible for Medicare or TennCare reimbursement for this home care service under existing reimbursement rules. The service, therefore, is proposed for privately insured patients, and a small number of charity patients. The same was true of the approved West Tennessee application.

The applicant home health agency, which expects to achieve State licensure for West Tennessee by February 2017, will maintain its principal office in Memphis/Shelby County and will provide home nursing service through R.N. field staff residing in one or more counties in East Tennessee to ensure appropriate drive time accessibility to the patients they serve.

Branch offices are not necessary for nurse training and support, which will be delivered in the field. As in other technologically advanced companies, principal office employees linked electronically will provide staff recruitment, training, scheduling, business management and other components of the program, both in Memphis and in varying locations in East Tennessee.

SUPPLEMENTAL #1

February 21, 2017
9:37 am

CHEYENNE JOHNSON

Assessor of Property

Shelby County, TN

Property Detail | Property Details | Map

Property

Property Address
5100 POPLAR AVE

Parcel ID
056033 00237

Owner Name
CLARK TOWER LLC

2015 Appraised Value
$22,010,300

Property/Assessment Details
Click Here

Deed Information
Click Here

County Tax
Click Here

City Tax
Click Here

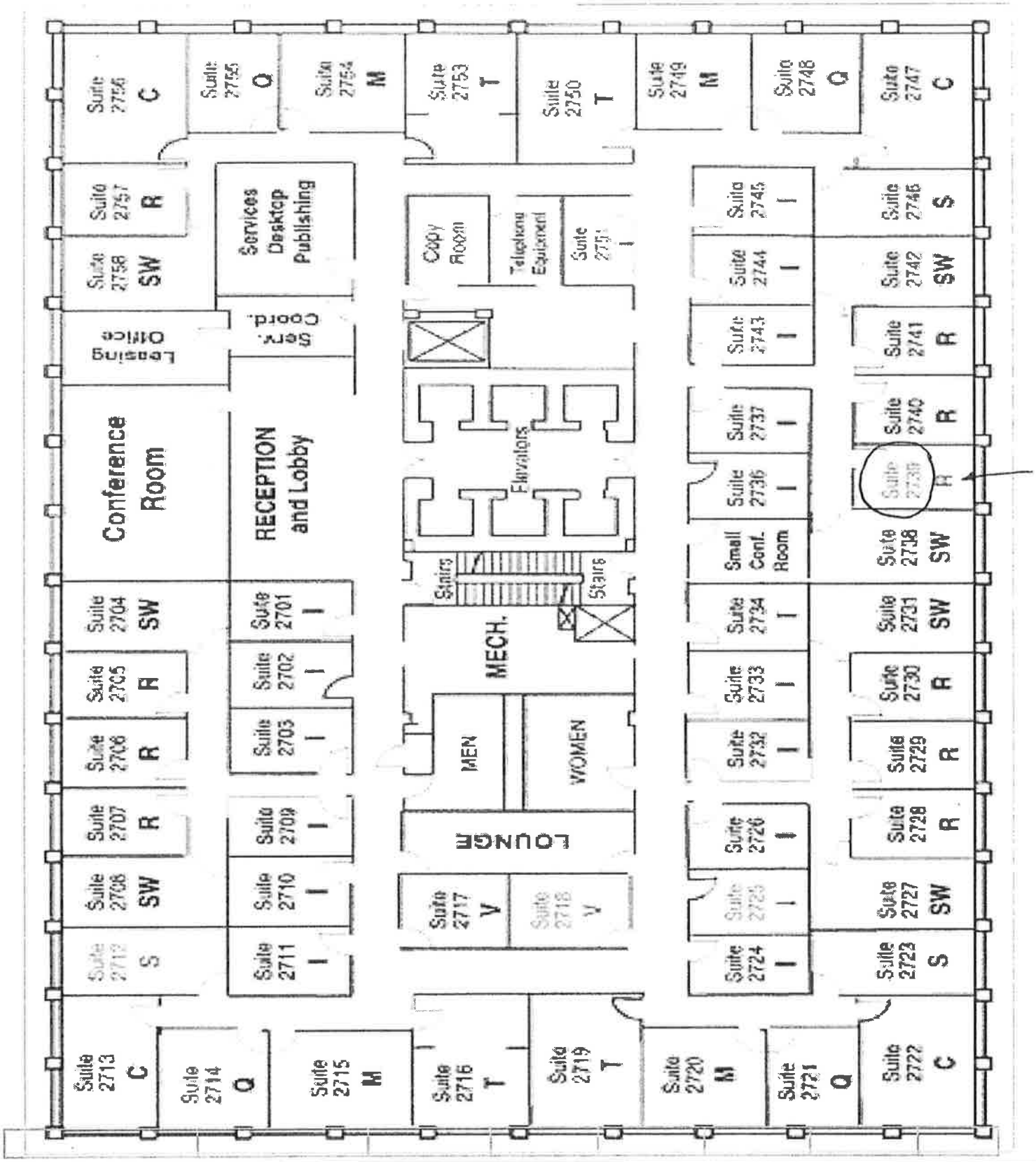
Layers

Search Property Sales

PROJECT ON
27th FLOOR

CLARK TOWER

SITE 7.79 acres


Suite 2756 C
Suite 2755 Q
Suite 2754 M
Suite 2753 T
Suite 2750 T
Suite 2749 M
Suite 2748 Q
Suite 2747 C
Suite 2757 R
Suite 2758 SW
Services Desktop Publishing
Copy Room
Telephone Equipment
Suite 2751 I
Suite 2745 I
Suite 2746 S
Suite 2744 I
Suite 2742 SW
Leasing Office
Serv. Coord.
Suite 2743 I
Suite 2741 R
Conference Room
RECEPTION and Lobby
Elevators
Suite 2737 I
Suite 2740 R
Suite 2736 I
Suite 2739 R
Small Conf. Room
Suite 2738 SW
Stairs
Stairs
Suite 2704 SW
Suite 2701 I
Suite 2734 I
Suite 2731 SW
MECH.
Suite 2705 R
Suite 2702 I
Suite 2733 I
Suite 2730 R
Suite 2706 R
Suite 2703 I
MEN
WOMEN
Suite 2732 I
Suite 2729 R
Suite 2707 R
Suite 2709 I
LOUNGE
Suite 2726 I
Suite 2728 R
Suite 2708 SW
Suite 2710 I
Suite 2717 V
Suite 2718 V
Suite 2725 I
Suite 2727 SW
Suite 2712 S
Suite 2711 I
Suite 2724 I
Suite 2723 S
Suite 2713 C
Suite 2714 Q
Suite 2715 M
Suite 2716 T
Suite 2719 T
Suite 2720 M
Suite 2721 Q
Suite 2722 C

4. Section A, Project Details, Home Health Organizations

The table of the applicant's licensed counties on page 19 is noted. However, the applicant checked 21 West Tennessee Counties as being licensed by the applicant. Please clarify if the applicant will be operating under one home health license for the whole state. If not, please revise the home health chart to only include the proposed 34 East Tennessee Counties.

No revision is necessary. This application and its companion application together propose expanding the applicant's West Tennessee license to include all other counties in the State. The applicant will be operating under a single home health license, with one principal office.

5. Section B, Need, Item 1.a. (Project Specific Criteria-Home Health Services) Item #4 County Need Standard

The applicant provided support letters from 2 patients that do not reside in the proposed service area. Please provide letters from each county in the proposed service area of potential patients and/or providers according to the listed County Need Standard criteria.

Additional support letters are being gathered by the applicant and will be submitted later in February. However, the applicant does not anticipate securing a support letter from every one of the forty counties in this proposed service area, before being accepted into the March review cycle.

6. Section B, Need, Item 1.a. (Project-Specific Criteria-Home Health Services) Item #5 Current Service Area Utilization

It is noted the applicant states "the tables are in the attachments" for the patients each agency served in CY2015 within the proposed service area. Please clarify the location of the attachments which the applicant is referring.

They are located in Attachment B-Need-5, as listed in the Index of Attachments on page 70 of the application.

7. Section B, Need, Item 1.a. (Project Specific Criteria-Home Health Services) Item #11 Quality Control and Monitoring

Please indicate where the referenced examples of AxelCare's Quality Improvement Program is located in the attachments.

It is in Attachment C, Need--1, described as "Performance Improvement Plan". This is the same corporate program accepted in review of the West Tennessee AxelaCare application.

8. Section B, Need, Item 5

a. On page 38 the applicant refers to Table B.5-3A. However, the table could not be located. Please clarify.

This was an inadvertent omission. That two-page table is attached following this page. It provides the same information that is in Tables B.5-3B and C but is sorted by agency name.

b. In the middle of page 40 the applicant notes the proposed service area is 40 counties rather than 34. Please correct and provide a revised page 38.

The corrected page 38R is attached following the tables after this page.

SUPPLEMENTAL #1

February 21, 2017

9:37 am

Table B.5-3A: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area
BY AGENCY NAME

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
30021	Greene	Advanced Home Care, Inc.	86	8/31/83	762	817	845	845	100.0%
82051	Sullivan	Advanced Home Care, Inc.	249	4/9/85	2,245	2,276	2,641	2,628	99.5%
33423	Hamilton	Alere Women's and Children's Health, LLC	457	11/13/98	61	50	40	32	80.0%
26054	Franklin	Amedisys Home Care	82	9/19/83	1,150	1,002	909	3	0.3%
33103	Hamilton	Amedisys Home Health	113	7/1/81	2,878	2,564	2,610	2,599	99.6%
67024	Overton	Amedisys Home Health	191	1/17/84	1,101	949	1,101	176	16.0%
90121	Washington	Amedisys Home Health	273	7/6/84	1,821	1,460	1,676	1,676	100.0%
10031	Carter	Amedisys Home Health Care	23	1/20/84	1,171	937	901	901	100.0%
32102	Hamblen	Amedisys Home Health Care	91	12/13/82	3,896	3,210	3,099	3,094	99.8%
47202	Knox	Amedisys Home Health Care	150	8/2/84	5,354	4,391	4,548	4,548	100.0%
75064	Rutherford	Amedisys Home Health Care	5	8/23/84	1,582	1,372	1,265	0	0.0%
13022	Claiborne	Amedisys Home Health of Tennessee	25	10/8/82	1,830	1,547	1,551	1,551	100.0%
05012	Blount	Blount Memorial Hospital Home Health Services	213	1/26/15	1,224	1,281	1,589	1,589	100.0%
47062	Knox	Camellia Home Health of East Tennessee	144	9/7/78	1,716	1,732	2,215	2,213	99.9%
19724	Davidson	Careall	295	7/5/84	1,562	1,665	891	116	13.0%
47232	Knox	Careall Home Care Services	131	8/21/89	510	686	0	0	0.0%
89074	Warren	Careall Home Care Services	265	1/31/84	637	974	749	456	60.9%
33253	Hamilton	CHI Memorial Health at Home	103	8/9/82	2,439	2,651	2,852	2,851	100.0%
01032	Anderson	Clinch River Home Health	1	10/26/76	461	481	450	450	0.0%
33213	Hamilton	Continuecare Healthservices, Inc. I	98	11/2/84	1,466	1,393	1,356	1,356	100.0%
33383	Hamilton	Continuecare Healthservices, Inc. II	108	5/7/76	8	7	7	7	100.0%
19734	Davidson	Corum CVS Specialty Infusion Services	624	1/30/13	11	26	36	0	0.0%
47402	Knox	Covenant Homecare	133	7/14/78	3,953	4,792	5,391	5,389	100.0%
14024	Clay	Cumberland River Homecare	135	12/28/82	392	393	293	38	13.0%
52024	Lincoln	Deaconess Homecare	161	2/25/76	842	1,294	731	0	0.0%
76032	Scott	Deaconess Homecare	211	9/20/85	394	603	338	316	93.5%
95034	Wilson	Deaconess Homecare I	282	12/18/78	1,222	1,706	956	53	5.5%
47222	Knox	East Tennessee Children's Hospital Home Health	132	9/13/84	586	600	560	560	100.0%
19494	Davidson	Elk Valley Health Services	42	7/17/84	277	293	457	115	25.2%
26024	Franklin	Encompass Home Health of Tennessee	83	1/29/76	2,030	2,444	2,581	745	28.9%
06043	Bradley	Family Home Care - Cleveland	13	1/10/84	598	1,454	1,494	1,494	100.0%
33093	Hamilton	Gentiva Health Services	100	8/24/84	328	348	426	424	99.5%
47042	Knox	Gentiva Health Services	142	11/28/77	779	413	80	80	100.0%
82061	Sullivan	Gentiva Health Services	251	11/3/83	936	612	598	597	99.8%
47182	Knox	Gentiva Health Services 2 (Girling Health Services)	149	8/15/84	1,467	1,815	1,675	1,673	99.9%
33083	Hamilton	Guardian Home Care, LLC	115	6/29/78	1,484	1,255	1,929	1,926	99.8%
34011	Hancock	Hancock County Home Health and Hospice Agency	117	7/23/75	463	488	648	648	100.0%
71014	Putnam	Highland Rim Home Health Agency	197	5/2/78	574	497	549	1	0.2%
33363	Hamilton	Home Care Solutions	338	11/14/96	663	540	473	465	98.3%
19544	Davidson	Home Care Solutions, Inc.	56	9/7/88	1,930	1,689	1,813	273	15.1%
06063	Bradley	Home Health Care of East Tennessee, Inc.	14	3/14/84	3,318	2,680	1,580	1,454	92.0%
37021	Hawkins	Hometown Home Health, Inc.	320	1/9/95	89	94	108	108	100.0%
	Knox	Implanted Pump Management	633				0	0	0.0%
62052	Monroe	Intrepid USA Healthcare Services	190	9/10/84	358	355	565	565	100.0%
71084	Putnam	Intrepid USA Healthcare Services	198	6/19/84	327	281	369	46	12.5%
89064	Warren	Intrepid USA Healthcare Services	263	8/1/84	822	804	843	0	0.0%
46031	Johnson	Johnson County Home Health.	130	6/29/84	446	492	447	447	100.0%
30041	Greene	Laughlin Home Health Agency	88	6/26/84	655	737	711	711	100.0%
33433	Hamilton	Maxim Healthcare Services	613	8/18/05	56	53	57	57	100.0%
	Washington	Maxim Healthcare Services	629				0	0	0.0%
47432	Knox	Maxim Healthcare Services, Inc.	2	6/20/84	159	154	214	214	0.0%
90081	Washington	Medical Center Homecare - Kingsport	269	11/4/83	1,960	1,846	1,923	1,923	100.0%
90091	Washington	Medical Center Homecare Services	271	5/4/84	3,503	3,714	3,625	3,625	0.0%
33033	Hamilton	NHC Homecare	111	6/10/77	354	411	278	278	100.0%
47012	Knox	NHC Homecare	143	6/10/77	613	883	870	870	100.0%
54043	McMinn	NHC Homecare	166	2/13/84	239	358	421	421	100.0%
75024	Rutherford	NHC Homecare	208	5/17/76	3,776	4,180	4,270	74	1.7%
90131	Washington	NHC Homecare	267	3/22/78	259	465	611	611	100.0%
19654	Davidson	Optum Women's and Children's Health, LLC	471	3/1/99	202	186	196	0	0.0%

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Table B.5-3A: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area BY AGENCY NAME

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
	Davidson	Pentec Health	632				0	0	0.0%
32132	Hamblen	Premier Support Services, Inc.	10	5/16/84	1,169	1,372	1,126	1,126	100.0%
30051	Greene	Procare Home Health Services	87	7/8/82	433	522	574	574	100.0%
01042	Anderson	Professional Case Management of Tennessee	620	1/30/08	164	173	249	242	97.2%
96030	London Co, KY	Professional Home Health Care Agency	298	9/2/77	12	21	6	6	100.0%
25044	Fentress	Quality Home Health	287	3/7/84	3,404	3,591	4,278	2,778	64.9%
25034	Fentress	Quality Private Duty Care	80	10/28/83	879	894	784	340	0.0%
15032	Cocke	Smoky Mountain Home Health and Hospice	27	11/9/89	1,296	1,102	1,128	1,128	100.0%
07032	Campbell	Sunbelt Homecare	16	8/10/84	261	243	253	253	100.0%
16034	Coffee	Suncrest Home Health	29	4/16/84	1,588	2,122	1,667	49	2.9%
13032	Claiborne	Suncrest Home Health and Hospice	93	9/14/84	852	1,008	663	663	100.0%
62062	Monroe	Sweetwater Hospital Home Health	189	8/20/84	613	625	651	651	100.0%
33303	Hamilton	Tennessee Home Health (Lifecare)	109	11/7/84	956	1,298	520	520	100.0%
47092	Knox	Tennova Healthcare Home Health	151	2/29/80	3,063	3,240	4,029	4,029	100.0%
01052	Anderson	The Home Option by Hardin Health Care	148	12/13/84			79	79	0.0%
32122	Hamblen	Univ. of TN Med Cntr Home Health / Hospice Service	153	12/18/84	1,327	751	1,145	1,145	0.0%
47132	Knox	UTMCK - Home Care Services: Hospice & Home Care	156	7/20/83	3,439	771	2,104	2,104	0.0%
		AREAWIDE TOTALS AND AVERAGES			**89,395**	**88,133**	**88,667**	**68,979**	**77.8%**

Source: TDH; 2013-2015 Joint Annual Reports of Home Health Agencies

5. Describe the existing and approved but unimplemented services of similar healthcare providers in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. List each provider and its utilization and/or occupancy individually. Inpatient bed projects must provide the following data: admissions or discharges, patient days, average length of stay, and occupancy. Other projects should use the appropriate measures, e.g., cases, procedures, visits, admissions, etc. This does not apply to projects that are solely relocating a service.

Attachment Need-B-5 contains a series of tables that identify all the home health agencies currently authorized to serve this area, and provide utilization data from their final 2013-2015 Joint Annual Reports. *(Note: these are the same categories of statistics that were accepted for AxelaCare's approved West Tennessee CN#1606-022.)*

Tables

- Tables B.5-1A & 1B: Service area counties that are authorized for each approved agency.

- Tables B.5-2A & 2B: Patients served during 2015, in each agency's authorized counties within the project service area.

- Tables B.5-3A & 3B & 3C: Area agencies' patient utilization 2013-2015, with agencies' dependence on patients from the project service area.

- Tables B.5-4A &4B & 4C: Agencies' TennCare gross revenues (charges) as a percent of their total gross revenues, and a ranking by level of TennCare participation.

These tables show the following:

1. There are 76 agencies licensed to serve one or more counties in this project's 34-county service area--ranging from 15 agencies for Johnson County to 31 agencies for Roane County.

2. Only 5 of 74 surveyed providers (one of whom consists of 3 separately licensed agencies under common ownership) indicated an ability to infuse IG patients. Of the 5, only 1 is licensed to serve all 34 service area counties. But it has only 1 IVIG nurse for all of that territory. The remaining five agencies do not have complete geographic coverage of the service area. Their gaps in licensure coverage vary from 82% to 90% of the service area counties. This demonstrates a shortage of home care providers for a small subset of IG patients with serious needs.

3. The agencies served 68,979 home care patients in the project service area in 2015.

4. The applicant's projected 35 patients in CY2019 equates to only .05% (five-hundredths of one percent) of the patients served by all agencies in 2015. Therefore the project will have almost no measurable impact on existing agencies collectively.

5. The 76 agencies' 23.3% *average* TennCare utilization is misleading. Only 17 of the 76 agencies had a TennCare mix that high; while 36 agencies (47% of the total) served no TennCare patients at all.

9. Section C, Need, Item 6

a. It is noted AxelaCare Health Solutions, CN1606-022A, approved at the October 26, 2016 Agency meeting to establish a home care organization and initiate home health services limited to the home infusion of immune globulin pharmaceuticals in 21 West Tennessee counties reduced the projected number of patients in Year One from 45 to 20. Please explain why the applicant overestimated projections for CN1606-022A and why patient projections for this project will not follow a similar pattern.

Following is an excerpt from response #10 on page 11 of CN1606-022A's June 22, 2016 supplemental information response letter. The "127" number in this excerpt was data for CY2015, the most current complete year prior to that applications' filing.

*"AxelaCare reviewed their Tennessee referrals and identified **127 referred IVIG patients Statewide**. It was assumed that at least this level of referrals will continue...One-third (43) patients were projected to be coming from West Tennessee...and that was...rounded up to 45 patients to allow for annual increases in demand. For the second year, a growth to 65 patients was assumed because where local marketing and community linkages are in place, AxelaCare typically sees a minimum of 5 to 6 new referrals per month."*

In researching CY2016 Statewide referral numbers for these two current applications for Middle and East Tennessee counties, AxelaCare found no record of total referral requests to AxelaCare, but did find that in CY2016, 37 patients were actually accepted, from an unrecorded larger number of referral requests. The company believes that the 127 number in the earlier application was an estimate of total referrals in CY2015--not patients actually accepted after clinical review.

To correct the prior error, in this current application, AxelaCare has submitted revised projections for the approved West Tennessee operation--20 and 30 patients in Years One and Two respectively (page 39 of the current application). The methodology for AxelaCare's Statewide projection is now based on a verified number of patients actually qualified and accepted for AxelaCare infusions. The methodology and Statewide allocation among West, Middle, and East Tennessee is detailed on page 39-40 of the current application.

Attached after this page is a Projected Development Chart for the West Tennessee territory alone, showing that it remains financially feasible even at these lower revised utilization projections. Also attached for this East Tennessee application is revised page 47R correcting the mislabeled chart title from "Middle" to "East Tennessee".

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PROJECTED DATA CHART-- AXELACARE WEST TENNESSEE ONEY

CONSOLIDATED OPERATIONS: NURSING, HOME OFFICE, & PHARMACEUTICALS

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

				CY 2018	CY 2019
		PATIENTS		20	30
A.	Utilization Data	VISITS		480	720
B.	Revenue from Services to Patients				
	1. Inpatient Services		$	$	
	2. Outpatient Services-home health nursing visits			2,035,200	3,052,800
	3. Emergency Services			0	0
	4. Other Operating Revenue (Specify)	See notes page		0	0
		Gross Operating Revenue	$	$ 2,035,200	3,052,800
C.	Deductions for Operating Revenue				
	1. Contractual Adjustments		$	0	0
	2. Provision for Charity Care			40,704	61,056
	3. Provisions for Bad Debt			20,352	30,528
		Total Deductions	$	$ 61,056	91,584
NET OPERATING REVENUE			$	$ 1,974,144	2,961,216
D.	Operating Expenses				
	1. Salaries and Wages		$	717,664	739,194
	2. Physicians Salaries and Wages			0	0
	3. Supplies			1,123,027	1,684,541
	4. Taxes			12,000	172,000
	5. Depreciation			7,500	5,000
	6. Rent			36,209	36,209
	7. Interest, other than Capital			0	0
	8. Management Fees			0	0
	a. Fees to Affiliates			0	0
	b. Fees to Non-Affiliates			0	0
	9. Other Expenses (Specify)	See notes page		58,783	58,783
		Total Operating Expenses	$	$ 1,955,183	2,695,727
E.	Other Revenue (Expenses) -- Net (Specify)		$	0	0
NET OPERATING INCOME (LOSS)			$	$ 18,961	265,489
F.	Capital Expenditures				
	1. Equipment		$	250,000	25,000
	2. Interest			0	0
		Total Capital Expenditures	$	$ 250,000	25,000
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES			$	$ (231,039)	240,489

New Supplemental

PROJECTED DATA CHART --AXELACARE EAST TENNESSEE (PHARMACEUTICALS ONLY)

information for the last three (3) years for which complete data are available for the facility or agency.
iscal year begins in January.

		Year 2018 (Year One)	Year 2019 (Year Two)
Utilization Data	Patients	25	35
(Specify unit or measure)	Visits	600	840
Revenue from Services to Patients			
1. Inpatient Services		$	$
2. Outpatient Services		2,400,000	3,360,000
3. Emergency Services			
4. Other Operating Revenue			
(Specify) See notes page			
	Gross Operating Revenue	$ 2,400,000	$ 3,360,000
Deductions from Gross Operating Revenue			
1. Contractual Adjustments		$	$
2. Provision for Charity Care		48,000	67,200
3. Provisions for Bad Debt		24,000	33,600
	Total Deductions	$ 72,000	$ 100,800
OPERATING REVENUE		$ 2,328,000	$ 3,259,200
Operating Expenses			
1. Salaries and Wages			
a. Clinical		$ 287,500	$ 296,125
b. Non-Clinical			
2. Physicians Salaries and Wages			
3. Supplies		1,396,800	1,955,520
4. Rent			
c. Paid to Affiliates			
d. Paid to Non-Affiliates			
5. Management Fees			
a. Paid to Affiliates			
b. Paid to Non-Affiliates			
6. Other Operating Expenses	See notes page	19,200	26,400
	Total Operating Expenses	$ 1,703,500	$ 2,278,045
Earnings Before Interest, Taxes, and Depreciation		$ 624,500	$ 981,155
Non-Operating Expenses			
1. Taxes		$ 120,000	$ 240,000
2. Depreciation		15,000	25,000
3. Interest			
4. Other Non-Operating Expenses			
	Total Non-Operating Expenses	$ 135,000	$ 265,000
NCOME (LOSS)		$ 489,500	$ 716,155

: *Continues Onto Next Page*

b. Page 39 (bottom)- If 37 patients were referred to other home health agencies in 2016, why is this project needed?

The reason why AxelaCare wants to retain these patients for treatment by its own staff are clearly stated on pages 6-7 ("Need") of the submitted application. It is difficult for AxelaCare to locate agencies that are staffed and prepared to meet AxelaCare's standards for infusion of AxelaCare immune globulin products. Those standards include prompt initiation of home service, use of the CareExchange technology to optimize communication with the physician and pharmacist during infusion, use of highly skilled nurses focused on home infusion, and contribution of clinical data to research efforts in this complex clinical field of medicine. There are almost no providers who meet these qualifications in all of the counties proposed in this project. This project will provide complete regional coverage for this specialized type of patient.

10. Section B. Economic Feasibility Item 2 Funding

It is noted the proposed project will be funded by the applicant's parent company. However, the financial balance sheets of UnitedHealth Group ending September 31, 2016 reflects total current assets of $35,768,000,000 and current liabilities of $51,096,000,000, and a current ratio of .70 to 1. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities. Please clarify if the applicant has the cash available to fund the proposed project. If so, please provide documentation from a bank or financial institution.

Yes, the applicant's parent company has ample cash available to finance the project; and no loan funding is needed or projected. UnitedHealth Group is a Fortune 6 company that had net earnings of almost $2 billion in the first nine months of 2016, as shown in its income statement in the Attachments to the application. This is clearly sufficient cash to cover the small, approximately $70,000 implementation costs associated with this application. As stated in Mr. Collins' letter assuring funding, UnitedHealth will provide this as a cash transfer to Axelacare Health Solutions via Briova Rx Home Infusion Services, AxelaCare Health Solutions' immediate parent company.

11. Section B. Economic Feasibility, Item 5.B

a. The applicant labeled Table Three on page 54 as "Middle Tennessee". Please correct and provide a replacement page 54.

Corrected page 54R is attached following this page.

b. Please discuss how reducing patient projections from 45 to 20 in CN1606-022A by the applicant in Year One impacted the financial viability of that project.

As noted above in response to your question 9a, attached after that page is a Projected Development Chart for the West Tennessee territory alone, showing that it remains financially feasible even at these lower revised utilization projections.

12. Section B, Economic Feasibility, Item 6.B.
The Net Operating Ratio for Year 2 in the table on the bottom of page 55 for AxelaCare West and East Tennessee Combined (Nursing + Pharmacy) appears incorrect. Please correct and submit a revised page 55.

Attached after this page is revised page 55R with the typographical error of 10.2% in Year Two corrected to 17.2%.

13. Project Completion Chart
The Project Completion Chart is noted. However, there are two number one phases listed. In addition, there is no Initial HSDA decision date listed and no date for the issuance of license. Please provide and submit a corrected Project Completion Chart.

Please clarify the question. That chart is on page 69 of the application. There is no reference to phases. It did list June 28, 2017 as the HSDA decision date. In accordance with the direction on the form, only items 11-13 are provided because the project does not "involve construction or renovation".

If approved, the applicant does expect to have Licensure add the proposed counties to its existing license on or before 12-15-17.

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B. Provide the proposed charges for the project and discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the project and the impact on existing patient charges.

AxelaCare negotiates a separate pricing structure with every insurer. Negotiated rates vary. They are proprietary and confidential. The insurers are billed only the negotiated amount. AxelaCare does not record or bill a "gross charge" that is discounted by "contractual adjustments" to yield "net revenue". The revenue figures shown in Section B of the Projected Data Charts are the billed or "expected" revenues -- i.e., the projected receipts based on pre-negotiated reimbursement contracts, before deductions for charity and bad debt.

The table below (repeated from a prior section of the application) shows the average expected (comparable to gross) charge/revenue data per patient and per visit for AxelaCare's nursing services (home office and field staff) in West Tennessee.

Table Three (Repeated): AxelaCare Healthcare Solutions, East Tennessee Nursing and Home Office Staff (Excluding Pharmaceuticals)

	Year One CY2018	Year Two CY2019
Expected (Gross) Nursing Revenue	$144,000	$201,600
Visits	600	840
Expected (Gross) Average Revenue/Visit	$240	$240
Patients	25	35
Expected (Gross) Average Revenue/Patient	$5,760	$5,760

C. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Although the applicant will not participate in Medicare for nursing services, Medicare pays for a 60-day episode of care at rates that vary by region and State. The approximate reimbursement for more than four visits is estimated by AxelaCare at $2400.

The only specialty infusion-specific charge data identified by the applicant in recently approved CON projects are in CN1406-018, approved for Coram/CVS Specialty Infusion Services two years ago, in June 2014. Coram projected average charges for its Middle Tennessee "specialty infusion patient" at $290-$348 (see page 87 of Coram CON application). In comparison, the average expected revenue per visit projected by AxelaCare for this project in 2017 is $240 for the nursing component. This is consistent with the Coram projections.

6.A. Discuss how projected utilization rates will be sufficient to support the financial performance. Indicate when the project's financial breakeven is expected and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Cost-effectiveness is demonstrated by the positive operating margin of the Projected Data Chart for the consolidated Nursing and Pharmaceutical components of the project. The Pharmaceutical operations attributable to the project will absorb losses projected by the Nursing operations of the project. The project will attain break-even during its first operational year.

Please see the Projected Data Chart for documentation of positive cash flow in the first and second years of operation.

Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For all projects, provide financial information for the corporation, partnership, or principal parties that will be a source of funding for the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility. NOTE: Publicly held entities only need to reference their SEC filings.

See Attachment Section B-Economic Feasibility-6A.

B. Net Operating Margin Ratio – Demonstrates how much revenue is left over after all the variable or operating costs have been paid. The formula for this ratio is: (Earnings before interest, Taxes, and Depreciation/Net Operating Revenue).

Utilizing information from the Historical and Projected Data Charts please report the net operating margin ratio trends in the following table:

AxelaCare Middle Tennessee Only (Nursing + Pharmacy)					
	2nd Yr Previous to Current Yr	1st Yr Previous to Current Yr	Current Yr	Projected Yr 1	Projected Yr 2
Net Operating Margin Ratio	NA	NA	NA	14.1%	19.1%

AxelaCare West and Middle Tennessee Combined (Nursing + Pharmacy)					
	2nd Yr Previous to Current Yr	1st Yr Previous to Current Yr	Current Yr	Projected Yr 1	Projected Yr 2
Net Operating Margin Ratio	NA	NA	NA	9.1%	17.2%

14. Proof of Publication

Please provide copies of the publication of intent of the required newspapers of general circulation in the proposed service area as listed in the letter of intent. Please submit a copy of the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit which is supplied by the newspaper as proof of the publication of the letter of intent that covers the 34 county proposed service area. Please insure the correct complete copy is paired with each appropriate affidavit.

The newspaper affidavits and/or tearsheets for proof of publication are being submitted to you by Brant Phillips' staff at Bass Berry & Sims. He is the CON legal counsel for this applicant and can serve as joint contact person.

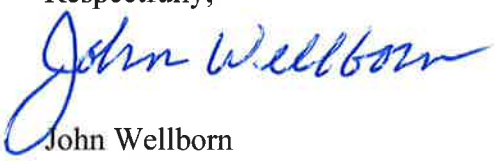
Additional Correction By the Applicant

The chart on page 53 of the average gross charge, average deduction from operating revenue, and average net charge for the West and East Tennessee Nursing and Pharma Combined contains errors on the per visit calculations.

The errors were caused by incorrect number of combined patient days entered in the Projected Data Chart for those combined territories (page 51). Attached following this page is a revised page 51R with the Year One and Year Two patient days corrected to 1,080 and 1,560 days respectively, and a revised page 53R with the table corrected for both Years One and Two.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email or telephone me so that we can respond in time to be deemed complete.

Respectfully,



John Wellborn

PROJECTED DATA CHART --AXELACARE WEST AND EAST TENNESSEE
(NURSING AND PHARMACEUTICALS COMBINED)

Give information for the last three (3) years for which complete data are available for the facility or agency. The fiscal year begins in January.

			Year 2018 (Year One)	Year 2019 (Year Two)
A.	Utilization Data	Patients	45	65
	(Specify unit or measure)	Visits	1,080	1,560
B.	Revenue from Services to Patients			
	1. Inpatient Services		$ 0	$ 0
	2. Outpatient Services		4,579,200	6,614,400
	3. Emergency Services		0	0
	4. Other Operating Revenue		0	0
	(Specify) See notes page			
		Gross Operating Revenue	$ 4,579,200	$ 6,614,400
C.	Deductions from Gross Operating Revenue			
	1. Contractual Adjustments		$ 0	$ 0
	2. Provision for Charity Care		91,584	132,288
	3. Provisions for Bad Debt		45,792	66,144
		Total Deductions	$ 137,376	$ 198,432
NET OPERATING REVENUE			$ 4,441,824	$ 6,415,968
D.	Operating Expenses			
	1. Salaries and Wages			
	a. Clinical		$ 1,375,004	$ 1,518,923
	b. Non-Clinical		0	$ 0
	2. Physicians Salaries and Wages		0	0
	3. Supplies		2,526,811	3,649,838
	4. Rent			
	c. Paid to Affiliates			
	d. Paid to Non-Affiliates		48,209	48,209
	5. Management Fees			
	a. Paid to Affiliates		0	0
	b. Paid to Non-Affiliates		0	0
	6. Other Operating Expenses	See notes page	87,781	98,166
		Total Operating Expenses	$ 4,037,805	$ 5,315,137
E.	**Earnings Before Interest, Taxes, and Depreciation**		$ 404,019	$ 1,100,831
F.	Non-Operating Expenses			
	1. Taxes		$ 132,000	$ 412,000
	2. Depreciation		22,500	30,000
	3. Interest		0	0
	4. Other Non-Operating Expenses		0	0
		Total Non-Operating Expenses	$ 154,500	$ 442,000
NET INCOME (LOSS)			$ 249,519	$ 658,831

Chart Continues Onto Next Page

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5.A. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge using information from the Projected Data Chart for Year 1 and Year 2 of the proposed project. Please complete the following table.

West and Middle Tennessee Nursing Only (both alike)	Project Previous Year	Project Current Year	Project Year One	Project Year Two	% Change (Current Yr to Yr2)
Gross Charge -- Gross Operating Revenue / PATIENT	NA	NA	$5,760	$5,760	0%
Revenue / VISIT	NA	NA	$240	$240	0%
Deduction from Revenue --Total Deductions / PATIENT	NA	NA	$173	$173	0%
Deductions / VISIT	NA	NA	$7	$7	0%
Average Net Charge -- Net Operating Revenue / PATIENT	NA	NA	$5,587	$5,587	0%
Revenue / VISIT	NA	NA	$233	$233	0%

West & Middle Tennessee Nursing and Pharma Combined	Project Previous Year	Project Current Year	Project Year One	Project Year Two	% Change (Current Yr to Yr2)
Gross Charge -- Gross Operating Revenue / PATIENT	NA	NA	$101,760	$101,760	0%
Revenue / VISIT			$4,240	$4,240	0%
Deduction from Revenue --Total Deductions / PATIENT	NA	NA	$3,053	$3,053	0%
Deductions / VISIT			$127	$127	0%
Average Net Charge -- Net Operating Revenue / PATIENT	NA	NA	$98,707	$98,707	0%
Revenue / VISIT			$4,113	$4,113	0%

SUPPLEMENTAL #1
February 21, 2017
9:37 am

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AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:
Avela Care Health Resources (East TN)

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

John L Wellborn
Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 21st day of February, 2017, witness my hand at office in the County of DAVIDSON, State of Tennessee.

NOTARY PUBLIC

My commission expires July 2, 2018.

HF-0043

Revised 7/02

JAN M. DANFORTH
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
My Commission Expires July 2, 2018

SUPPLEMENTAL 1

COPY

AxelaCare Health Solutions LLC (East TN)

CN1702-008

SUPPLEMENTAL #1
February 21, 2017
9:37 am

FEB 21 '17 AM 9:37

DSG Development Support Group

February 20, 2017

Phillip M. Earhart, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN 1702-008
AxelaCare Health Solutions, LLC--East Tennessee Expansion

Dear Mr. Earhart:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

1. **Section A: Executive Summary, A. Overview**
   In the middle of page 3 the applicant refers to two East Tennessee applications. If incorrect, please revise and submit a replacement page 3.

   The corrected page 3R is attached following this page.

2. **Section A, Project Details, Item 6.A**
   As required for all projects, a Plot Plan must provide the size of the site (in acres), location of the structure on the site, the location of the proposed construction, and the names of streets, roads, highways that cross or border the site. Please provide a new Plot Plan with all the required information.

   See the response to question #3 below.

3. **Section A, Project Details, Item 6.B**
   Please provide a floor plan of the principal office located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis (Shelby County) Tennessee.

   The requested plot plan and floor plan of the principal office are provided following this page.

4219 Hillsboro Road, Suite 203
Nashville, TN 37215
jwdsg@comcast.net
Tel 615.665.2022
Fax 615.665.2042

3. SECTION A: EXECUTIVE SUMMARY

A. Overview

Please provide an overview not to exceed three pages in total, explaining each numbered point.

(1) Description (Address the establishment of a health care institution, initiation of health services, bed complement changes, and/or how this project relates to any other outstanding but unimplemented certificates of need held by the applicant.)

Specialty home infusion is the process of providing very specialized medications intravenously in a patient's home, with the presence and support of a skilled registered nurse (R.N.) who works under the direction of the patient's referring physician. This is a very specialized therapy needed by a small group of seriously ill patients. It requires prolonged hours of onsite, in-home skilled nursing care, often on several consecutive days each month. Almost no nursing agencies are willing or able to staff for this type of therapy routinely -- especially since patient demand is small due to lack of Medicare reimbursement except when the infusion patient is totally homebound and, therefore, qualifies for Medicare reimbursement.

In 2016, AxelaCare Health Solutions, the applicant, requested CON approval to establish a home health agency to serve 21 West Tennessee counties. Its scope of service was to be limited to the home infusion of specialized immune globulin pharmaceuticals and nursing services necessary to provide for that specific type of infusion therapy.

The CON Board unanimously approved the application.

The approved application stated that, in two subsequent applications, AxelaCare would propose extending this limited home health service to all other Tennessee counties. This present application is to expand AxelaCare's authorized service area to cover 34 additional East Tennessee counties. A companion application has been filed simultaneously to serve 40 counties of Middle Tennessee. If both are approved, AxelaCare's specialized home health nurses will be able to meet specialized patient needs for immune globulin infusions in all 95 Tennessee counties.

As in the approved West Tennessee project, this service will be provided only to a very small number of patients whose physicians have prescribed infusion of specialized immune globulin medications. The non-homebound patients served by the project will not be eligible for Medicare or TennCare reimbursement for this home care service under existing reimbursement rules. The service, therefore, is proposed for privately insured patients, and a small number of charity patients. The same was true of the approved West Tennessee application.

The applicant home health agency, which expects to achieve State licensure for West Tennessee by February 2017, will maintain its principal office in Memphis/Shelby County and will provide home nursing service through R.N. field staff residing in one or more counties in East Tennessee to ensure appropriate drive time accessibility to the patients they serve.

Branch offices are not necessary for nurse training and support, which will be delivered in the field. As in other technologically advanced companies, principal office employees linked electronically will provide staff recruitment, training, scheduling, business management and other components of the program, both in Memphis and in varying locations in East Tennessee.

SUPPLEMENTAL #1

February 21, 2017
9:37 am

CHEYENNE JOHNSON

Assessor of Property

Shelby County, TN

Property

Property Address
5100 POPLAR AVE

Parcel ID
056033 00237

Owner Name
CLARK TOWER LLC

2015 Appraised Value
$22,010,300

Property/Assessment Details
Click Here

Deed Information
Click Here

County Tax
Click Here

City Tax
Click Here

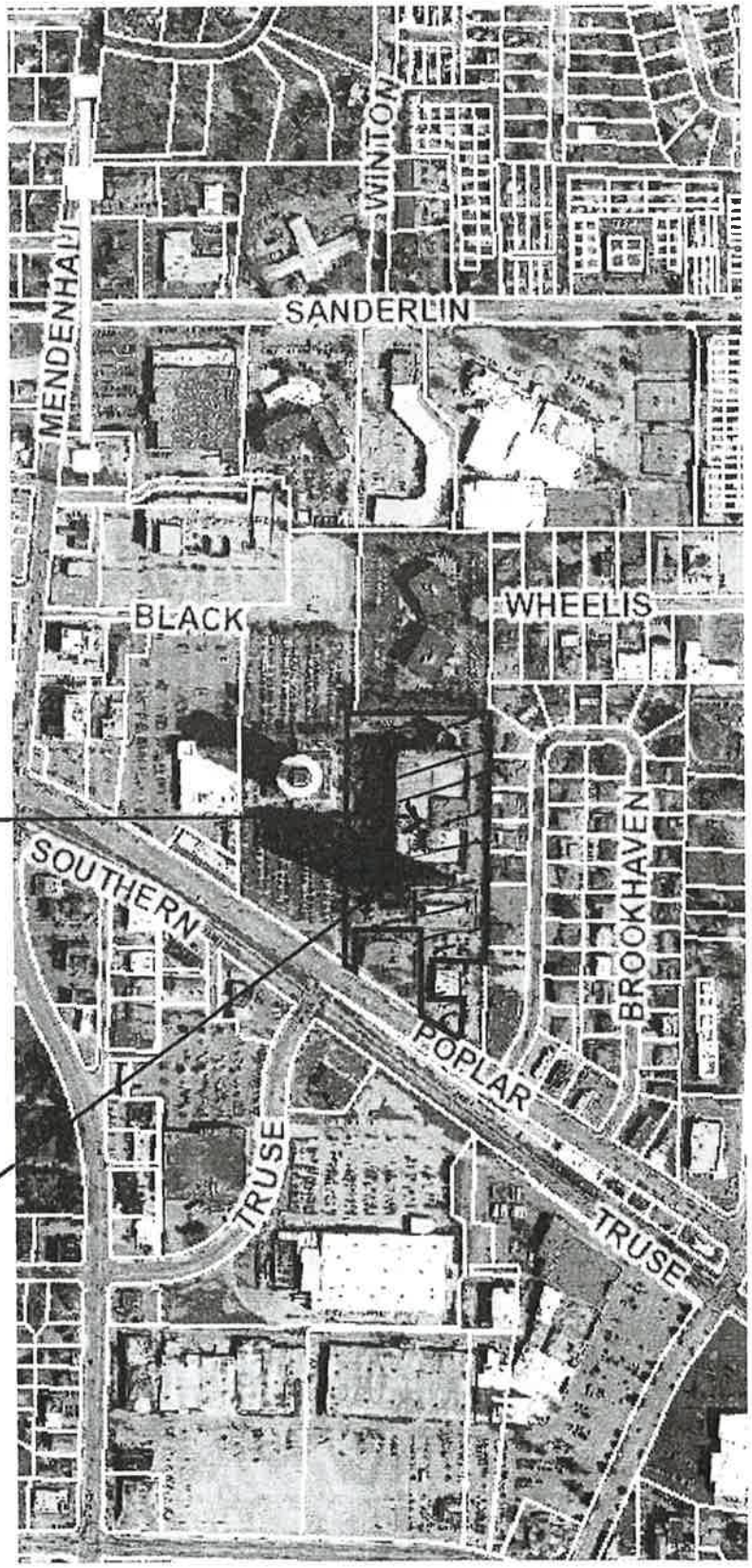
Layers

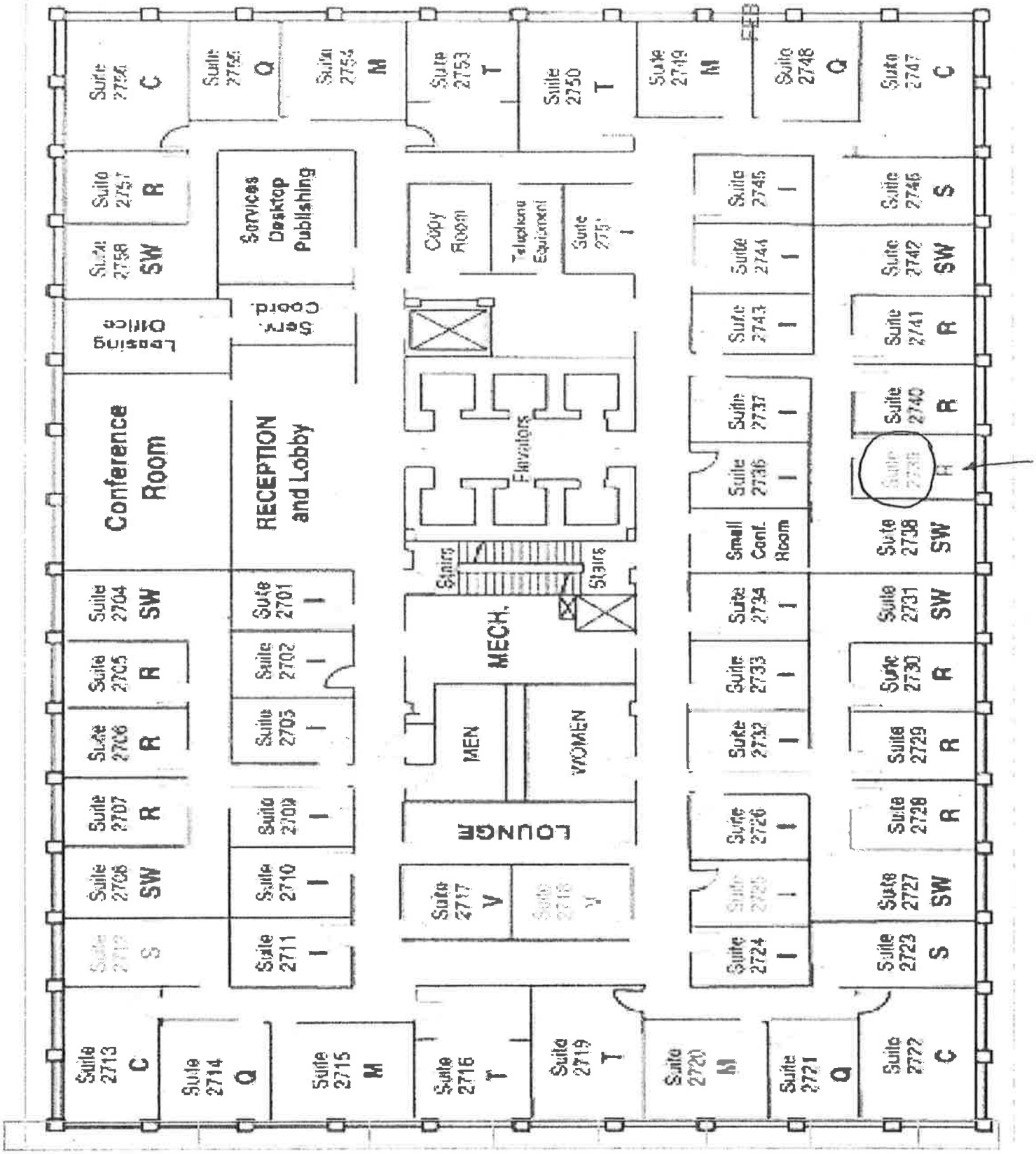
Search Property Sales

PROJECT ON
27th FLOOR

CLARK TOWER

SITE 7.79 acres




Suite 2756 C
Suite 2755 Q
Suite 2754 M
Suite 2753 T
Suite 2750 T
Suite 2749 M
Suite 2748 Q
Suite 2747 C
Suite 2757 R
Services Desktop Publishing
Copy Room
Telephone Equipment
Suite 2751 I
Suite 2745 I
Suite 2746 S
Suite 2758 SW
Leasing Office
Serv. Coord.
Suite 2744 I
Suite 2742 SW
Suite 2743 I
Suite 2741 R
Conference Room
RECEPTION and Lobby
Elevators
Suite 2737 I
Suite 2740 R
Suite 2736 I
Suite 2739 H
Small Conf. Room
Suite 2738 SW
Stairs
Stairs
Suite 2704 SW
Suite 2701 I
MECH.
Suite 2734 I
Suite 2731 SW
Suite 2705 R
Suite 2702 I
Suite 2733 I
Suite 2730 R
Suite 2706 R
Suite 2703 I
MEN
WOMEN
Suite 2732 I
Suite 2729 R
Suite 2707 R
Suite 2709 I
LOUNGE
Suite 2726 I
Suite 2728 R
Suite 2708 SW
Suite 2710 I
Suite 2717 V
Suite 2718 V
Suite 2725 I
Suite 2727 SW
Suite 2712 S
Suite 2711 I
Suite 2724 I
Suite 2723 S
Suite 2713 C
Suite 2714 Q
Suite 2715 M
Suite 2716 T
Suite 2719 T
Suite 2720 M
Suite 2721 Q
Suite 2722 C

4. Section A, Project Details, Home Health Organizations

The table of the applicant's licensed counties on page 19 is noted. However, the applicant checked 21 West Tennessee Counties as being licensed by the applicant. Please clarify if the applicant will be operating under one home health license for the whole state. If not, please revise the home health chart to only include the proposed 34 East Tennessee Counties.

No revision is necessary. This application and its companion application together propose expanding the applicant's West Tennessee license to include all other counties in the State. The applicant will be operating under a single home health license, with one principal office.

5. Section B, Need, Item 1.a. (Project Specific Criteria-Home Health Services) Item #4 County Need Standard

The applicant provided support letters from 2 patients that do not reside in the proposed service area. Please provide letters from each county in the proposed service area of potential patients and/or providers according to the listed County Need Standard criteria.

Additional support letters are being gathered by the applicant and will be submitted later in February. However, the applicant does not anticipate securing a support letter from every one of the forty counties in this proposed service area, before being accepted into the March review cycle.

6. Section B, Need, Item 1.a. (Project-Specific Criteria-Home Health Services) Item #5 Current Service Area Utilization

It is noted the applicant states "the tables are in the attachments" for the patients each agency served in CY2015 within the proposed service area. Please clarify the location of the attachments which the applicant is referring.

They are located in Attachment B-Need-5, as listed in the Index of Attachments on page 70 of the application.

7. Section B, Need, Item 1.a. (Project Specific Criteria-Home Health Services) Item #11 Quality Control and Monitoring

Please indicate where the referenced examples of AxelCare's Quality Improvement Program is located in the attachments.

It is in Attachment C, Need--1, described as "Performance Improvement Plan". This is the same corporate program accepted in review of the West Tennessee AxelaCare application.

8. Section B, Need, Item 5

a. On page 38 the applicant refers to Table B.5-3A. However, the table could not be located. Please clarify.

This was an inadvertent omission. That two-page table is attached following this page. It provides the same information that is in Tables B.5-3B and C but is sorted by agency name.

b. In the middle of page 40 the applicant notes the proposed service area is 40 counties rather than 34. Please correct and provide a revised page 38.

The corrected page 38R is attached following the tables after this page.

SUPPLEMENTAL #1

February 21, 2017

9:37 am

Table B.5-3A: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area BY AGENCY NAME

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
30021	Greene	Advanced Home Care, Inc.	86	8/31/83	762	817	845	845	100.0%
82051	Sullivan	Advanced Home Care, Inc.	249	4/9/85	2,245	2,276	2,641	2,628	99.5%
33423	Hamilton	Aiere Women's and Children's Health, LLC	457	11/13/98	61	50	40	32	80.0%
26054	Franklin	Amedisys Home Care	82	9/19/83	1,150	1,002	909	3	0.3%
33103	Hamilton	Amedisys Home Health	113	7/1/81	2,878	2,564	2,610	2,599	99.6%
67024	Overton	Amedisys Home Health	191	1/17/84	1,101	949	1,101	176	16.0%
90121	Washington	Amedisys Home Health	273	7/6/84	1,821	1,460	1,676	1,676	100.0%
10031	Carter	Amedisys Home Health Care	23	1/20/84	1,171	937	901	901	100.0%
32102	Hamblen	Amedisys Home Health Care	91	12/13/82	3,896	3,210	3,099	3,094	99.8%
47202	Knox	Amedisys Home Health Care	150	8/2/84	5,354	4,391	4,548	4,548	100.0%
75064	Rutherford	Amedisys Home Health Care	5	8/23/84	1,582	1,372	1,265	0	0.0%
13022	Claiborne	Amedisys Home Health of Tennessee	25	10/8/82	1,830	1,547	1,551	1,551	100.0%
05012	Blount	Blount Memorial Hospital Home Health Services	213	1/26/15	1,224	1,281	1,589	1,589	100.0%
47062	Knox	Camellia Home Health of East Tennessee	144	9/7/78	1,716	1,732	2,215	2,213	99.9%
19724	Davidson	Careall	295	7/5/84	1,562	1,665	891	116	13.0%
47232	Knox	Careall Home Care Services	131	8/21/89	510	686	0	0	0.0%
89074	Warren	Careall Home Care Services	265	1/31/84	637	974	749	456	60.9%
33253	Hamilton	CHI Memorial Health at Home	103	8/9/82	2,439	2,651	2,852	2,851	100.0%
01032	Anderson	Clinch River Home Health	1	10/26/76	461	481	450	450	0.0%
33213	Hamilton	Continuecare Healthservices, Inc. I	98	11/2/84	1,466	1,393	1,356	1,356	100.0%
33383	Hamilton	Continuecare Healthservices, Inc. II	108	5/7/76	8	7	7	7	100.0%
19734	Davidson	Corum CVS Specialty Infusion Services	624	1/30/13	11	26	36	0	0.0%
47402	Knox	Covenant Homecare	133	7/14/78	3,953	4,792	5,391	5,389	100.0%
14024	Clay	Cumberland River Homecare	135	12/28/82	392	393	293	38	13.0%
52024	Lincoln	Deaconess Homecare	161	2/25/76	842	1,294	731	0	0.0%
76032	Scott	Deaconess Homecare	211	9/20/85	394	603	338	316	93.5%
95034	Wilson	Deaconess Homecare I	282	12/18/78	1,222	1,706	956	53	5.5%
47222	Knox	East Tennessee Children's Hospital Home Health	132	9/13/84	586	600	560	560	100.0%
19494	Davidson	Elk Valley Health Services	42	7/17/84	277	293	457	115	25.2%
26024	Franklin	Encompass Home Health of Tennessee	83	1/29/76	2,030	2,444	2,581	745	28.9%
06043	Bradley	Family Home Care - Cleveland	13	1/10/84	598	1,454	1,494	1,494	100.0%
33093	Hamilton	Gentiva Health Services	100	8/24/84	328	348	426	424	99.5%
47042	Knox	Gentiva Health Services	142	11/28/77	779	413	80	80	100.0%
82061	Sullivan	Gentiva Health Services	251	11/3/83	936	612	598	597	99.8%
47182	Knox	Gentiva Health Services 2 (Girling Health Services)	149	8/15/84	1,467	1,815	1,675	1,673	99.9%
33083	Hamilton	Guardian Home Care, LLC	115	6/29/78	1,484	1,255	1,929	1,926	99.8%
34011	Hancock	Hancock County Home Health and Hospice Agency	117	7/23/75	463	488	648	648	100.0%
71014	Putnam	Highland Rim Home Health Agency	197	5/2/78	574	497	549	1	0.2%
33363	Hamilton	Home Care Solutions	338	11/14/96	663	540	473	465	98.3%
19544	Davidson	Home Care Solutions, Inc.	56	9/7/88	1,930	1,689	1,813	273	15.1%
06063	Bradley	Home Health Care of East Tennessee, Inc.	14	3/14/84	3,318	2,680	1,580	1,454	92.0%
37021	Hawkins	Hometown Home Health, Inc.	320	1/9/95	89	94	108	108	100.0%
	Knox	Implanted Pump Management	633				0	0	0.0%
62052	Monroe	Intrepid USA Healthcare Services	190	9/10/84	358	355	565	565	100.0%
71084	Putnam	Intrepid USA Healthcare Services	198	6/19/84	327	281	369	46	12.5%
89064	Warren	Intrepid USA Healthcare Services	263	8/1/84	822	804	843	0	0.0%
46031	Johnson	Johnson County Home Health.	130	6/29/84	446	492	447	447	100.0%
30041	Greene	Laughlin Home Health Agency	88	6/26/84	655	737	711	711	100.0%
33433	Hamilton	Maxim Healthcare Services	613	8/18/05	56	53	57	57	100.0%
	Washington	Maxim Healthcare Services	629				0	0	0.0%
47432	Knox	Maxim Healthcare Services, Inc.	2	6/20/84	159	154	214	214	0.0%
90081	Washington	Medical Center Homecare - Kingsport	269	11/4/83	1,960	1,846	1,923	1,923	100.0%
90091	Washington	Medical Center Homecare Services	271	5/4/84	3,503	3,714	3,625	3,625	0.0%
33033	Hamilton	NHC Homecare	111	6/10/77	354	411	278	278	100.0%
47012	Knox	NHC Homecare	143	6/10/77	613	883	870	870	100.0%
54043	McMinn	NHC Homecare	166	2/13/84	239	358	421	421	100.0%
75024	Rutherford	NHC Homecare	208	5/17/76	3,776	4,180	4,270	74	1.7%
90131	Washington	NHC Homecare	267	3/22/78	259	465	611	611	100.0%
19654	Davidson	Optum Women's and Children's Health, LLC	471	3/1/99	202	186	196	0	0.0%

SUPPLEMENTAL #1

February 21, 2017

9:37 am

Table B.5-3A: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area BY AGENCY NAME

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
	Davidson	Pentec Health	632				0	0	0.0%
32132	Hamblen	Premier Support Services, Inc.	10	5/16/84	1,169	1,372	1,126	1,126	100.0%
30051	Greene	Procare Home Health Services	87	7/8/82	433	522	574	574	100.0%
01042	Anderson	Professional Case Management of Tennessee	620	1/30/08	164	173	249	242	97.2%
96030	London Co, KY	Professional Home Health Care Agency	298	9/2/77	12	21	6	6	100.0%
25044	Fentress	Quality Home Health	287	3/7/84	3,404	3,591	4,278	2,778	64.9%
25034	Fentress	Quality Private Duty Care	80	10/28/83	879	894	784	340	0.0%
15032	Cocke	Smoky Mountain Home Health and Hospice	27	11/9/89	1,296	1,102	1,128	1,128	100.0%
07032	Campbell	Sunbelt Homecare	16	8/10/84	261	243	253	253	100.0%
16034	Coffee	Suncrest Home Health	29	4/16/84	1,588	2,122	1,667	49	2.9%
13032	Claiborne	Suncrest Home Health and Hospice	93	9/14/84	852	1,008	663	663	100.0%
62062	Monroe	Sweetwater Hospital Home Health	189	8/20/84	613	625	651	651	100.0%
33303	Hamilton	Tennessee Home Health (Lifecare)	109	11/7/84	956	1,298	520	520	100.0%
47092	Knox	Tennova Healthcare Home Health	151	2/29/80	3,063	3,240	4,029	4,029	100.0%
01052	Anderson	The Home Option by Hardin Health Care	148	12/13/84			79	79	0.0%
32122	Hamblen	Univ. of TN Med Cntr Home Health / Hospice Service	153	12/18/84	1,327	751	1,145	1,145	0.0%
47132	Knox	UTMCK - Home Care Services: Hospice & Home Care	156	7/20/83	3,439	771	2,104	2,104	0.0%
		AREAWIDE TOTALS AND AVERAGES			**89,395**	**88,133**	**88,667**	**68,979**	**77.8%**

Source: TDH; 2013-2015 Joint Annual Reports of Home Health Agencies

5. Describe the existing and approved but unimplemented services of similar healthcare providers in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. List each provider and its utilization and/or occupancy individually. Inpatient bed projects must provide the following data: admissions or discharges, patient days, average length of stay, and occupancy. Other projects should use the appropriate measures, e.g., cases, procedures, visits, admissions, etc. This does not apply to projects that are solely relocating a service.

Attachment Need-B-5 contains a series of tables that identify all the home health agencies currently authorized to serve this area, and provide utilization data from their final 2013-2015 Joint Annual Reports. *(Note: these are the same categories of statistics that were accepted for AxelaCare's approved West Tennessee CN#1606-022.)*

Tables

- Tables B.5-1A & 1B: Service area counties that are authorized for each approved agency.

- Tables B.5-2A & 2B: Patients served during 2015, in each agency's authorized counties within the project service area.

- Tables B.5-3A & 3B & 3C: Area agencies' patient utilization 2013-2015, with agencies' dependence on patients from the project service area.

- Tables B.5-4A &4B & 4C: Agencies' TennCare gross revenues (charges) as a percent of their total gross revenues, and a ranking by level of TennCare participation.

These tables show the following:

1. There are 76 agencies licensed to serve one or more counties in this project's 34-county service area--ranging from 15 agencies for Johnson County to 31 agencies for Roane County.

2. Only 5 of 74 surveyed providers (one of whom consists of 3 separately licensed agencies under common ownership) indicated an ability to infuse IG patients. Of the 5, only 1 is licensed to serve all 34 service area counties. But it has only 1 IVIG nurse for all of that territory. The remaining five agencies do not have complete geographic coverage of the service area. Their gaps in licensure coverage vary from 82% to 90% of the service area counties. This demonstrates a shortage of home care providers for a small subset of IG patients with serious needs.

3. The agencies served 68,979 home care patients in the project service area in 2015.

4. The applicant's projected 35 patients in CY2019 equates to only .05% (five-hundredths of one percent) of the patients served by all agencies in 2015. Therefore the project will have almost no measurable impact on existing agencies collectively.

5. The 76 agencies' 23.3% *average* TennCare utilization is misleading. Only 17 of the 76 agencies had a TennCare mix that high; while 36 agencies (47% of the total) served no TennCare patients at all.

9. Section C, Need, Item 6

a. It is noted AxelaCare Health Solutions, CN1606-022A, approved at the October 26, 2016 Agency meeting to establish a home care organization and initiate home health services limited to the home infusion of immune globulin pharmaceuticals in 21 West Tennessee counties reduced the projected number of patients in Year One from 45 to 20. Please explain why the applicant overestimated projections for CN1606-022A and why patient projections for this project will not follow a similar pattern.

Following is an excerpt from response #10 on page 11 of CN1606-022A's June 22, 2016 supplemental information response letter. The "127" number in this excerpt was data for CY2015, the most current complete year prior to that applications' filing.

*"AxelaCare reviewed their Tennessee referrals and identified **127 referred IVIG patients Statewide**. It was assumed that at least this level of referrals will continue...One-third (43) patients were projected to be coming from West Tennessee...and that was...rounded up to 45 patients to allow for annual increases in demand. For the second year, a growth to 65 patients was assumed because where local marketing and community linkages are in place, AxelaCare typically sees a minimum of 5 to 6 new referrals per month."*

In researching CY2016 Statewide referral numbers for these two current applications for Middle and East Tennessee counties, AxelaCare found no record of total referral requests to AxelaCare, but did find that in CY2016, 37 patients were actually accepted, from an unrecorded larger number of referral requests. The company believes that the 127 number in the earlier application was an estimate of total referrals in CY2015--not patients actually accepted after clinical review.

To correct the prior error, in this current application, AxelaCare has submitted revised projections for the approved West Tennessee operation--20 and 30 patients in Years One and Two respectively (page 39 of the current application). The methodology for AxelaCare's Statewide projection is now based on a verified number of patients actually qualified and accepted for AxelaCare infusions. The methodology and Statewide allocation among West, Middle, and East Tennessee is detailed on page 39-40 of the current application.

Attached after this page is a Projected Development Chart for the West Tennessee territory alone, showing that it remains financially feasible even at these lower revised utilization projections. Also attached for this East Tennessee application is revised page 47R correcting the mislabeled chart title from "Middle" to "East Tennessee".

SUPPLEMENTAL #1

February 21, 2017
9:37 am

PROJECTED DATA CHART-- AXELACARE WEST TENNESSEE ONLY
CONSOLIDATED OPERATIONS: NURSING, HOME OFFICE, & PHARMACEUTICALS

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

				CY 2018	CY 2019
		PATIENTS		20	30
A.	Utilization Data	VISITS		480	720
B.	Revenue from Services to Patients				
	1. Inpatient Services		$	$	
	2. Outpatient Services-home health nursing visits			2,035,200	3,052,800
	3. Emergency Services			0	0
	4. Other Operating Revenue (Specify)	See notes page		0	0
		Gross Operating Revenue	$	$ 2,035,200	3,052,800
C.	Deductions for Operating Revenue				
	1. Contractual Adjustments		$	0	0
	2. Provision for Charity Care			40,704	61,056
	3. Provisions for Bad Debt			20,352	30,528
		Total Deductions	$	$ 61,056	91,584
NET OPERATING REVENUE			$	$ 1,974,144	2,961,216
D.	Operating Expenses				
	1. Salaries and Wages		$	717,664	739,194
	2. Physicians Salaries and Wages			0	0
	3. Supplies			1,123,027	1,684,541
	4. Taxes			12,000	172,000
	5. Depreciation			7,500	5,000
	6. Rent			36,209	36,209
	7. Interest, other than Capital			0	0
	8. Management Fees			0	0
	a. Fees to Affiliates			0	0
	b. Fees to Non-Affiliates			0	0
	9. Other Expenses (Specify)	See notes page		58,783	58,783
		Total Operating Expenses	$	$ 1,955,183	2,695,727
E.	Other Revenue (Expenses) -- Net (Specify)		$	0	0
NET OPERATING INCOME (LOSS)			$	$ 18,961	265,489
F.	Capital Expenditures				
	1. Equipment		$	250,000	25,000
	2. Interest			0	0
		Total Capital Expenditures	$	$ 250,000	25,000
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES			$	$ (231,039)	240,489

New Supplemental

SUPPLEMENTAL #1
O TOTAL FACILITY
February 21, 2017
X PROJECT ONLY
9:37 am

PROJECTED DATA CHART --AXELACARE EAST TENNESSEE
(PHARMACEUTICALS ONLY)

information for the last three (3) years for which complete data are available for the facility or agency.
iscal year begins in January.

		Year 2018 (Year One)	Year 2019 (Year Two)
Utilization Data	Patients	25	35
(Specify unit or measure)	Visits	600	840
Revenue from Services to Patients			
1. Inpatient Services		$	$
2. Outpatient Services		2,400,000	3,360,000
3. Emergency Services			
4. Other Operating Revenue			
(Specify) See notes page			
	Gross Operating Revenue	$ 2,400,000	$ 3,360,000
Deductions from Gross Operating Revenue			
1. Contractual Adjustments		$	$
2. Provision for Charity Care		48,000	67,200
3. Provisions for Bad Debt		24,000	33,600
	Total Deductions	$ 72,000	$ 100,800
OPERATING REVENUE		$ 2,328,000	$ 3,259,200
Operating Expenses			
1. Salaries and Wages			
a. Clinical		$ 287,500	$ 296,125
b. Non-Clinical			
2. Physicians Salaries and Wages			
3. Supplies		1,396,800	1,955,520
4. Rent			
c. Paid to Affiliates			
d. Paid to Non-Affiliates			
5. Management Fees			
a. Paid to Affiliates			
b. Paid to Non-Affiliates			
6. Other Operating Expenses	See notes page	19,200	26,400
	Total Operating Expenses	$ 1,703,500	$ 2,278,045
Earnings Before Interest, Taxes, and Depreciation		$ 624,500	$ 981,155
Non-Operating Expenses			
1. Taxes		$ 120,000	$ 240,000
2. Depreciation		15,000	25,000
3. Interest			
4. Other Non-Operating Expenses			
	Total Non-Operating Expenses	$ 135,000	$ 265,000
NCOME (LOSS)		$ 489,500	$ 716,155

: *Continues Onto Next Page*

b. Page 39 (bottom)- If 37 patients were referred to other home health agencies in 2016, why is this project needed?

The reason why AxelaCare wants to retain these patients for treatment by its own staff are clearly stated on pages 6-7 ("Need") of the submitted application. It is difficult for AxelaCare to locate agencies that are staffed and prepared to meet AxelaCare's standards for infusion of AxelaCare immune globulin products. Those standards include prompt initiation of home service, use of the CareExchange technology to optimize communication with the physician and pharmacist during infusion, use of highly skilled nurses focused on home infusion, and contribution of clinical data to research efforts in this complex clinical field of medicine. There are almost no providers who meet these qualifications in all of the counties proposed in this project. This project will provide complete regional coverage for this specialized type of patient.

10. Section B. Economic Feasibility Item 2 Funding

It is noted the proposed project will be funded by the applicant's parent company. However, the financial balance sheets of UnitedHealth Group ending September 31, 2016 reflects total current assets of $35,768,000,000 and current liabilities of $51,096,000,000, and a current ratio of .70 to 1. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities. Please clarify if the applicant has the cash available to fund the proposed project. If so, please provide documentation from a bank or financial institution.

Yes, the applicant's parent company has ample cash available to finance the project; and no loan funding is needed or projected. UnitedHealth Group is a Fortune 6 company that had net earnings of almost $2 billion in the first nine months of 2016, as shown in its income statement in the Attachments to the application. This is clearly sufficient cash to cover the small, approximately $70,000 implementation costs associated with this application. As stated in Mr. Collins' letter assuring funding, UnitedHealth will provide this as a cash transfer to Axelacare Health Solutions via Briova Rx Home Infusion Services, AxelaCare Health Solutions' immediate parent company.

FEB 21 '17 AM9:39

SUPPLEMENTAL #1
February 21, 2017
9:37 am

11. Section B. Economic Feasibility, Item 5.B

a. The applicant labeled Table Three on page 54 as "Middle Tennessee". Please correct and provide a replacement page 54.

Corrected page 54R is attached following this page.

b. Please discuss how reducing patient projections from 45 to 20 in CN1606-022A by the applicant in Year One impacted the financial viability of that project.

As noted above in response to your question 9a, attached after that page is a Projected Development Chart for the West Tennessee territory alone, showing that it remains financially feasible even at these lower revised utilization projections.

12. Section B, Economic Feasibility, Item 6.B.

The Net Operating Ratio for Year 2 in the table on the bottom of page 55 for AxelaCare West and East Tennessee Combined (Nursing + Pharmacy) appears incorrect. Please correct and submit a revised page 55.

Attached after this page is revised page 55R with the typographical error of 10.2% in Year Two corrected to 17.2%.

13. Project Completion Chart

The Project Completion Chart is noted. However, there are two number one phases listed. In addition, there is no Initial HSDA decision date listed and no date for the issuance of license. Please provide and submit a corrected Project Completion Chart.

Please clarify the question. That chart is on page 69 of the application. There is no reference to phases. It did list June 28, 2017 as the HSDA decision date. In accordance with the direction on the form, only items 11-13 are provided because the project does not "involve construction or renovation".

If approved, the applicant does expect to have Licensure add the proposed counties to its existing license on or before 12-15-17.

B. Provide the proposed charges for the project and discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the project and the impact on existing patient charges.

AxelaCare negotiates a separate pricing structure with every insurer. Negotiated rates vary. They are proprietary and confidential. The insurers are billed only the negotiated amount. AxelaCare does not record or bill a "gross charge" that is discounted by "contractual adjustments" to yield "net revenue". The revenue figures shown in Section B of the Projected Data Charts are the billed or "expected" revenues -- i.e., the projected receipts based on pre-negotiated reimbursement contracts, before deductions for charity and bad debt.

The table below (repeated from a prior section of the application) shows the average expected (comparable to gross) charge/revenue data per patient and per visit for AxelaCare's nursing services (home office and field staff) in West Tennessee.

Table Three (Repeated): AxelaCare Healthcare Solutions, East Tennessee Nursing and Home Office Staff (Excluding Pharmaceuticals)

	Year One CY2018	Year Two CY2019
Expected (Gross) Nursing Revenue	$144,000	$201,600
Visits	600	840
Expected (Gross) Average Revenue/Visit	$240	$240
Patients	25	35
Expected (Gross) Average Revenue/Patient	$5,760	$5,760

C. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Although the applicant will not participate in Medicare for nursing services, Medicare pays for a 60-day episode of care at rates that vary by region and State. The approximate reimbursement for more than four visits is estimated by AxelaCare at $2400.

The only specialty infusion-specific charge data identified by the applicant in recently approved CON projects are in CN1406-018, approved for Coram/CVS Specialty Infusion Services two years ago, in June 2014. Coram projected average charges for its Middle Tennessee "specialty infusion patient" at $290-$348 (see page 87 of Coram CON application). In comparison, the average expected revenue per visit projected by AxelaCare for this project in 2017 is $240 for the nursing component. This is consistent with the Coram projections.

6.A. Discuss how projected utilization rates will be sufficient to support the financial performance. Indicate when the project's financial breakeven is expected and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Cost-effectiveness is demonstrated by the positive operating margin of the Projected Data Chart for the consolidated Nursing and Pharmaceutical components of the project. The Pharmaceutical operations attributable to the project will absorb losses projected by the Nursing operations of the project. The project will attain break-even during its first operational year.

Please see the Projected Data Chart for documentation of positive cash flow in the first and second years of operation.

Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For all projects, provide financial information for the corporation, partnership, or principal parties that will be a source of funding for the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility. NOTE: Publicly held entities only need to reference their SEC filings.

See Attachment Section B-Economic Feasibility-6A.

B. Net Operating Margin Ratio – Demonstrates how much revenue is left over after all the variable or operating costs have been paid. The formula for this ratio is: (Earnings before interest, Taxes, and Depreciation/Net Operating Revenue).

Utilizing information from the Historical and Projected Data Charts please report the net operating margin ratio trends in the following table:

AxelaCare Middle Tennessee Only (Nursing + Pharmacy)					
	2nd Yr Previous to Current Yr	1st Yr Previous to Current Yr	Current Yr	Projected Yr 1	Projected Yr 2
Net Operating Margin Ratio	NA	NA	NA	14.1%	19.1%

AxelaCare West and Middle Tennessee Combined (Nursing + Pharmacy)					
	2nd Yr Previous to Current Yr	1st Yr Previous to Current Yr	Current Yr	Projected Yr 1	Projected Yr 2
Net Operating Margin Ratio	NA	NA	NA	9.1%	17.2%

14. Proof of Publication

Please provide copies of the publication of intent of the required newspapers of general circulation in the proposed service area as listed in the letter of intent. Please submit a copy of the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit which is supplied by the newspaper as proof of the publication of the letter of intent that covers the 34 county proposed service area. Please insure the correct complete copy is paired with each appropriate affidavit.

The newspaper affidavits and/or tearsheets for proof of publication are being submitted to you by Brant Phillips' staff at Bass Berry & Sims. He is the CON legal counsel for this applicant and can serve as joint contact person.

Additional Correction By the Applicant

The chart on page 53 of the average gross charge, average deduction from operating revenue, and average net charge for the West and East Tennessee Nursing and Pharma Combined contains errors on the per visit calculations.

The errors were caused by incorrect number of combined patient days entered in the Projected Data Chart for those combined territories (page 51). Attached following this page is a revised page 51R with the Year One and Year Two patient days corrected to 1,080 and 1,560 days respectively, and a revised page 53R with the table corrected for both Years One and Two.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email or telephone me so that we can respond in time to be deemed complete.

Respectfully,

John Wellborn

John Wellborn

SUPPLEMENTAL #1

February 21, 2017
9:37 am

X TOTAL FACILITY
O PROJECT ONLY

PROJECTED DATA CHART –AXELACARE WEST AND EAST TENNESSEE
(NURSING AND PHARMACEUTICALS COMBINED)

Give information for the last three (3) years for which complete data are available for the facility or agency. The fiscal year begins in January.

			Year 2018 (Year One)	Year 2019 (Year Two)
A.	Utilization Data	Patients	45	65
	(Specify unit or measure)	Visits	1,080	1,560
B.	Revenue from Services to Patients			
	1. Inpatient Services		$ 0	$ 0
	2. Outpatient Services		4,579,200	6,614,400
	3. Emergency Services		0	0
	4. Other Operating Revenue		0	0
	(Specify) See notes page			
		Gross Operating Revenue	$ 4,579,200	$ 6,614,400
C.	Deductions from Gross Operating Revenue			
	1. Contractual Adjustments		$ 0	$ 0
	2. Provision for Charity Care		91,584	132,288
	3. Provisions for Bad Debt		45,792	66,144
		Total Deductions	$ 137,376	$ 198,432
NET OPERATING REVENUE			$ 4,441,824	$ 6,415,968
D.	Operating Expenses			
	1. Salaries and Wages			
	a. Clinical		$ 1,375,004	$ 1,518,923
	b. Non-Clinical		0	$ 0
	2. Physicians Salaries and Wages		0	0
	3. Supplies		2,526,811	3,649,838
	4. Rent			
	c. Paid to Affiliates			
	d. Paid to Non-Affiliates		48,209	48,209
	5. Management Fees			
	a. Paid to Affiliates		0	0
	b. Paid to Non-Affiliates		0	0
	6. Other Operating Expenses	See notes page	87,781	98,166
		Total Operating Expenses	$ 4,037,805	$ 5,315,137
E.	**Earnings Before Interest, Taxes, and Depreciation**		$ 404,019	$ 1,100,831
F.	Non-Operating Expenses			
	1. Taxes		$ 132,000	$ 412,000
	2. Depreciation		22,500	30,000
	3. Interest		0	0
	4. Other Non-Operating Expenses		0	0
		Total Non-Operating Expenses	$ 154,500	$ 442,000
NET INCOME (LOSS)			$ 249,519	$ 658,831

Chart Continues Onto Next Page

5.A. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge using information from the Projected Data Chart for Year 1 and Year 2 of the proposed project. Please complete the following table.

West and Middle Tennessee Nursing Only (both alike)	Project Previous Year	Project Current Year	Project Year One	Project Year Two	% Change (Current Yr to Yr2)
Gross Charge -- Gross Operating Revenue / PATIENT	NA	NA	$5,760	$5,760	0%
Revenue / VISIT	NA	NA	$240	$240	0%
Deduction from Revenue --Total Deductions / PATIENT	NA	NA	$173	$173	0%
Deductions / VISIT	NA	NA	$7	$7	0%
Average Net Charge -- Net Operating Revenue / PATIENT	NA	NA	$5,587	$5,587	0%
Revenue / VISIT	NA	NA	$233	$233	0%

West & Middle Tennessee Nursing and Pharma Combined	Project Previous Year	Project Current Year	Project Year One	Project Year Two	% Change (Current Yr to Yr2)
Gross Charge -- Gross Operating Revenue / PATIENT	NA	NA	$101,760	$101,760	0%
Revenue / VISIT			$4,240	$4,240	0%
Deduction from Revenue --Total Deductions / PATIENT	NA	NA	$3,053	$3,053	0%
Deductions / VISIT			$127	$127	0%
Average Net Charge -- Net Operating Revenue / PATIENT	NA	NA	$98,707	$98,707	0%
Revenue / VISIT			$4,113	$4,113	0%

SUPPLEMENTAL #1
February 22, 2017
12:04 pm

FEB 22 '17 12:04

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

AxulaCare Health Solutions - East Tennessee

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

John Wellborn

Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 21st day of February, 2017, witness my hand at office in the County of DAVIDSON, State of Tennessee.

NOTARY PUBLIC

My commission expires July 2, 2018.

HF-0043

Revised 7/02

JAN M. DANFORTH
STATE OF TENNESSEE NOTARY PUBLIC
My Commission Expires July 2, 2018

Supplemental- #2
-COPY-

AxelaCare Health Solutions, LLC (East TN)

CN1702-008

FEB 27 '17 PM 12:36

SUPPLEMENTAL #2
February 27, 2017
12:36 am

DSG Development Support Group

February 27, 2017

Phillip M. Earhart, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN 1702-008
AxelaCare Health Solutions, LLC--East Tennessee Expansion

Dear Mr. Earhart:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

1. **Section B. Economic Feasibility Item 2 Funding**
It is noted the applicant's parent company is a Fortune 6 company that had earnings of almost $2 billion in the first nine month of 2016. However, the unaudited financial balance sheets of UnitedHealth Group ending September 31, 2016 reflects total current assets of $35,768,000,000 and current liabilities of $51,096,000,000, and a current ratio of .70 to 1. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities. In addition, the current ratio overall for UnitedHealth Group has deteriorated from .77 to 1 for the period ending December 31, 2013 (audited) to the unaudited current ratio of .70 to 1 for the period ending December 31, 2016.
UnitedHealth Group's latest balance sheet reflects $15,328,000,000 more in current liabilities than current assets. In addition, United Health Group's current liabilities has exceeded current assets and declined on a consistent basis since December 2013. A company experiencing a worsening liquidity position can be a primary indication of a company experiencing financial distress. Please explain the reasons for this decline and provide documentation from a bank or financial institution of available funds to finance the $70,000 project.

The Vice President for Finance of the Optum RX Division of UnitedHealth Group has responded to this request with the following information.

UnitedHealth Group's median current ratio over the past 13 years has been 0.77. During that time, its revenues grew from approximately $75 billion to $185 billion, and its operating cash flows grew from approximately $5.8 billion to more than $9 billion. It has quarterly operating cash flows exceeding $9 billion.

4219 Hillsboro Road, Suite 203
Nashville, TN 37215
jwdsg@comcast.net
Tel 615.665.2022
Fax 615.665.2042

With such empirical proof of financial strength over time, neither its management, nor its investors, nor professional financial analysts known to the company, are expressing concerns about the financial stability of the company based on its current ratio. Please review the attached documents that provide significant additional financial characteristics of the company to document its financial stability.

Current ratios should be evaluated in the context of each company. In the insurance industry of which the parent company is a part, it is not unusual for current ratios to be below 1:1, particularly high-growth companies such as United HealthGroup. One reason for this is their frequent utilization of short-term debt instruments for corporate acquisitions, which increases the denominator in the current ratio formula and lowers the ratio slightly.

As further reassurance of the ability of the parent company to fund its AxelaCare projects, please know that before making these three applications for home health service areas across Tennessee, AxelaCare's parent company approved the project budgets and committed cash for funding them if they were approved. The first application, CN1606-022A for West Tennessee, was approved at a Project Cost almost identical to the two projects now seeking CON review. That first project was immediately funded by the company; and today it is completed and awaiting licensure. This would seem to be adequate reassurance that the company's funding commitment letters for projects of this size are reliable. With ample cash on hand, the company does not intend to finance the proposed project with a bank loan, and it would be misleading to represent to the Agency that loan funding will be sought.

2. Proof of Publication

Please provide copies of the publication of intent of the required newspapers of general circulation in the proposed service area as listed in the letter of intent. Please submit a copy of the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit which is supplied by the newspaper as proof of the publication of the letter of intent that covers the 34 county proposed service area. Please insure the correct complete copy is paired with each appropriate affidavit.

The requested documents are attached after the last page of this letter.

SUPPLEMENTAL #2
February 27, 2017
12:36 am

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email or telephone me so that we can respond in time to be deemed complete.

Respectfully,

John Wellborn

John Wellborn

SUPPLEMENTAL #2

February 27, 2017
12:36 am

FEB 27 '17 PM 12:36

PROOF OF PUBLICATION

Acct. Name:

BASS, BERRY & SIMS,

Acct. # 136428

COST OF PUBLICATION

Total $393.88

STATE OF TENNESSEE

COUNTY OF GREENE

PERSONALLY appeared before me TKA

_____ of Greene County, Tennessee.

who being duly sworn, made oath that he/she is a representative of the Publisher of THE GREENEVILLE SUN, a newspaper of general circulation, published in the City of Greeneville, County of Greene and State of Tennessee and that the hereto attached publication appeared in the same on the following dates:

NOTIFICATION OF INTENT T

02/08/2017

The Greeneville Sun

P.O. BOX 1630, GREENEVILLE, TN 37744

(423) 638-4181

Subscribed and sworn to before me on this 13th day of February, 2017

JANET L. MEDCALF STATE OF TENNESSEE NOTARY PUBLIC GREENE COUNTY

Newspaper Representative: TKA

Notary Public: Janet L Medcalf

My Commission Expires: 6/28/20

The referenced publication of notice has also been posted (1) On the newspaper's website, where it shall be published contemporaneously with the notice's first print publication and will remain on the website for at least as long as the notice appears in the newspaper; and (2) On a statewide web site established and maintained as an initiative and service of the Tennessee Press Association as a repository for such notices.

SUPPLEMENTAL #2

February 27, 2017
12:36 am

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that AxelaCare Health Solutions, LLC (a home health agency with its principal office in Shelby County), owned and managed by AxelaCare Health Solutions, LLC (a limited liability company), intends to file an application for a Certificate of Need to expand its authorized service area to include 34 East Tennessee counties, which are Anderson, Bledsoe, Blount, Bradley, Campbell, Carter, Claiborne, Cocke, Cumberland, Grainger, Greene, Hamblen, Hamilton, Hancock, Hawkins, Jefferson, Johnson, Knox, Loudon, McMinn, Marion, Meigs, Monroe, Morgan, Polk, Rhea, Roane, Scott, Sequatchie, Sevier, Sullivan, Unicoi, Union, and Washington Counties. The project cost is estimated at $70,000. The agencys principal office is located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis, TN 38137. The project will not expand the agencys authorized scope of service, which is exclusively limited to the home infusion of immune globulin pharmaceuticals and related nursing services.

The applicants initial licensure as a Home Health Agency (limited as described above) is pending before the Board for Licensing Health Care facilities. The project does not contain major medical equipment or initiate or discontinue any other health service, and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before February 13, 2017. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street, Nashville, TN 37243

Pursuant to TCA Sec. 68-11-1607(c)(1): (A) any health care institution wishing to oppose a Certificate of Need application must file a written objection with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled, and (B) any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency. 2.8.17

FEB 27 '17 PM 12:36

SUPPLEMENTAL #2
February 27, 2017
12:36 am

JOHNSON CITY PRESS
204 W. Main Street
Johnson City, TN 37604
AFFIDAVIT OF PUBLICATION

AD# 1347505

DATES: 2-8-2017

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State of Tennessee)
Carter County)
Washington County)

Teresa Hicks makes the oath that she is a Representative of The Johnson City Press, a daily newspaper published in Johnson City, in said County and State, and that the advertisement was published in said paper for 1 insertion (s) commencing on 2-8-2017 and ending on 2-8-2017.

Teresa Hicks

Sworn to and Subscribed before me this 2 10 2017
Month Day Year

Connie N. Guinn
Notary Public

My commission expires on 03/28/2017

This legal notice was published online at www.johnsoncitypress.com and www.publicnoticeads.com during the duration of the run dates listed. This publication fully complies with Tennessee Code Annotated 1-3-20

SUPPLEMENTAL #2

February 27, 2017
12:36 am

JOHNSON CITY PRESS
204 W. Main Street
Johnson City, TN 37604
AFFIDAVIT OF PUBLICATION

AD# 1347505

DATES: 2-8-2017

State of Tennessee)
Carter County)
Washington County)

Teresa Hicks makes the oath that s

daily newspaper published in John

advertisement was published in sa

2-8-2017 and en

Sworn to and Subscribed before m

This legal notice was published onl
www.publicnoticeads.com during
complies with Tennessee Code An

NOTIFICATION OF INTENT
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1347526

SUPPLEMENTAL #2

KINGSPORT TIMES-NEWS

February 27, 2017
12:36 am

FEB 27 '17 12:36

PUBLICATION CERTIFICATE

Kingsport, TN 2/8/17

This is to certify that the Legal Notice hereto attached was published in the Kingsport Times-News, a daily newspaper published in the City of Kingsport, County of Sullivan, State of Tennessee, beginning in the issue of February 8, 2017, and appearing 1 consecutive weeks/times, as per order of Bass, Berry + Sims

Signed Sheryl Edwards

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

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502 Deaderick Street
Nashville, TN 37243

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PUB1T: 02/08/17

STATE OF TENNESSEE, SULLIVAN COUNTY, TO-WIT:

Personally appeared before me this 8th day of February 2017, Sheryl Edwards of the Kingsport Times-News and in due form of law made oath that the foregoing statement was true to the best of my knowledge and belief.

JANICE REESE
STATE OF TENNESSEE NOTARY PUBLIC
WASHINGTON COUNTY

Janice Reese
NOTARY PUBLIC

My commission expires 4-6-20

1347526

SUPPLEMENTAL #2

KINGSPORT TIMES-NEWS

February 27, 2017
12:36 am

PUBLICATION CERTIFICATE

Kingsport, TN 2/8/17

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PUB1T: 02/08/17

LLIVAN COUNTY, TO-WIT:

Pe h day of February

20

of orm of law made oath that the foregoing

st wledge and belief.

Janice Reese
NOTARY PUBLIC

My 20

Attn:
To: BASS, BERRY & SIMS PLC

(Advertising) NOTIFICATION OF INTENT TO APPLY

P.O.#:

FEB 27 '17 PM 12:36

SUPPLEMENTAL #2

February 27, 2017

NOTIFICATION OF INTENT
TO APPLY FOR A CERTIFICATE OF NEED

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The applicant's initial licensure as a Home Health Agency (limited as described above) is pending before the Board for Licensing Health Care facilities. The project does not contain major medical equipment or initiate or discontinue any other health service, and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before February 13, 2017. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street, Nashville, TN 37243

Pursuant to TCA Sec. 68-11-1607(c)(1): (A) any health care institution wishing to oppose a Certificate of Need application must file a written objection with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled, and (B) any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

PUBLISHER'S AFF

State of Tennessee }
s.s
County of Knox }

Before me, the undersigned, a Notary Public in and for sai
Watkins first duly sworn, according to law, says that he/sh
Knoxville News-Sentinel, a daily newspaper published at K
the advertisement of:

(The Above-Refere

of which the annexed is a copy, was published in said pape

02/08/2017

and that the statement of account herewith is correct to the best of his/her knowledge, information, and belief.

Louise Watt

Subscribed and sworn to before me this 8 day of Feb 20 17

Notary Public

My commission expires _____ 20____

ASHLEY BREEDEN
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF KNOX
MY COMMISSION EXPIRES: MAY 5, 2019

SUPPLEMENTAL #2

Attn:
To: BASS, BERRY & SIMS PLC

February 27, 2017
12:36 am

(Advertising) NOTIFICATION OF INTENT TO APPLY FOR **(Ref No:** 1476957)

P.O.#:

PUBLISHER'S AFFIDAVIT

State of Tennessee }
s.s
County of Knox }

Before me, the undersigned, a Notary Public in and for said county, this day personally came Louise Watkins first duly sworn, according to law, says that he/she is a duly authorized representative of *The Knoxville News-Sentinel*, a daily newspaper published at Knoxville, in said county and state, and that the advertisement of:

(The Above-Referenced)

of which the annexed is a copy, was published in said paper on the following date(s):

02/08/2017

and that the statement of account herewith is correct to the best of his/her knowledge, information, and belief.

Louise Watk

Subscribed and sworn to before me this 8 day of Feb 20 17

Notary Public

My commission expires _____ 20_____

ASHLEY BREEDEN
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF KNOX
MY COMMISSION EXPIRES: MAY 5, 2019

SUPPLEMENTAL #2

February 27, 2017

12:36 am

FEB 27 '17 PM12:36

PROOF OF PUBLICATION

Acct. Name:

BASS BERRY + SIMS

Acct. # 258905

COST OF PUBLICATION

Total $120.25

STATE OF TENNESSEE

COUNTY OF HAWKINS

PERSONALLY appeared before me Tommy Campbell

_____ of Hawkins County, Tennessee.

who being duly sworn, made oath that he/she is a representative of the Publisher of THE ROGERSVILLE REVIEW, a newspaper of general circulation, published in the City of Rogersville, County of Hawkins and State of Tennessee and that the hereto attached publication appeared in the same on the following dates:

AXELACARE INTENT TO APPLY

02/08/2017

The Rogersville Review

P.O. BOX 100, ROGERSVILLE, TN 37857

(423) 272-7422

Subscribed and sworn to before me on this 14th day of February, 2017

Newspaper Representative: _____

Notary Public: Sharon F Roberts

My Commission Expires: May 06, 2018

SHARON F. ROBERTS STATE OF TENNESSEE NOTARY PUBLIC COUNTY OF HAWKINS

The referenced publication of notice has also been posted (1) On the newspaper's website, where it shall be published contemporaneously with the notice's first print publication and will remain on the website for at least as long as the notice appears in the newspaper; and (2) On a statewide web site established and maintained as an initiative and service of the Tennessee Press Association as a repository for such notices.

SUPPLEMENTAL #2

February 27, 2017
12:36 am

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502 Deaderick Street
Nashville, TN 37243

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1x 02/08/2017

SUPPLEMENTAL #2

February 27, 2017
12:36 am

Account #: 1[illegible]
Company: BASS BERRY & SIMS
Client:
Ad number: 31292
PO#:
Note:

AFFIDAVIT • STATE OF TENNESSEE • HAMILTON COUNTY

Before me personally appeared Jim Stevens, who being duly sworn that he is the Legal Sales Representative of the CHATTANOOGA TIMES FREE PRESS, and that the Legal Ad of which the attached is a true copy, has been published in the above named newspaper and on the corresponding newspaper website on the following dates, to-wit:

Chattanooga Times Free Press: 02/08/17; TimesFreePress.com: 02/08/17.

And that there is due or has been paid the CHATTANOOGA TIMES FREE PRESS for publication the sum of $258.72. (Includes $0.00 Affidavit Charge).

Jim Stevens

Sworn to and subscribed before me this date: 02/08/2017

Martha M. Tiffin

My Commission Expires 08/13/2019

MARTHA M. TIFFIN
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF HAMILTON
My Comm. Expires August 13, 2019

Chattanooga
Times Free Press

400 EAST 11TH ST
CHATTANOOGA, TN 37403

SUPPLEMENTAL #2

TRUE COPY OF PUBLISHED LEGAL AD

February 27, 2017
Chattanooga Times Free Press

NOTIFICATION OF INTENT
TO APPLY FOR A CERTIFICATE OF NEED

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Nashville, TN 37243

31292-1

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FEB 27 '17 PM 12:36

SUPPLEMENTAL #2
February 27, 2017
12:36 am

AFFIDAVIT

STATE OF TENNESSEE
COUNTY OF DAVIDSON

NAME OF FACILITY: AxelaCare Health Solutions LLC
CN 1702-008 (East Tennessee expansion)

I, **W. Brantley Phillips, Jr.**, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application, or one of the lawful agents thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate and complete to the best of my information and knowledge.

W. Brantley Phillips, Jr.
Attorney

Sworn to and subscribed before me, a Notary Public, this the 27th day of February, 2017, witness my hand at office in the County of Davidson, State of Tennessee.

Laura Bilbrey
Notary Public

My commission expires: 05/05/2020

LAURA BILBREY
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY