West Tennessee HEALTHCARE

620 Skyline Drive • Jackson, Tennessee • 731-541-5000 • www.wth.org

October 7, 2019

Mr. Logan Grant
Executive Director
Tennessee Health Services and
Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Re: Magnolia Regional Health Center, CN1907-027

Dear Mr. Grant:

On behalf of West Tennessee Healthcare and its affiliates ("WTH"), we are submitting this letter relative to the proposal by Magnolia Regional Medical Center ("MRMC") to establish a freestanding emergency department in Selmer, TN.

By way of background, WTH is a public, nonprofit health system with systems and services serving an 18-county region in West Tennessee. WTH has facilities and services throughout West Tennessee, anchored by our flagship hospital, Jackson-Madison County General Hospital. We are a significant provider of services to the residents of McNairy County. Last year, we had 1,446 inpatient admissions from McNairy County and we provided 8,331 outpatient procedures to residents of the county. Our services to McNairy County residents included approximately $2.6 million in bad debt and charity care.

WTH does not oppose the project, but we have patient care concerns regarding the proposal. We believe the concerns should be addressed through the certificate of need ("CON") process, particularly considering the Agency's increased emphasis on quality of care since the 2016 amendments to the Agency's statutes. Our concerns, and our requests to address these concerns if the Agency decides to approve the application, are as follows:

- The CON application does not address the process for transferring a patient to a hospital if the patient needs a higher level of care. Patients should have their choice as to the hospitals to which they will be transferred, so that patients can make informed decisions based on insurance networks, physician relationships and other considerations. We recommend that a certificate of need for this project include a condition that MRMC be required to inform patients that they have a choice as to which hospital they be transferred if the patient needs a higher level of care.
- The CON application indicates MRMC intention to maintain only a part-time pharmacy at the FSED. We are concerned that patients who present at the FSED when the pharmacy is not

operational will be unable to receive needed care. We request that a CON for this facility include a condition that the FSED maintain a pharmacy 24/7.

- The CON application indicates that ultrasound will not be available. The availability of ultrasound images is a basic and necessary service for emergency departments. We request that a CON for this facility include a condition that it maintain ultrasound services.
- The FSED in Selmer will be operated as a department of MRMC, a hospital based in and licensed by Mississippi. It is unclear to us how the FSED will be regulated. Will the requirements in Tennessee law and regulations for hospital emergency departments be applicable the proposed FSED? If so, how will these requirements be enforced with regard to a facility that is not licensed in Tennessee? We recommend that the FSED have a clear understanding of this from the Tennessee Department of Health before approving this application.

We appreciate this opportunity to express our concerns. WTH representatives will be present at the Agency's meeting on October 23 to answer any questions the members may have.

Very truly yours,

James E. Ross, MSHA, BSN, AEMT
President and CEO

Cc: Ronny Humes

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October 11, 2019

Via Hand Delivery

Mr. Logan Grant
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Re: West Tennessee Healthcare Letter of Concern re Magnolia Regional Health Center CON Application CN1907-027

Dear Mr. Grant:

The HSDA has provided me with a copy of the October 7, 2019 letter to you from Mr. James Ross, the CEO of West Tennessee Healthcare ("WTH") concerning Magnolia Regional Health Center's application to establish a satellite emergency department (commonly known as a free-standing emergency department or "FSED") in Selmer, McNairy County, Tennessee.

As you know, this firm represents Magnolia Regional Health Center ("MRHC") in this and other matters. While the WTH letter is not a letter of opposition, because it clearly indicates that "WTH does not oppose the project", it is appropriate for MRHC to respond to the "concerns" WTH raised in this letter about the FSED to be built in Selmer, Tennessee.

Representatives and executives have been working on a response to all four of WTH's concerns. As to the first three of those concerns, MRHC will file a responsive letter addressing them early next week. This letter is MRHC's response to WTH's fourth concern.

WTH's last "concern" is regulation. The FSED described in this CON application will be governed by Tennessee law and regulations because it is located in Tennessee. The requirements of those laws and regulations will apply to this FSED.

The Mississippi State Department of Health and the Tennessee Department of Health are currently reviewing a proposed formal agreement which would cover the regulation of this FSED. A copy of that "Reciprocal Agreement Between States for Survey, Certification and Licensure of Hospital-Based Freestanding Emergency Department" is attached to this letter as Exhibit A. This "Reciprocal Agreement" is modeled on ones which have been approved previously by the federal Centers for Medicare and Medicaid Services ("CMS") for other types of

providers. CMS has made clear that it will approve separate sites of a Medicare facility located in, and regulated by, contiguous states. Tennessee and Mississippi can satisfy these requirements as to this proposed FSED, and the respective departments of health in each state are now reviewing the proposed Reciprocal Agreement by which this can be carried out.

In light of this letter and the draft "Reciprocal Agreement" attached hereto, the final concern expressed in WTH's October 7, 2019 letter should be resolved in favor of keeping MRHC's CON application on the consent agenda.

This FSED CON project can be a historic step in helping to resolve rural healthcare problems through the cooperation of neighboring state and local governments.

Sincerely,

BAKER DONELSON BEARMAN CALDWELL & BERKOWITZ, PC

William West

WHW/mhh
Attachment

RECIPROCAL AGREEMENT BETWEEN STATES FOR SURVEY, CERTIFICATION AND LICENSURE OF HOSPITAL-BASED FREESTANDING EMERGENCY DEPARTMENT

In order to promote critical access to emergency medical care in rural and medically underserved areas, the State of Mississippi, through the Mississippi State Department of Health ("MSDH"), and the State of Tennessee, through the Tennessee Department of Health ("TDH"), hereby enter into this Reciprocal Agreement (the "Agreement") to establish their respective duties and obligations with regard to the survey, certification and licensure of a freestanding emergency department that is located in Tennessee (the "Tennessee FSED") but owned and operated by a hospital located in Mississippi (the "Mississippi Hospital").

GENERAL

The MSDH and the TDH will coordinate the administration of the responsibilities under Section 1864 of the Social Security Act with respect to hospitals that are approved to provide services across state lines under a single Medicare provider agreement and/or number. In general, the MSDH and the TDH agree to cooperate and conduct their respective responsibilities related to these providers in a coordinated manner in order to promote streamlined operations and minimize necessary burdens on beneficiaries, providers, survey personnel of the states and the Centers for Medicare and Medicaid Services ("CMS").

In addition, this Agreement will set forth the respective duties of the MSDH and the TDH regarding the enforcement of each State's laws and regulations governing health care facilities that provide services within the States, including, but not limited to, licensure and certificate of need.

PROCEDURES ON FEDERAL REGULATIONS AND ENFORCEMENT

The State of Mississippi, where the approved Mississippi Hospital issued the Medicare provider agreement/number is located, shall be referred to as the Primary State. The Primary State, through the MSDH, maintains the overall responsibility for coordinating all surveys, including initial surveys, re-surveys, revisits, and complaint surveys of Mississippi Hospitals providing services across state lines with the State of Tennessee, through the TDH. The Primary State, through the MSDH, will also report the survey results and the certification recommendations to the CMS Regional Office responsible for the Primary State.

The Primary State and the State of Tennessee have agreed that the State of Tennessee, through the TDH, will be responsible for conducting any necessary surveys of a practice location in the State of Tennessee, including a Tennessee FSED owned and operated by a Mississippi Hospital. The Medicare survey findings of the practice location will be incorporated into the findings of the Medicare survey of the approved provider, the Mississippi Hospital. The MSDH will notify the approved provider of the survey findings, and will also process any necessary termination or denials or other recommendations resulting from surveys by either State.

These same procedures will be followed for any alleged violations or other matters under the Emergency Medical Treatment and Active Labor Act ("EMTALA").

Both the MSDH and the TDH will use CMS forms, guidelines, policies and instructions in processing surveys of providers that operate in both States.

STATE LICENSURE

1. The State of Mississippi, through the MSDH, and the State of Tennessee, through the TDH, will be responsible for ensuring that their respective State laws and regulations, including those related to licensure of health facilities, certificate of need and any other applicable requirements relating to hospitals and/or freestanding emergency departments operating within their State, are met. Specifically, the MSDH will monitor compliance with and enforce all Mississippi laws and regulations applicable to the Mississippi Hospital. The TDH will monitor compliance with and enforce all Tennessee laws and regulations applicable to the Tennessee FSED, The MSDH and the TDH will notify each other of any findings of licensure violations issued by either agency.

2. The State of Mississippi and the State of Tennessee will use survey funds allocated by CMS as compensation for their costs related to a particular survey, re-survey, revisit or complaint survey of a particular provider.

TERM OF AGREEMENT

This Agreement will remain in effect until terminated by mutual consent of the parties.

SO AGREED, this the ___ day of _____, 2019.

THE STATE OF MISSISSIPPI, BY AND THROUGH THE MISSISSIPPI STATE DEPARTMENT OF HEALTH

By:_____

THE STATE OF TENNESSEE, BY AND THROUGH THE TENNESSEE DEPARTMENT OF HEALTH

By:_____

ACKNOWLEDGED AND APPROVED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES

By:_____

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October 14, 2019

Mr. Logan Grant
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Via Hand Delivery

Re: West Tennessee Healthcare Letter of Concern re Magnolia Regional Health Center CON Application CN1907-027

Dear Mr. Grant:

The HSDA has provided me with a copy of the October 7, 2019 letter to you from Mr. James Ross, the CEO of West Tennessee Healthcare ("WTH") concerning Magnolia Regional Health Center's application to establish a satellite emergency department (commonly known as a free-standing emergency department or "FSED") in Selmer, McNairy County, Tennessee.

As you know, this firm represents Magnolia Regional Health Center ("MRHC") in this and other matters. While the WTH letter is not a letter of opposition, because it clearly indicates that "WTH does not oppose the project", it is appropriate for MRHC to respond to the "concerns" WTH raised in this letter about the FSED to be built in Selmer, Tennessee. In our first letter responding to the WTH letter, which we filed on October 11, 2019, we addressed the fourth and final concern raised in the WTH letter of 10/7/19. In this letter, we address the first three of WTH's concerns.

The first concern raised in the letter was that "the CON application does not address the process for transferring a patient to the hospital if the patient needs a higher level of care," which leads to WTH's request that Magnolia "be required to inform patients that they have a choice as to which hospital they be transferred if the patient needs a higher level of care."

In response, MRHC asserts that its FSED in Selmer will be bound by legal, regulatory and ethical requirements which are reflected in Section 16 of the HSDA's "Freestanding Emergency Department Application Guide", which calls for the MRHC FSED to plan to rapidly transport such patients "from the FSED to the most appropriate facility with a higher level of emergency care for further treatment." (Emphasis added.) Among these legal requirements are those under the federal Emergency Medical Treatment and Labor Act ("EMTALA") which

concern patient transfers from hospital emergency departments such as this proposed FSED. EMTALA and the federal regulations thereunder address the process for transferring emergency patients to a hospital when they need a higher level of care. MRHC itself transfers patients to WTH hospitals in Madison County, Tennessee from the emergency department at its main campus in Corinth, Mississippi, on occasions when the patient needs a higher level of care and requests to be transferred to an appropriate WTH facility. The FSED will be part of the emergency department of MRHC, and will follow EMTALA requirements and the policies of the MRHC ED. MRHC is a 200-bed hospital located in Corinth, Mississippi, just south of the Tennessee line. WTH has two hospitals in Madison County, Tennessee with a combined 792 beds. Clearly, WTH is larger than MRHC and has a wider range of services, as well as significantly more beds. MRHC, following currently existing legal, regulatory and ethical directives will rapidly transport patients needing a higher level of emergency care from the FSED to "the most appropriate facility with a higher level of emergency care", whether that is a WTH facility, Baptist Memorial Hospital, or elsewhere. Furthermore, WTH currently handles the ambulance service for McNairy County. There is no need for the HSDA to attach the requirement requested in WTH's first "concern" as a condition to the CON given these facts and existing legal and regulatory requirements.

The second concern that WTH expresses arises from their conclusion that MRHC intends "to maintain only a part-time pharmacy at the FSED." However, this concern misperceives the nature of the "institutional pharmacy practice site" that the FSED will have as defined in Rule 1140-01-.01(33) and (34) of the Tennessee Board of Pharmacy. Pharmacy Board Rule 1140-04-.14 governs what happens at an institutional pharmacy practice site, such as the one at the proposed FSED in Selmer, when the "institutional pharmacy practice is closed." In this event, this rule provides that a pharmacist must be on call 24 hours a day, seven days per week, but that, at subsection (1)(b), the Pharmacy Board specifically covers "after hours drug provision". Subsection (c) of the same rule section provides and authorizes "access to the pharmacy practice site within an institutional facility may be obtained from the pharmacy practice site in accordance with the requirements of this paragraph." The rule goes on to provide detailed instructions as to how access to the pharmacy practice site within an institutional facility can be obtained when the pharmacist is not available. The FSED staff will comply with the rules of the Tennessee Board of Pharmacy. A copy of this rule is attached hereto as Exhibit A.

MRHC has extensive experience in operating an emergency department for a hospital, including applicable pharmacy requirements. Therefore, there will be an institutional pharmacy practice site at the FSED 24 hours a day, seven days per week. There will not be pharmacists at that institutional pharmacy working in the institutional pharmacy 24 hours a day, seven days a week, although a pharmacist will be "on call" as required by the rules of the Pharmacy Board. MRHC's FSED will comply with all rules of the Tennessee Board of Pharmacy related to operating the institutional pharmacy at this site. Bolivar General Hospital, the hospital in Hardeman County, Tennessee that is owned by WTH, reports on its 2018 JAR that it is staffed by a .63 FTE pharmacist at that hospital. Thus, it is possible for a hospital such as Bolivar General Hospital or an FSED such as the one proposed in this certificate of need application to comply with all the requirements for an institutional pharmacy without having a pharmacist on site for 24

hours per day. MRHC's CON application indicates that it will have one FTE pharmacist on site at the FSED.

The third concern expressed by WTH is "the CON application indicates that ultrasound will not be available." HSDA's FSED Application Guide ("Guide") specifically requires, at Item No. 11, that "X-ray and CT scanners, shall be available on-site during all hours of operations." (Emphasis added.) MRHC's CON application specifically makes clear that its FSED in Selmer will have X-ray and CT scanning available 24 hours per day, seven days per week. See Response to First Set of Supplemental Requests No. 26, as well as Guide Item No. 11 response. There is no similar specificity in the Guide as to ultrasound. Similarly, in the "Radiologic Services" section of the Licensing Board's Standards for Hospitals at Licensing Board Rule 1200-08-01-.06(7), ultrasound is not specifically mentioned, while "X-ray equipment" and "radiation-producing equipment" are mentioned. CT scanning also utilizes X-ray radiation.

In light of the matters set forth in this letter and the exhibit attached, as well as in MRHC's initial response letter filed on 10/11/19, the concerns expressed in WTH's October 7, 2019 letter should fully be resolved in favor of keeping MRHC's CON application on the consent agenda.

Sincerely,

BAKER DONELSON BEARMAN CALDWELL & BERKOWITZ, PC

William West

WHW/mhh
Attachments

(Rule 1140-04-.12, continued)
Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed August 30, 1991; effective November 27, 1991. Amendments filed November 22, 2016; effective February 20, 2017.

1140-04-.13 RECALLS.

The recall procedure shall be readily activated to ensure that all prescription drugs and devices and related materials included on the recall are returned to the pharmacy practice site for proper disposition. The pharmacist in charge shall develop and implement policies and procedures for recalls.

Authority: *T.C.A. §§ 63-10-404(8), (14), (27), and (28) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed August 30, 1991; effective November 27, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-04-.14 ABSENCE OF PHARMACIST.

(1) Institutional pharmacy practice site.

(a) General. During such times as an institutional pharmacy practice site is closed, facility policy as approved by the pharmacist in charge shall provide a process for authorized personnel to obtain drugs necessary for the provision of patient care. This function may also be accomplished as outlined in the After Hours Drug Provision of this section. A pharmacist must be "on call" twenty four (24) hours per day, seven (7) days per week.

(b) After Hours Drug Provision. When an institutional pharmacy practice site is closed, access to prescription drugs shall be by locked cabinet(s), automated dispensing machines or other enclosure(s) constructed and located outside of the pharmacy practice site, to which only personnel authorized by the pharmacist in charge may obtain access. Access should be sufficiently secured to deny entry to unauthorized persons by force or otherwise. Those practice sites utilizing automated dispensing devices for after hours drug provision shall meet the requirements of rule 1140-04-.15. The pharmacist in charge shall develop an inventory listing of those drugs to be included in such after hours storage, and shall ensure that:

1. Such prescription drugs are available therein, properly labeled;

2. Such prescription drugs are prepackaged in amounts not to exceed a seventy-two (72) hour medication period; unless available in a commercially prepared package dictating multiple dose therapy (e.g., ophthalmic products, topical products, otic products);

3. All prescription drugs therein are inventoried at least once a month;

4. A record shall be made at the after hours storage location including the following elements:

(i) The date and time of removal of a drug;

(ii) The patient's name and location;

(iii) The name, strength, dosage form, and quantity of the prescription drug; and

(iv) The identification of the authorized personnel removing the drug.

Ex. A

(Rule 1140-04-.14, continued)

5. The prescription order shall be verified by a pharmacist or designee in a timely manner.

6. The above record shall be used by authorized pharmacy personnel to replenish the after hours storage location, and this record shall be kept at the institutional pharmacy practice site so as to be readily retrievable for at least two (2) years;

7. Policies and procedures shall be established to implement the requirements of this section.

(c) Access to the Pharmacy Practice Site within an Institutional Facility. Whenever any prescription drug is not available from floor supplies, emergency kits, or other approved distribution system for the facility, and such prescription drug or device or related material is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such prescription drug, device or related material may be obtained from the pharmacy practice site in accordance with the requirements of this paragraph. Only authorized personnel, accompanied by a security guard or other authorized employee of the institution may have access to the pharmacy practice site and may remove the required drug, device or related material. Such person(s) shall be designated through policies of the facility and shall receive appropriate education and training in the proper methods of access and removal of prescription drugs, records and procedures required prior to such person(s) being permitted to obtain access to the pharmacy practice site. Such education and training shall be conducted by the pharmacist in charge or designee, who shall require, at a minimum, the following records and procedures;

1. Removal of any prescription drug, device or related material from the pharmacy practice site by an authorized person(s) must be recorded in a suitable form at the pharmacy practice site showing:

(i) The date and time of removal of the drug;

(ii) Patient identification and location;

(iii) The name, strength, dosage form, and quantity of the drug, device or related material removed; and

(iv) The signatures of the authorized personnel and the accompanying witness;

2. The above record shall be maintained at least two (2) years at the pharmacy practice site electronically, or in a separate file or log book;

3. The medication or prescription order shall be verified by a pharmacist or authorized personnel; and

4. The quantity of drug removed shall not exceed the amount needed plus one (1) dose until the pharmacy practice site reopens; unless available in a commercially prepared package dictating multiple dose therapy (e.g., ophthalmic products, topical products, otic products).

(2) Alternate or Alternative Infusion pharmacy practice site.

(a) During such times as an alternate or alternative infusion pharmacy practice site is closed, policies and procedures shall be established by the pharmacist in charge for