

Public Hearing Questions for  
**Health Services Development Agency**  
Created by Section 68-11-1604, *Tennessee Code Annotated*  
(Sunset termination June 2018)

---

1. Please address changes to the certificate of need statute made by Chapter 1043 of the Tenn. Public Acts of 2016. Provide a list that details the provisions added, modified and/or deleted by the legislation.

**This legislation significantly altered the certificate of need (CON) program by eliminating a number of services from review, adding one new service (organ transplantation), modifying a number of other provisions, and adding a fourth criterion for certificate of need approval — that the proposed health care meets appropriate quality standards. While the quality of health care being provided has always been a consideration, this new emphasis on continuing need, quality standards, and quality measures, formally elevates quality and adds accountability to the CON process.**

**The legislation directed the agency to work in conjunction with certain departments to develop quality measures and requires it to maintain continuing oversight of all certificates of need approved after July 1, 2016 by requiring CON holders to submit annual reports concerning continued need and appropriate quality measures.**

**The statutory changes include noting the action the Agency shall take for failure to meet quality measures. If the Agency determines that an entity fails to meet the quality measures developed under this section, the Agency shall refer that entity to Department of Health or Mental Health and Substance Abuse Services, whichever is appropriate, for action on the license. If the Agency determines that an entity fails to meet any quality measure imposed as a condition upon a Certificate of Need it may impose penalties ranging from \$100-\$500 daily or revoke the Certificate of Need. Due process would occur before penalties or revocation would occur, and the Agency has discussed a plan of correction process.**

**This emphasis on accountability is the most significant change in CON law since 2002 when the Health Services and Development Agency was created to oversee the certificate of need program.**

**Please see the attached table entitled “Public Chapter 1043 Changes to the TN Certificate of Need Statute” for a detailed list of the provisions added, modified, and/or deleted.**

- a. Chapter 1043 of the Tenn. Public Acts of 2016 added a fourth criterion to be considered when approving or denying a certificate of need application: whether the proposal will provide health care that meets appropriate quality standards. Chapter 1043 of the Tenn. Public Acts of 2016, Section 21, requires the agency to develop the new quality standards, after consultation with the Department of Health and the Department of Mental Health and Substance Abuse Services, and promulgate rules to adopt the new quality standards. How has the agency complied with this charge?

- **Extensive research on current quality standards**
- **Consultation with the Tennessee Departments of Health and Mental Health and Substance Abuse Services as directed by the legislation as well as the Department of Intellectual and Developmental Disabilities since they are a participant in the CON process as a reviewing agency for certificate of need applications under their licensing jurisdiction.**
- **Stakeholder communication/Public meetings**
- **Draft revisions to reflect input received by stakeholders/state agencies**
- **Quality Measures Emergency Rules adopted - 2/22/17**
- **Emergency Rule, effective May 31, 2017**
- **Revision of permanent Rules considered and approved at 8/23/17 Agency Meeting**

**Please see the attached document entitled “Health Services and Development Agency Certificate of Need Program Emergency Rule Pertaining to Quality Measures July 20, 2017” for more detailed information.**

- b. Chapter 1043 of the Tenn. Public Acts of 2016, Section 16 added annual reporting requirements upon holders of certificates of need issued on or after July 1, 2016. How has the agency complied with this charge?

**Rulemaking is in progress, specifying what reporting is to be made annually, and that the reporting is to be made each year on the anniversary date of implementation of the certificate of need. Forms are being prepared by the Agency for this reporting, as these reports will soon start being made.**

- c. Chapter 1043 of the Tenn. Public Acts of 2016, Section 6, requires a certificate of need for the initiation of organ transplantation services. Have Criteria and

Standards been developed for this service? How many certificate of need applications were filed for organ transplantation services during FY 17?

**Yes. The Division of Health Planning which is administratively attached to the Tennessee Department of Health is charged with developing the criteria and standards for granting a certificate of need. The organ transplantation standards were developed and adopted as part of the 2016 State Health Plan Update.**

**There have been no CON applications for organ transplantation services filed since the legislation was enacted.**

- d. Chapter 1043 of the Tenn. Public Acts of 2016, Section 10, permits the initiation of magnetic resonance imaging services or the increase of the magnetic resonance imaging equipment inventory, regardless of cost, in any county with a population in excess of two hundred fifty thousand (250,000), unless pediatric patients will be treated, without obtaining a certificate of need. Does the agency have a system to track additional providers and equipment allowed under this provision? If so, how many were added pursuant to this provision during FY 17? How many certificate of need applications were filed for magnetic resonance imaging for pediatric patients in these counties during FY 17?

**Yes. TCA §68-11-1607 has required the owners of certain types of medical equipment including MRI to register the equipment with the Agency since 2002 so a registration process has been in place since that time.**

**The Agency has received inquiries regarding new MRI units in Davidson, Hamilton, Rutherford and Shelby Counties but no registrations were received until an August 25, 2017 (FY 18) notification regarding the acquisition of a 1.5 T MRI in Rutherford County on August 8, 2017.**

**One pediatric provider application was received in FY17. It was approved.**

**It is not yet known if additional MRI units have been added in those counties without being registered with the Agency.**

- e. Chapter 1043 of the Tenn. Public Acts of 2016, Section 10, requires a certificate of need for the initiation of magnetic resonance imaging services or the increase of the magnetic resonance imaging equipment inventory, regardless of cost, in any county with a population of two hundred fifty thousand (250,000) or less. How many certificate of need applications were filed for magnetic resonance imaging in these counties during FY 17, and which pertained only to the addition of equipment to existing providers?

**Two applications were filed in counties with a population of 250,000 or less. In Sullivan County, an application was filed to initiate adult and pediatric MRI services and in Washington County, an application was filed to acquire an additional MRI scanner. Both applications were approved.**

- f. Chapter 1043 of the Tenn. Public Acts of 2016, Section 11, permits a hospital, rehabilitation facility or mental health hospital no more frequently than one (1) time every three (3) years to increase its total number of licensed beds in any category by ten percent (10%) or less of its licensed capacity at any one (1) campus over a period of one (1) year for any services or purposes it is licensed to perform without obtaining a certificate of need. Does the agency have a system to track beds allowed under this provision? If so, how many beds were added pursuant to this provision during FY 17?

**Yes. The Agency has a notification process in place whereby a provider may download a notification form and mail or e-mail it to the Agency. After review and any needed communication with the provider for correction, notification is then made to the provider and the licensing entity that the Intent to Alter Bed Capacity form has been processed by the Agency per PC 1043.**

**For FY 17, 326 beds were added without a certificate of need. The breakdown is as follows:**

**FY 17-----INTENT TO ALTER BED CAPACITY**

<b>Licensure Entity</b>	<b>A/G Psych</b>	<b>C/A Psych</b>	<b>Acute</b>	<b>NICU</b>	<b>Rehab</b>	<b>TOTAL</b>
<b>MHSAS</b>	44	8				<b>52</b>
<b>TDH</b>	3	2	255	6	8	<b>274</b>
<b>TOTAL</b>	<b>47</b>	<b>10</b>	<b>255</b>	<b>6</b>	<b>8</b>	<b>326</b>

***Bed Categories-Psychiatric (Adult/Geriatric, Child/Adolescent); Acute including subcategory of NICU, and Rehabilitation.***

- g. Chapter 1043 of the Tenn. Public Acts of 2016, Section 13, requires any person who provides magnetic resonance imaging services in this state to file an annual report by March 1 of each year with the agency concerning the adult and pediatric patients that details the mix of payors by percentage of cases for the prior calendar year for its patients, including private pay, private insurance, uncompensated care, charity care, Medicare and Medicaid. Has the agency implemented a system to maintain the reported data?

**Yes. The existing medical equipment registry system was modified. Per TCA § 68-11-1607 (i) the Agency has maintained a medical equipment registry which captures magnetic resonance imaging (MRI), computed tomography (CT), linear accelerator (LINAC), and positron emission tomography (PET) equipment utilization data since 2002. However, there is a conflict between reporting requirements for the two. The existing system requires utilization data be reported on the referenced equipment no later than 30 days following the close of the state's fiscal year.**

**The MRI data request was modified to differentiate adult and pediatric MRI services as well as to try to capture private pay, private insurance, uncompensated care, charity care, Medicare and Medicaid and to capture it by the March 1 deadline instead of the usual 30 days following the close of the state's fiscal year.**

**All but four providers reported adult and pediatric MRI utilization for 2016. Not all MRI providers were able to meet the March 1 deadline because many also report on multiple equipment types and were unable to further break down the categories of payment types without more definitive definitions.**

- h. Chapter 1043 of the Tenn. Public Acts of 2016, Section 13, requires an outpatient diagnostic center to become accredited by the American College of Radiology in the modalities provided by that facility within a period of time set by rule by the agency as a condition of receiving a certificate of need. Has the agency set this period of time by rule?

**Becoming accredited by the American College of Radiology within two years was added to the quality measures to be considered by the Agency, by Emergency Rule, effective May 31, 2017. Rulemaking is in progress for the permanent rule.**

- i. Chapter 1043 of the Tenn. Public Acts of 2016, Section 16, requires the agency to maintain continued oversight over any certificate of need that it approves on or after July 1, 2016 of continued need and appropriate quality measures as determined by the agency. How has the agency complied with this charge?

**Appropriate quality measures have been adopted by Emergency Rule, after consultation with the Department of Health, Department of Mental Health and Substance Abuse Services, and Department of Intellectual Disabilities; stakeholder input was also considered. Rulemaking is in progress for the permanent rule, which also specifies the annual reporting to be made regarding continued need and appropriate quality measures.**

- j. Chapter 1043 of the Tenn. Public Acts of 2016, Section 17, requires the agency to refund twenty-five percent (25%) of the filing fee of a denied application, upon request. How has the agency complied with this charge?

**The Agency has complied with the law, issuing \$10,996.21 in refunds to applicants.**

- k. Chapter 1043 of the Tenn. Public Acts of 2016, Section 18, imposes a fee equal to twenty-five percent (25%) of the filing fee of an application upon any party, who is not the applicant or agency, seeking a contested case review of the agency's decision to approve or deny the application. Detail the instances this occurred during FY 16/17, and any revenue generated.

**There have been no appeals like this since July 1, 2016.**

- l. Chapter 1043 of the Tenn. Public Acts of 2016, Section 20, requires the agency to prescribe fees by rule in an amount that provides for the cost of administering the implementation and enforcement of the certificate of need statute by the agency. Fees prescribed by the agency shall be adjusted as necessary to provide that the account is fiscally self-sufficient and that revenues from fees do not exceed necessary and required expenditures. How has the agency complied with this charge?

**The Agency adjusted fees to comply with this section. While fees did not entirely cover expenses during FY 16/17, the new fees were not in effect during the entire FY. The carry forward covered the shortfall (slightly over \$35,000). It is expected that fees will cover expenses going forward, particularly with additional cost-cutting measures.**

- m. Compare revenue from FY 16 to FY 17. Describe any cost-cutting measures undertaken by the Agency in FY 16/17. Are any additional measures being considered in FY 18?

**REVENUE COMPARISON**

FY	APPLICATIONS	FEE	FUND
16	66 (17 ICF/IID)	\$956,342	General
17	35	\$931,863	Agency

## **COST CUTTING MEASURES**

### **FY17-**

- **20% reduction in staff**
- **50% reduction in Agency meetings**
- **other cost-cutting measures including web-based meeting packets instead of paper, reduction in copy machines.**

### **FY18-**

- **ASA 3 downgraded to Clerk 3**
- **AO position unfilled due to retirement-will utilize former AO on a part-time basis along with Memorandum of Understanding with DOHR for Human Resources assistance and F & A, Division of Accounts for Budget Assistance.**

Sunset Q & A-HSDA 2018- 9.5.2017

## PUBLIC CHAPTER 1043

### CHANGES TO TN CERTIFICATE OF NEED STATUTE

Provisions Deleted	Provisions Added	Provisions Modified
<ul style="list-style-type: none"> <li>• Major Medical Equipment &gt;2M\$</li> <li>• Establishment of Birthing Center</li> <li>• Modifications, renovations or additions to healthcare institutions (Capital Expenditure thresholds &gt;5M\$/ &gt;2M\$)</li> <li>• Extracorporeal lithotripsy</li> <li>• Swing beds</li> <li>• Rehabilitation services</li> <li>• Hospital-based alcohol and drug treatment for adolescents provided under a systematic program of care longer than 28 days</li> <li>• Discontinuation of OB Services</li> <li>• Critical Access Hospital Closure or elimination of CON required service at CAH</li> </ul>	<ul style="list-style-type: none"> <li>• 4<sup>th</sup> criterion-provide health care that meets appropriate quality standards</li> <li>• Accountability- Develop Quality Measures w/TDH &amp; TDMHSAS; Maintain continuing oversight re: continuing need/ appropriate quality measures/ annual reporting; referral to licensing entity &amp; ability to impose penalties or revocation for failure to meet quality measures</li> <li>• Organ Transplant</li> <li>• Satellite Emergency Department (codifies AG Opinion 14-95)</li> <li>• Annual report by 3/1 each yr. from MRI providers concerning adult &amp; pediatric patients detailing mix of payers by percentage of cases for prior year</li> <li>• ODC shall become accredited by ACR in modalities provided by facility as a condition of receiving CON-period of time is to be set by rule</li> <li>• Refund 25% of applicant's denied application fee</li> <li>• Contested Case fee equal to 25% of filing fee when not filed by applicant</li> </ul>	<ul style="list-style-type: none"> <li>• Initiation of MRI (A) In counties with population &gt;250,000 to pediatric patients (14 and under);</li> <li>• (B) In any county with population of &lt;250,000</li> <li>• Increase in number of MRI units in county with population of &lt;250,000, except for replacing or decommissioning</li> <li>• No more frequently than 1 time every 3 years, Hospital, Rehab Facility, or Mental Health Hospital may increase total # licensed beds in any bed category by 10% or less of its licensed bed capacity at any 1 campus over any period of 1 year for any services or purposes it is licensed to perform without obtaining a CON</li> <li>• Agency Funding Mechanism</li> </ul>



**HEALTH SERVICES AND DEVELOPMENT AGENCY  
CERTIFICATE OF NEED PROGRAM  
EMERGENCY RULE PERTAINING TO QUALITY MEASURES  
JULY 20, 2017**

---

**CON Criteria Pre PC 1043, Acts of 2016:**

- NEED-Will it provide needed health care in the area to be served?
- ECONOMIC FEASIBILITY -Can the project be economically accomplished and maintained?
- ORDERLY DEVELOPMENT of HEALTH CARE-Will it contribute to the orderly development of adequate and effective health care facilities or services?

**Necessity:**

Chapter 1043 of the Tenn. Public Acts of 2016 (“Act”) amended the Tennessee Health Services and Planning Act of 2002, T.C.A. § 68-11-1601, et seq. (CON statute), which amendments included, among other things:

The addition of a fourth criterion to be considered when approving or denying a CON application: **whether the proposal will provide health care that meets appropriate QUALITY STANDARDS;**

- The Act directed that continuing oversight of certificates of need approved after July 1, 2016 be maintained by requiring applicants to submit annual reports concerning continued need and appropriate quality measures and that the new quality measures be adopted as rules; and

Quality Measure Rules shall be developed by the Agency after consultation with the TDH, TDMHSAS, & others

**Process:**

Deputy Director Mark Farber spearheaded the process

- Extensive Research
- Consultation with TDH, TDMHSAS, & DIDD
- Stakeholder communication/Public meetings
- Revision of drafts to reflect input received by stakeholders and state agencies

**Timeline**

**June/July 2016**

- Initial HSDA staff research on quality measures development.
- Informal Meetings/conference calls with select health care providers

**HEALTH SERVICES AND DEVELOPMENT AGENCY  
CERTIFICATE OF NEED PROGRAM  
EMERGENCY RULE PERTAINING TO QUALITY MEASURES  
JULY 20, 2017**

---

August 2016

- Kickoff meeting w/TDH (Licensure & Health Planning) & TDMHSAS per PC 1043. Also included TDIDD. Discussed development of quality standards, quality measure reporting, and discussion concerning appropriate action by licensing entity for CON holders failing to meet quality measures.

September 2016

- September 21-Vice-Chair & Executive Staff made presentation to Joint Government Operations Committee. Committee directed the Agency to develop emergency rules with detailed Quality Measures.

October/November 2016

- Additional staff research including review of numerous quality measure programs (Medicare Compare, multiple Accreditation and Certification organizations and other State CON Programs).

December 2016

- December 5-Call for Comments pertaining to development of quality measures to Stakeholders/Interested Parties
- December 20-Comments received from 10 health care organizations
- Informal Meetings/Conference Calls with health care providers

January 2017

- Additional research conducted by HSDA staff based on comments received in December 2016
- January 12-Quality Measure Update Meeting with TDH, TDMHSAS, TDIDD (CON Reviewing Agencies).
- HSDA staff develops draft document of quality standards with detailed and measurable thresholds for each CON service.
- January 27-Draft quality measures document sent to Stakeholders

February 2017

- February 2-Stakeholder meeting held. Approximately 50 individuals in attendance. 4.5 + hour meeting where stakeholders presented testimony on draft quality standards.
- Calls/emails w/ Michigan CON program since Michigan is preparing to implement a quality assessment program.
- Extensive revisions to draft standards to address stakeholder concerns
- February 22-Emergency rules were discussed & adopted unanimously by Agency

**HEALTH SERVICES AND DEVELOPMENT AGENCY  
CERTIFICATE OF NEED PROGRAM  
EMERGENCY RULE PERTAINING TO QUALITY MEASURES  
JULY 20, 2017**

---

March, 2017 - April 2017

- Emergency Rules submitted informally to AG for review and then formally with several non-substantive revisions.

April 2017

- April 26—Agency unanimously approves rulemaking process for Permanent Rules.

April/May 2017

- Tools developed to include changes to CON application form & development of a draft Quality Assessment form that CON holders will complete one year after project completion & each year thereafter.

May 2017

- May 9-Draft Changes to CON Application form & draft Annual Quality Assessment Form emailed to Agency members for comment.
- Changes recommended by Agency members incorporated into both draft forms.
- May 25-Revised drafts emailed to frequent CON filers for comment.
- May 31-Emergency Rules effective.

July 2017

- July 28,2017-Rulemaking Hearing-Permanent Rules

August 2017

- Revised draft CON application form & Annual Quality Assessment form to be considered at 8/23/17 Agency meeting.
- Agency vote on final form of Permanent Rules based on July 28,2017 Rulemaking Hearing

**Result:**

- Quality health care has always been a consideration in CON review but it is now a formally elevated consideration because PC 1043 requires the ongoing monitoring of continuing need & quality measures through annual reporting on all CONs granted after the effective date of the legislation.

**HEALTH SERVICES AND DEVELOPMENT AGENCY  
CERTIFICATE OF NEED PROGRAM  
EMERGENCY RULE PERTAINING TO QUALITY MEASURES  
JULY 20, 2017**

---

- Quality measures are the accountability tools that are being put in place in place to help improve the quality of health care - - by scrutinizing whether CON applicants intend to meet appropriate standards of care. Participation in peer review organizations or other accepted ways to measure performance against the industry's best practices should continue to raise the bar on the quality of health care.
- Failure to meet these measures results in referrals to the licensing entity and failure to meet a measure imposed as a condition may result in a monetary penalty or revocation of the CON.

**HEALTH SERVICES AND DEVELOPMENT AGENCY  
CERTIFICATE OF NEED PROGRAM  
EMERGENCY RULE PERTAINING TO QUALITY MEASURES  
JULY 20, 2017**

---

**PC 1043-Sections Pertinent to Quality Standards and Measures**

*Section 14 adds language to item 5 of TCA 68-11-1608- Review of Applications-Report (a) (5) Specific determination as to whether a proposed project is consistent with any applicable quality measures under § 68-11 1609 (b) the state health plan. Reviewing agencies reports must now include this determination.*

*Section 15 adds the fourth criterion. TCA §68-11-1609(b) (b) No certificate of need shall be granted unless the action proposed in the application 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 facilities or services.*

*Section 16 directs the Health Services and Development Agency to maintain continuing oversight of certificates of need approved after July 1, 2016 by requiring applicants to submit annual reports concerning continued need and appropriate quality measures as determined by the agency. The agency may impose conditions that require the demonstration of compliance with continued need and quality measures; provided, that the conditions for quality measures may not be more stringent than those measures identified in the applicant's submitted application.*

*Section 19 adds the following language to the civil penalty section of the statute .....The failure to meet a quality standard applicable to the violator. (A CP may be assessed in an amount not less than \$100 nor more than \$500 per day of continued operations after notice and a hearing).*

*Section 21 adds a new part to be designated as TCA §68-11-1633.....*

*(a) In consultation with the state health planning division and the board for licensing healthcare facilities or the department of mental health and substance abuse services, whichever is appropriate, and subject to Section 16 of this act, the agency shall develop measures by rule for assessing quality for entities that, on or after July 1, 2016, receive a certificate of need under this part. In developing quality measures, the agency may seek the advice of stakeholders with respect to certificates of need for specific institutions or services.*

*(b) If the agency determines that an entity has failed to meet the quality measures developed under this section, the agency shall refer that finding to the board for licensing healthcare facilities or the department of mental health and substance abuse services, whichever is appropriate, for appropriate action on the license of the entity under part 2 of this chapter.*

*(c) If the agency determines that an entity has failed to meet any quality measure imposed as a condition for a certificate of need by the agency, the agency may impose penalties pursuant to § 68-11-1617 or revoke a certificate of need pursuant to § 68-11-1619.*

