



Certificate of Public Advantage

2019 Department Annual Report

Tennessee Department of Health | May 7, 2019



COPA: 2019 Department Annual Report

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Introduction and Background

The COPA

A **Certificate of Public Advantage (COPA)** is the written approval by the Tennessee Department of Health (TDH) that governs a Cooperative Agreement (including a merger) among two or more hospitals. A COPA provides state action immunity to the hospitals from state and federal antitrust laws by **replacing competition with state regulation and Active Supervision**.

TDH has the authority to issue a COPA if applicants pursuing a COPA demonstrate that the **likely benefits** of the proposed Cooperative Agreement **outweigh the likely disadvantages** that would result from the loss of competition. The ability to grant a COPA is authorized by Tennessee's Hospital Cooperation Act of 1993, amended in 2015. Permanent Rules 1200-38-01 implement T.C.A. § 68-11-1301 – 68-11-1309.

In February of 2016, the two largest health systems in Northeast Tennessee, Wellmont Health System and Mountain States Health Alliance, submitted an application for a COPA. The applicants explained that if allowed to merge, they would realize savings by reducing duplication and improving efficiencies that **they would reinvested in ways that would substantially benefit** those residing in their Geographic Service Area (GSA).

Their combined GSA includes 10 counties in Northeast Tennessee and eleven counties in Southwest Virginia. This region is part of the Appalachian Region, is largely rural, and has a number of health, economic, and other challenging factors that when combined present a unique and difficult environment for the improvement of the quality of and access to health care and health outcomes.

On January 31, 2018, in coordination with the Tennessee Attorney General's Office, TDH issued a COPA to Mountain States Health Alliance and Wellmont Health System, allowing them to merge and become **Ballad Health**. The TDH and AG's Office developed the **Terms of Certification** (TOC), to govern the COPA. The TOC lays out the Ballad obligations and responsibilities and the regulatory role of the State. This document **details the conditions required by TDH for Ballad to demonstrate ongoing public advantage**.

Within the TOC is a description of the **Index and scoring system** that **will be used to track and evaluate** the demonstration of ongoing public advantage along four categories (sub-indices):

- Access to Health Services
- Population Health Improvement
- Economics
- Other (primarily quality of care)

Via the COPA Index, TDH will track the progress under the Cooperative Agreement and annually determine if a public advantage is maintained for the residents of the GSA. Based on the size of the region, the size of the population impacted, and the involvement of two states, this COPA is an unprecedented process.

The Department Annual Report

Pursuant to the TOC, TDH is required to prepare an Annual Report that incorporates findings from (i) Ballad Health's Periodic Reports, (ii) the COPA Compliance Office Annual Report, (iii) the Local Advisory Council Annual Report, (iv) the COPA Monitor Annual Report, (v) the Healthcare Access Report, and (vi) the Population Health Report. The Department Annual Report must also include determinations of compliance, the Index Scores, the Final Score, the Pass/Fail Grade, and trends relevant to the Active Supervision of the COPA and continued Public Advantage for each Fiscal Year **when this information is available**.

The Department Annual Report is the last in a series of Annual Reports required by the TOC this Fiscal Year. The Ballad Health Annual Report and COPA Compliance Office Annual Report were submitted roughly 120 days after the end of Ballad's Fiscal year. The Local Advisory Council (LAC) held a Public Hearing on February 7, 2019 to allow residents to respond to the Ballad Health Annual Report and subsequently published the Local Advisory Council Annual Report on public feedback. The LAC's report included recommendations to the COPA Monitor and to TDH. The COPA Monitor Annual Report was provided to TDH on April 7, 2019, in which the COPA Monitor responded to several recommendations and provided recommendations of his own to TDH as well as to Ballad Health.

TDH is one of several entities that have an Active Supervision role under the TOC. A graphic that illustrates the responsibilities of each of the Active Supervision roles is included as an attachment to this report.

Annual Review

Section 7.02 of the TOC reads:

Pursuant to Tenn. Code Ann. §68-11-1303(g), the Department shall review, on at least an annual basis, the COPA to determine Public Advantage (the “Annual Review”). The Department shall review whether Public Advantage is demonstrated or not for each Fiscal Year during the COPA Term, in accordance with the procedures and requirements of the COPA Act and (the TOC). This Annual Review shall include, without limitation, the following: (i) the determination of the Final Score and Pass/Fail Grade, ... (ii) the COPA Parties’ degree of compliance with the Terms and Conditions, ... and any and all COPA Modifications and Corrective Actions occurring prior to such review, and (iii) trends of (Ballad Health’s) performance hereunder since the Issue Date and other factors (which may or may be reflected in the Index) relevant to the Department’s determination of the likely benefits and disadvantages of the Affiliation which, as of the time of such determination, can reasonably be expected if the Affiliation is continued.

Score

As discussed more fully below, a Final Score cannot be calculated at this time. TDH will calculate its first Final Score in the spring of 2020. Consequently, TDH’s initial finding of public advantage continues.

Population Health, Access to Health Services, and Other (Quality) Sub-Index scores are largely calculated by comparing baseline data to data in subsequent years. Other components of the first year score include annual spending investments and the implementation of plans for the period that **begins January 31, 2018 and concludes on June 30, 2019**. (For complete details on the Scoring calculations see the TDH’s Certificate of Public Advantage: Index Reports and the TOC.) TDH’s first Population Health, Access to Health Services, and Other (Quality) Reports included baseline values for each measure with the most recent Calendar or School Year data, as appropriate, that were available in 2018. In future years, TDH will report post-merger trend data to evaluate if there was a statistically significant change in performance on the measures.

For these reasons an Annual Review with Sub-Index Scores, a Final Score, the Pass/Fail Grade, and trends, as described in the TOC, cannot be provided until after the first full Fiscal Year. In this first Department Annual Report, TDH will 1) comment on things that are working well,

challenges, and concerns throughout the first year; 2) report on findings from other Annual Reports; 3) respond to recommendations; and 4) provide recommendations.

Things that are working well.

TDH has identified the following COPA-related successes of the past year:

- Hospitals that were under threat of closure remain open, as required by the TOC.
- There have been fewer layoffs post-merger than had been expected.
- Ballad Health submitted each of the required periodic reports and three-year plans in compliance with the TOC.
- Ballad Health promptly provided additional data and information on quality performance upon request.
- Ballad Health promptly provided additional data and information on the Accountable Care Community upon request.
- The COPA Compliance Office responds quickly and thoroughly to inquiries from TDH.
- Ballad's Health's executive staff meets frequently with the COPA Monitor and provides information upon request.
- Ballad Health's Greene County hospital consolidation plan appears to be an innovative and successful solution. TDH is optimistic about this experiment. A description of the plan is available [here](#).
- Ballad Health's three year plans outline bold approaches to improving [Population Health](#), [Children's Health](#), [Behavioral Health Access](#), Rural Health Access, Region-wide Health Information Exchange, Health Graduate Research, and Graduate Medical Education in the region.
- TDH is particularly impressed by the Accountable Care Community that Ballad Health is playing a lead role in establishing in the region.

Challenges

TDH has identified the following items as COPA-related challenges:

- **Public messaging.** Community engagement is a positive step and accurate information is helpful to the public and to TDH as it provides oversight. However, insufficient

information provided well in advance to the public can result in rumors and misinformation, making the work of both the regulated and the regulator more difficult.

- **Communication.** Ballad Health, the Local Advisory Council, and TDH staff have all received criticism for ineffective communication with the public.
- **Complexity of the COPA and of the provision of health care in general.** The COPA is a complex and unique undertaking. Additionally there are laws that apply to all health care facilities regardless of whether or not they have a COPA. The general public is not familiar with the nuances of these laws.
- **Public's interest in an immediate evaluation of benefits v disadvantages.** The TOC lays out the detailed process TDH is required to use to determine if the COPA results in an ongoing public advantage. This annual determination will begin following the completion of FY 2019.
- **TOC strength.** TDH and the Attorney General's Office have identified opportunities for clarification and refinements to the Terms of Certification, most notably to Addendum I, which provides for limits upon, measurement, and reporting of price increases for specific services, including hospital inpatient and outpatient, non-hospital outpatient, physician and physician extender charge-based and cost-based services.
- **Change is difficult.** Improving efficiencies includes coordinating and sometimes consolidating services, which involves making tough decisions at a system level. While system level changes create overall efficiencies, they are often perceived negatively by those impacted. The COPA and the COPA Index are designed to ensure that the region experiences an overall benefit.
- **Data availability.** Population Health Sub-Index data, as listed in the TOC, have not been available at the level of detail that was expected at the outset of the Index development. Access to Health Services Sub-Index data have also proven to be problematic once in-depth discussions were held with Ballad Health regarding the definitions of data measures and the differences in data collected by their two electronic health record systems. TDH has also learned that the national data definitions, to which COPA's Quality Sub-Index data are linked, change from time to time making trend comparisons problematic. Efforts are underway between TDH, VDH, and Ballad Health to define more stable measures that allow better ongoing assessment and establish a more solid and comparable baseline.
- **Economic development.** The ability of Ballad Health to maintain quality of care across its facilities and access to care across the geographic service area will become increasingly challenging in a region with a declining birth rate and an aging population.

- **Recruitment capabilities.** TDH has particular concerns about Ballad Health’s ability to recruit the number of children’s health specialists listed in Ballad Health’s Children’s Health Plan. This recruitment uncertainty is a direct result of declining birth rates; without a growing pediatric population, TDH believes Ballad Health will continue to have difficulty attracting and retaining the specialists it lists.

Concerns specific to Ballad

TDH has the following concerns regarding Ballad Health’s initial experience operating under a COPA.

- TDH has not always received what it regards as adequate advance notice of major decisions made by Ballad Health.
- Ballad Health should develop a plan for better interactions with independent primary care physician groups
- In the past, TDH felt it did not receive complete answers to written questions. TDH considers the issue to have been resolved.

Certain General Complaints that have been Resolved

The following are complaints that have been investigated and resolved:

- **TDH received complaints that pay and benefits for nurses have declined since the merger.** The COPA Monitor found that as a result of Ballad Health’s efforts to equalize pay rates and employee benefits across the new merged system, overall employee pay and benefits had gone up slightly. Ballad Health announced on May 7, 2019 a decision to increase pay to nurses.
- **TDH received complaints that health care prices have increased since the merger.** The COPA Monitor found that certain price increases were negotiated by Ballad Health last fall. After auditing a large sample of files, from January 2018, July 2018, and November 2018 it was determined that Ballad Health complied with TOC’s Addendum I requirements.

Unexpected consequences

- The move of the Wellmont Cancer Center in Allandale to Indian Path Community Hospital is resulting in higher costs for the patients, as a higher facility fee can now be charged.
 - TDH staff received complaints that the consolidation of the Wellmont Cancer Center in Allandale to the new cancer facility at Indian Path Community Hospital had a negative financial impact on some patients. Ballad Health has attempted to address this matter by not charging all current patients a higher facility fee for six months, as well as providing lower Section 340b drug pricing. After review, TDH believes that the net result of the consolidation of all cancer treatment services into Indian Path Community Hospital is a benefit overall to the patient population in terms of access, quality of care, and ultimately – due to the ability of Ballad Health to obtain lower Section 340b pricing on cancer drugs – cost.
- Ballad Health’s care coordination changes related to its trauma center consolidations could impact established regional EMS providers.
- TDH has received complaints that Ballad Health has made a system-wide billing change that results in separate bills being generated for an individual patient, with minimum payments due on each bill. The complainants state that Ballad Health is refusing to consolidate these bills so that one payment plan can be created.
 - This situation is not a COPA violation, but a change in billing practice. The COPA Monitor is reviewing this situation.

Resolved instances on potential non-compliance

As of the date of this report’s publication, there have been no confirmed non-compliance events under the Terms of Certification. The following potential non-compliance events were all swiftly resolved as required by the TOC:

- Resolved Instance No. 1: Within the first two months of the merger, Ballad Health discovered their payment invoicing system did not comply with TOC requirement 4.03(d). Ballad reported this issue in its first quarterly report and stated it had begun working to adjust its payment invoicing system and had identified certain payments that would be retroactively adjusted by June 30, 2018. TDH received confirmation on 10/26/2018 that any adjustments to patient balances where the patient would be positively impacted were made to ensure compliance and that for the four patients who had paid in full by the time the error was caught, refunds had been paid out.

- Resolved Instance No. 2: TDH received a letter from the COPA Compliance Officer dated 12/03/2018 regarding its not having included facilities that exist in counties contiguous to the Ballad hospitals' counties on Ballad's List of Competing Services for Ancillary and Post-Acute Services. Ballad Health printed new packets and provided a copy to the COPA Monitor by December 31, 2018. Ballad Health's Office of Patient Resource Management confirmed that the new packets are being distributed to all patients requiring post-acute services at discharge.
- Resolved Instance No. 3: As of the submission date of the Ballad Health Quarterly Report for Fiscal Year 2019, Quarter 2, the COPA Compliance Office informed TDH that it received a complaint regarding collection efforts for services provided to patients who are insured by an out-of-network Payor. The complaint identified a non-compliance issue with the provisions of Addendum 1 Part XII (f) of the TOC regarding collection efforts from Payors of a never in-network party. Ballad Health and TDH are discussing the requirements for billing never-in-network Payors and patients and are working on a remediation process.

Findings from Reports

The COPA Compliance Office Annual Report;

The COPA Compliance Office Annual Report is available [here](#).

Findings:

- The COPA Compliance Office Annual Report was filed in compliance with the Terms of Certification and included required information.
- TDH engaged in lengthy follow up discussions with Ballad Health regarding the following Requests for Modifications/Extensions listed in the report:
 - Request for extension on Payment Indices for Outpatient, Physician Clinics, Ambulatory Surgery Centers and for Never Contracted Percent;
 - Proposed Base Charity Care provisions in the Terms of Certification; and
 - Request for Measurement changes.
- The Situation, Background, Assessment, Recommendation (SBAR) process implemented by the COPA Compliance Office is well-crafted and very helpful from a regulator's perspective. Any Waiver or Modification request will go through an extensive internal vetting process before submission to TDH.
- The COPA Compliance Department projected spending \$4.77 million in FY19 on COPA Compliance, of which \$1.827 Million is allocated to TN COPA fees and \$1.827 is allocated to VA Cooperative Agreement fees. TDH expects that these estimates will likely be adjusted downward for future reports.

Ballad's Periodic Reports;

Ballad Health Quarterly reports are available at the following links:

- FY18 Q3 (reporting period: February 2018-March 2018) can be read [here](#).
- FY18 Q4 (reporting period: April 2018-June 2018) can be read [here](#).
- FY19 Q1 (reporting period: July 1, 2018-September 30, 2018) can be read [here](#).
- FY19 Q2 (reporting period: October 1, 2018-December 31, 2018) can be read [here](#).

Findings:

- Ballad Health's four quarterly reports were submitted in compliance with the Terms of Certification and included all required information.

- The TDH and the COPA Monitor engaged in lengthy conversations with Ballad Health regarding several items reported in Ballad’s Quarterly reports, including:
 - Establishment of Base Charity Care Amount;
 - Baseline Spending Calculations;
 - Format of Quality Measure reporting; and
 - Policies for Financial Assistance and Credit/Collections.

The Ballad Health Annual Report is available [here](#).

Findings:

- The 225 page Ballad Health Annual report was submitted in compliance with the TOC.
- The report is thorough and comprehensive. It includes sufficient data and detail as well as narratives about the progress of various undertakings and the challenges associated with a few of them.
- The report was also laid out well. The information required to be included in the Annual Report pursuant to the TOC was clearly labeled and easy to find.
- Ballad mentions in its Annual Report that it has invested in the MedeAnalytics Enterprise Performance Management Tool to track progress under the Health Services Plans. Ballad Health provided a demonstration of the program’s capabilities to TDH and VDH, which the states found impressive. TDH looks forward to seeing reports generated from this performance management tool to confirm that plan strategies are being implemented according to the timelines, that investments are producing intended results, and to understanding where potential issues might arise that could negatively impact TDH’s scoring of Ballad’s performance so that TDH can address those with Ballad.
- Related to Access:
 - There are certain Access to Health Services Sub-Index data development activities assigned to Ballad Health under the TOC that, due to certain data recovery issues, TDH now recognizes cannot be provided by Ballad Health. Data discussions on sources, baselines, and targets are ongoing.

- TDH appreciated the summary of Ballard’s efforts to create and expand programs for oral health care, addiction medicine, 340B designations in Hawkins and Hancock County.
 - TDH is optimistic about Ballard’s repositioning Greene County Hospitals to preserve their viability and the opening a new hospital in Unicoi County. The Greene County Hospital changes include consolidation of certain services at each campus and a repurposing by adding a new 12-bed progressive care unit. The new hospital in Unicoi offers acute care beds, an Emergency Department, diagnostic imaging, and physician office space. One unique feature for the new hospital is that it is in a partnership with the International Storytelling Center with a goal to embed storytelling into the culture for staff, patients, and visitors.
 - TDH was pleased to read that in addition to recruiting to its own staff of employed physicians, Ballard Health has assisted in recruiting physicians to independent physician groups to improve access and to work to maintain pre-merger levels of competition in the region.
- Related to Population Health:
 - Population Health Sub-Index data, as listed in the TOC, are not available at the level of detail that was anticipated by both Ballard Health and by TDH at the outset of the Index development. Ballard Health’s Annual Report cites among other things, discussions with TDH on the population health measures. Data discussions on sources, baselines, and targets are ongoing. (See the bullet on “data availability” on page 8 for more information.)
 - TDH is pleased with the following accomplishments that were reported:
 - The establishment of a Department of Population Health staffed with both community health and value-based healthcare professionals.
 - Establishment of a Population Health Clinical Steering Committee to create seamless transitions between clinical interventions and community interventions.
 - Growing its regional business health services to incorporate employer-based community health programming. Growing the parish nurse program, where parish nurses serve parishioners in the community, and expanding the Health Resource Centers

presence in the region to provide, for example, mobile food distribution.

- Establishment of Ballad Health as an Example for Community Health Improvement. This initiative is particularly encouraging considering the number of Ballad Health employees who will be impacted and who will potentially go on to be influencers in their communities. Features of this comprehensive effort include employee risk assessment, health coaching, health plan redesign, food and vending policies, and worksite wellness interventions.
 - Ballad's participation in health care innovation and transformation initiatives such as the National Medicaid Transformation Project and the Accountable Health Communities.
 - Ballad's role in establishing an Accountable Care Community in the region with broad participation.
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- Related to Economic factors. In Ballad's Annual report TDH notes the following:
 - In Fiscal Year 2018 Ballad reported that legacy MSHA facilities had implemented a 5% global price increase, but legacy WHS had not.
 - \$3.8 million in cost reductions were achieved by the elimination of duplicate corporate positions.
 - FTE personnel increased between Feb 2018 to June 2018 from 11,494 to 11,514.
 - Related to Quality:
 - The data provided on quality indicators by Ballad Health was comprehensive and presented in a user-friendly format.
 - According to Ballad's Annual Report, an improvement in Ballad's performance was identified in 12 of the 16 Target Quality Measures over the baselines. However, TDH's comparison between the baseline data reported in TDH's Other (Quality) Report and the baseline data referenced in the Ballad Health Annual Report had discrepancies. We understand these inconsistencies were due to delayed claims data. As a result, TDH, VDH, and

Ballad Health have been engaging in developing quality data guidelines and standards for COPA reporting.

- TDH is encouraged by the work undertaken by the Clinical Council and its sub-committees as described in Ballad's Annual Report. TDH supports the council's focus on evidence-based medicine/high value care, patient experience, health informatics, and promotion of safe use of controlled substances within communities.

The Local Advisory Council Annual Report;

The Local Advisory Council Annual Report is available [here](#).

The Local Advisory Council Annual Report included recommendations to TDH. These recommendations and the department's responses are on page 20.

The COPA Monitor Annual Report;

The COPA Monitor Annual Report is available [here](#).

Findings:

The COPA Monitor Annual Report included recommendations to TDH. These recommendations and the department's responses are on page 25.

The Population Health Report

The Population Health Report can be found inside the collection of COPA Index Reports and is available [here](#).

There currently are 56 measures being monitored on the population health scorecard, 25 of which are calculated into the population health sub-index for scoring. In the past year, extensive work has been undertaken by Ballad Health and TDH to agree upon and document the exact source and methodologies for each measure. This effort has resulted in several measures being changed and/or refined while maintaining the intent of the measure. An example of this is the work to adequately define vaccination rates in the COPA region within the limitations of the possible data gathering tools available to Ballad Health and/or TDH.

The March 2019 publication of the Certificate of Public Advantage: Index Reports included 26 values for baseline values for the COPA region of Tennessee -- the others are new measures or the data have not been tabulated at this time. Some measures show the values for the COPA region are often less healthy than peer counties, the state and the nation (mothers who smoke during pregnancy at 22.6%, 20.6%, 12.7% and 6.9% for COPA, peer counties, state and US respectively; overweight among TN public school students at 43.6%, 42.3% and 39.2% for COPA, peer counties and state, respectively; neonatal abstinence syndrome at 49.7, 26.2 and 13.5 per 1,000 live births in COPA, peer counties and state, respectively; and cardiovascular deaths at 317.2, 287.7, 238.4 and 165.0 deaths per 100,000 population in COPA, peer counties, state and US respectively). Several measures show the COPA region performing better than peer counties, though still lagging state and US estimates (breastfeeding initiation at 73.5%, 72.5%, 78.0% and 83.2% of live births in COPA, peer counties, state and US, respectively; suicides at 18.1, 22.2, 17.3, 14.0 deaths per 100,000 population in COPA, peer counties, state and US, respectively; diabetes deaths at 29.36, 37.9, 28.5, 21.5 deaths per 100,000 in COPA, peer counties, state and US, respectively; and MME for pain at 1,211.2, 1,316.9, 912.7 and 511.1 morphine milligram equivalents for pain per capita for COPA, peer counties, state and US, respectively). In a few cases, the COPA region rates are better than current state rates (low birthweight infants at 8.7%, 8.8%, 9.1% and 8.3% of live births in COPA, peer counties, state and US, respectively; and on-time vaccinations at 97.3%, 96.4%, 95.3%, and 95% of children up-to-date at kindergarten entry in COPA, peer counties, state and US, respectively).

The Access to Health Services Report

The Access to Health Services Report can be found inside the collection of COPA Index Reports and is available [here](#).

The 28 measures include those related to geographic proximity, emergency department response, personnel requirements and recruitment, and behavioral care access. Data sources include health system records, Behavioral Risk Factor Surveillance System (BRFSS) and Tennessee Discharge Data System. Success is measured by maintaining and/or improving the values, depending upon the measure. As of the baseline report published in March 2019, five metrics had baseline values, four metrics are awaiting analysis by the Tennessee Department of Health of weighted BRFSS data, and TDH is in discussions with Ballad Health regarding the best manner through which both entities will work to provide 19 metrics.

An example is the baseline value for prenatal care in the first trimester in the COPA region was 66.8%. This is considerably below the national rate of 77.1% receiving care in the first trimester. (NVSr, Volume 67, No. 3, May 30, 2018. Data for 2016. https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_03.pdf).

In the past year, measure definitions have been extensively refined to be more precise, including the data source and the methodology used to calculate values. Changes to improve the usability, accuracy and reliability of the measures are being implemented and include tasks such as refining geographic reference points, customized weighting of BRFSS survey data, and establishing and/or refining health system data collection processes.

Other refinements are actively being discussed as challenges with data collection and analysis are uncovered.

The Other (Quality) Report.

The Other (Quality) Report can be found inside the collection of COPA Index Reports and is available [here](#).

The original 16 measures in the Target Quality Measures have been expanded to 17 measures because of changes in Agency for Healthcare Research and Quality (AHRQ) data definitions and data gathering processes. The 83 Quality Monitoring Measures are largely the same.

The Target Quality Measures focus on measurement of items that can cause harm such as in-hospital infection and adverse event rates. The Quality Monitoring Measures focus on processes, communications and other operational methods.

Comparing the target quality measures to national norms indicate that the Tennessee baseline has nine of 17 measures in the bottom quartile including pressure ulcer rate, iatrogenic pneumothorax rate, perioperative hemorrhage or hematoma rate and hysterectomy surgical site infection rate. Two of the 17 measures are in the upper quartile and are the in-hospital fall with hip fracture rate and the postoperative physiologic and metabolic derangement rate.

In the past year, efforts have focused on refining these measures to account for on-going changes in AHRQ data collection processes that are outside of Ballad and TDH control and to align with Virginia Department of Health where possible. Efforts are also underway to define

more stable measures that allow better on-going assessment of the measures, to establish a more solid and comparably baseline, to minimize collection and reporting requirements of Ballad, to ease analysis required by the department for surveillance, and to make reports easier to understand for all parties, including the general public. Proposed changes are being developed in a joint effort between Ballad and the Tennessee and Virginia departments of health.

TDH received feedback that the data as presented in the report was difficult to read. The department is revising the quality data table in the Other (Quality) Report and plans to publish an amended version in May.

Response to Local Advisory Council (LAC) recommendations

The Department of Health appreciates the excellent work accomplished by the LAC in its first 12 months. It has developed a webpage, comment form, and email address to facilitate public input; held its first series of working meetings; conducted a review of the Ballard Health Annual Report; held its first Public Hearing; and published its first LAC Annual Report with recommendations for the COPA Monitor and TDH. Below are the recommendations for TDH and the department's responses:

Recommendation 1: Consider taking an active role in supporting the efforts of the proposed Accountable Care Community to improve the health of the population.

TDH is impressed by the early work of Ballard to coordinate the establishment of an ACC to improve the health of residents in the region. TDH's local health departments are engaged in the ACC's work (specifically related to opioid abuse). TDH is eager to cooperate, collaborate, and coordinate with the ACC's work where it aligns with the mission and goals of local health departments and TDH. The department is open to discussing ways we may support the ACC as its work moves forward.

Recommendation 2: Consider refining to a smaller list of population health measures upon which Ballard will be scored.

The process TDH used to establish the Population Health Sub-Index was robust. We engaged an Index Advisory Group, hired consultants, and met with internal and external experts. Ultimately 25 measures were selected as the measures that would comprise the Population Health Sub-Index score and be factored into the department's Annual Review and determination of ongoing public advantage. The original 25 Priority Population Health Sub-Index measures and data sources are listed in the Terms of Certification.

TDH's Division of Health Planning had frequent discussions with the department's epidemiologists, data stewards, and program evaluation experts regarding the limitations of various data sources for the Population Health Sub-Index measures since the COPA was issued. Issues with data lags, high confidence intervals, and validity had been identified. Some of the issues were addressed through revisions to the measures described in a letter dated 2/22/19 (https://www.tn.gov/content/dam/tn/health/documents/copa/2019.02.22_letter_to_Ballad_re_P

[H measurement revisions with Attachment.pdf](#)). Many other issues could not be easily resolved, such as the length of time required for a change in the region's adult smoking rate, cancer rate, or premature death rate to be said to be attributable to an intervention, campaign, or other effort(s) initiated by Ballad Health.

While it is important to TDH that the work of the Index Advisory Group be honored as well as the intent and spirit of the Population Health Sub-Index as described in the TOC, the department agrees that more refinement (possibly including a reduction in the number of population health measures) are critical to improving the quality and validity of the department's evaluation of Ballad Health's performance and its determination of ongoing public advantage.

Recommendation 3: Consider assisting the LAC in clarifying its role and in clarifying and communicating the LAC's role to the public.

The Terms of Certification state that the role of the LAC is to facilitate public input. The TOC outlines three specific responsibilities of the LAC:

- 1) Host an annual public hearing;
- 2) Publish a Local Advisory Council Annual Report; and
- 3) Recommend to the department how population health funds should be spent.

TDH acknowledges the need to better clarify the LAC's role to the public. As a first step, a graphic of the Active Supervision roles has been created and is included as an attachment to this report. Secondly, an informative complaint form has been developed that will outline what constitutes a violation of the COPA, what constitutes a violation of another state regulatory office, and what constitutes a legal matter that is beyond the purview of the TOC. Thirdly, TDH is updating its COPA webpage to include the Active Supervision graphic and explanations of each roles in the Active Supervision structure. TDH will look for additional opportunities to clarify roles to the public.

TDH relies on the public to alert it of potential violations that should be investigated. However, it is important to understand that some of the issues brought to the LAC's attention are not a result of the merger of the two hospital systems and thus, not resolvable under the COPA Terms of Certification. TDH has had processes in place for receiving and investigating certain health care complaints long before the merger. Examples of issues that are not COPA-related,

and that the LAC – or the Monitor or the Office of Health Planning -- is not able to address include:

- **Cleanliness, staffing concerns, and certain health care issues.** These issues may or may not have happened as a result of the merger of the hospital systems and are not violations of the COPA Terms of Certification. Safety concerns should be directed to TDH's Office of Health Care Facilities. The Office of Health Care Facilities remains responsible for the licensing and regulation of hospitals in the State. The process for filing a complaint against a Tennessee health care facility or provider is available [here](#).

To be clear, while it is not the role of the TDH nor the LAC under the TOC to assist or track individual patients who have a negative experience at a Ballad Facility, TDH is tracking Ballad's performance on dozens of safety and quality measures including timely and effective care, infection rates, and patient satisfaction scores at 1) a system level, 2) a statewide level, and 3) each Ballad facility. Quarterly and Annual data for Ballad Health's total patient population will absolutely be used to track demonstration of an overall improvement or decline in care quality subsequent to the issuance of the COPA.

- **Labor concerns.** Staff labor concerns are regulated by the Tennessee Department of Labor and Workforce Development. Information on its statutes governing employee meals and breaks, wage regulation, and fringe benefits can be accessed from that Department's website [here](#) and its Labor Standards Unit with information how to file a complaint can be contacted by calling 844-224-5818.

Certain employee benefits and protections are covered by the COPA and are described under Section 3.08 Terms of Certification. The TOC is available [here](#).

- **Billing issues.** High deductibles, high premiums, and co-pays are a part of the complex United States health care system and not related to the COPA. Double billing or coding issues may be errors caused by a human data entry error. Those issues should be directed to Ballad Health's billing department, which can be reached by calling at (423) 431-1700 or (423) 408-7400.

Systemic changes in Ballad Health's billing practices may be related to the COPA. The public is encouraged to contact TDH with details of systemic changes at Ballad Health that impact costs.

Recommendation 4: Consider assisting Ballad in educating the public on the types of care that their local hospital CAN provide and in better informing and engaging the public on future proposed changes in health care delivery.

TDH agrees that Ballad has not been successful in educating the public on the types of care that will be provided in its local hospital after trauma center consolidations are completed.

In November 2018, Ballad Health announced its previously approved plans to downgrade Holston Valley Medical Center from a Level I Trauma Center to a Level III Trauma Center and its plan to downgrade Bristol Regional Medical Center from a Level II Trauma Center to a Level III. TDH has approved the move to a Level III Trauma Center at Bristol Regional Medical Center. The LAC received numerous comments from the public expressing concern over the risks to their health associated with the loss of services being proposed. The following details, provided to TDH by Ballad Health, regarding the services that will remain at various Ballad facilities include:

- » All Kingsport-based interventional cardiology; orthopedic surgery and neurosurgery in Kingsport will take place at Holston Valley Medical Center. Medical cardiology services will remain at Indian Path Community Hospital.
- » Bristol Regional Medical Center and Holston Valley Medical Center will continue to be trauma centers. More than 65% of the trauma cases are orthopedic; and orthopedic and neurosurgical services will continue to be available at these locations.
- » There is an important distinction between an emergency department and a Trauma Center. The TOC requires that all emergency departments will remain open.
- » Ballad Health is not closing any Trauma Centers. By implementing a better coordinated comprehensive regional trauma system, Ballad can improve the performance of the overall trauma system. Because the data show that the region has a relatively small number of trauma cases that are objectively categorized as "major" trauma, the

evidence supports integrating those cases at one center, where the volumes can be high enough to sustain the skills of the practitioners and improve overall outcomes for patients.

Recommendation 5: Consider confirming that the region has (or will have) sufficient EMS resources to support any changes in demand caused by the consolidation of the Level I Trauma Centers.

TDH commits to engaging with Ballad Health and EMS providers to ensure that patient safety and timely access to care are reasonably maintained as a result of the changes in demand caused by the consolidation of the Level I Trauma Centers.

Recommendation 6: Consider requesting that Ballad consult and engage the providers who would be affected by changes for their input prior to making material changes.

TDH strongly agrees with this recommendation and has included this point as one of its recommendations to Ballad Health in this report. (See page 26.)

Recommendation 7: Consider encouraging Ballad to engage local stakeholders and the community in a public input process before finalizing and rolling out plans going forward and to revisit their current communication strategy.

TDH agrees that a better public input process would have helped the public feel included and listened to, and would have improved the public's understanding of the changes regarding the consolidation of the Level I Trauma Centers proposed by Ballad Health. TDH encourages Ballad Health to engage in a more robust public input process prior to finalizing plans going forward.

Response to the COPA Monitor recommendations

TDH appreciates the excellent work of the COPA Monitor in auditing, investigating, and reporting on his findings regularly to TDH. TDH is in receipt of the COPA Monitor Annual Report, which includes a recommendation to the department. Below is TDH's response:

COPA Monitor Recommendation: ...TDH (should) continue to review and assess the application of Addendum I, and modify it if necessary, in order to achieve the following goals:

- **Provide a high degree of certainty that Ballad Health has not negotiated prices above the cap currently in Addendum I;**
- **Provide the assurance of acceptable price increases such that it represents real-time active supervision; and**
- **Provide a method that does not require significant time and resources to administer.**

TDH agrees that the three goals listed above are important and commits to reviewing Addendum I with the COPA Monitor and discussing possible modifications that would enable these goals to be better met.

Department's Recommendations

To Ballad

- **Avoid announcing significant changes that require approval before receiving that approval.** In recent service line change announcements, Ballad did not clearly identify which elements of the proposed changes had been pre-approved and which required approval by the TDH. When making announcements, take care to clearly acknowledge what has not yet been approved.
- **Engage others.** Ballad Health is encouraged to engage local stakeholders and the community in a public input process before finalizing plans going forward and to revisit its current communication strategy. Ballad is more specifically encouraged to consult and engage the providers who would be affected by changes for their input prior to making material changes.
- TDH recommends that the TOC be amended regarding the composition of the Board of Directors of Ballad Health to reflect that the separate Chief Executive Officer position no longer exists.

Conclusion

It is important to view the COPA in relation to current health care system trends. Both regionally and nationally, health care systems are becoming more regional and are consolidating. These changes reflect the nation's overall changes in societal mobility (i.e., movement to more urban areas) as well as the health care system's reimbursement changes. The impact on rural communities is not positive; across Tennessee and the nation, rural hospitals are having difficulty remaining financially viable. Increasingly, if a region's population isn't growing, rural hospitals may have to stop providing specialty services in order to remain open.

In considering whether to grant the COPA, TDH did a thorough review and assessment of the economic conditions and of the population in Northeast Tennessee. It ultimately decided that with a focus on improving health outcomes for the region, a COPA could provide a clear and convincing public benefit.

This assessment is set out in this September 19, 2017 letter that can be read [here](#).

Achieving the goals of the COPA will continue to be a challenging process. Objectively determining the existence of an ongoing public advantage will be established through the application of the Index each year.

Ballad Health Complaints

Type of Public Inquiry – Individual Occurrence

Facility / Safety

Ballad's Risk Management

TDH Division of Health Care Facilities:

Billing

Ballad's Billing Department

Insurance Company

Labor

Ballad's Human Resources Dept.

TN Department of Labor and Workforce Delivery

Operations/ Management Decisions

Ballad's Board/ Management

Type of Public Inquiry - Systemic Concerns

COPA Compliance Office

Local Advisory Council (LAC)

TDH – Division of Health Planning / Commissioner

Ballad Health Complaints – contact information

Ballad Health

- **Risk Management:** 423-302-3397
JCMC 423-431-6936; HVMC 423-224-5025; BRMC 423-844-3471
- **Billing Department :** 423-431-1700 or 423-408-7400
- **Human Resources:** 423-431-4748

TDH Division of Health Care Facilities

Complaints regarding patient care standards, compliance standards and regulations, reporting standards and regulations, specifications for construction plans, and fire and life safety code regulations, should be reported to the TDH Division of Health Care Facilities at: <https://www.tn.gov/health/health-professionals/hcf-main/filing-a-complaint.html>

TN Department of Labor and Workforce Delivery

Information on Tennessee statutes governing employee meals and breaks, wage regulation, and fringe benefits can be accessed at: <https://www.tn.gov/workforce/employees/labor-laws/labor-laws-redirect/wages-breaks.html>

The Labor Standards Unit 844-224-5818.

COPA Compliance Office

Anonymous AlertLine: 1-800-535-9057
General email: copa.compliance@balladhealth.org

COPA Compliance Officer: Gary Miller
423-302-6511
gary.miller@balladhealth.org

Director: Linda Edwards
423-302-6512
linda.edwards2@balladhealth.org

Local Advisory Council (LAC)

LAC email: COPA.Advisory-Council@tn.gov

Anonymous Complaint form:
<https://www.tn.gov/health/health-program-areas/health-planning/copa-local-advisory-council.html>

TDH – Division of Health Planning

Director: Jeff Ockerman
jeff.ockerman@tn.gov

Program Manager: Judi Knecht 615-253-9979
Judi.knecht@tn.gov