Certificate of Need Reform Working Group Report

113th General Assembly

2024

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Background

Certificate of Need

The federal government mandated state Certificate of Need (CON) programs in 1972 as an effort to limit the unsustainably high construction rate of new health care facilities. The Medicare/Medicaid programs were new at the time and reimbursed providers at a far more generous level than they do now. The federal government had been subsidizing the construction of hospitals since the 1946 Hill-Burton Act, which- combined with the generous reimbursement rates of Medicare/Medicaid- created a very favorable environment for investment in the construction of health care facilities. Health care cost inflation was immediately out of control, which led Congress to replace the cost-plus reimbursement system (in which providers were reimbursed for the cost of their services plus a little extra for the trouble) with a prospective payment system based on diagnosis-related groups (DRGs) in 1982. This cost-cutting measure reduced the federal government's reimbursements to health care providers. However, in 1986 Congress also passed the Emergency Medical Treatment and Labor Relations Act, which requires hospitals to treat anyone who enters their emergency room regardless of their ability to pay. Thus, in the span of a few years the federal government went from subsidizing the construction and profits of hospitals to requiring them to subsidize the care of indigent patients by shifting those costs onto insured patients.

This shift also had the effect of changing the practical function of CON programs. Instead of regulating the construction of health care facilities as a means of restraining growth in Medicare/Medicaid expenditures, CON began to be used to minimize patient cost-shifting by protecting the market share and high-margin services of hospitals. In 1987, Congress repealed the federal mandate for state CON programs. Although a few states immediately eliminated theirs, most states maintained them. In the ensuing decades, further reductions in government reimbursement exacerbated cost-shifting such that care provided to Medicaid patients (and more recently certain Medicare patients) would also be subsidized by patients with non-governmental insurance.

Even supporters of CON acknowledge that CON no longer serves its original function, though they contend that it still serves a public interest. It is therefore the responsibility of the General Assembly to evaluate and determine what, if any, public interest remains in maintaining CON.

CON Reform in Tennessee

Until 2016, reform of Tennessee's CON program was largely limited to adding services and attempting to insulate it from political influence. Public Chapter 1043, sponsored by Rep. Cameron Sexton and Sen. Todd Gardenhire,[1] was the first legislation which substantially reduced the number of activities subject to CON regulation. It eliminated the CON requirement for capital projects such as additions, renovations, and equipment. The legislation also carved out PET and non-pediatric MRI services from CON regulation in counties with a population above 250,000, which included Davidson, Hamilton, Knox, Rutherford, and Shelby.

[1] Cosponsored by Rep. Martin Daniel, Rep. Judd Matheny, Rep. John Ray Clemmons, and Sen. Bo Watson.

The sponsors of Public Chapter 1043 gave the industry three years to evaluate and adapt to the impact of those reforms. To date, no evidence has been provided by the industry that the reforms had a deleterious impact on the access, quality, or cost of health care.

Legislative CON Reform Working Group

By 2019, there were several bills being filed every year to carve out additional services or eliminate the CON program entirely. Appreciating the diversity of opinion on the issue as well as its complexity, members of the House and Senate convened the CON Reform Working Group to hold lengthy deep dives into CON Reform with stakeholders and advocates. After more than a dozen such meetings and having met with more than two dozen such stakeholders and advocates, the CON Working Group began to chart a course for the final disposition of CON as a recurring controversy.

Vision of the Working Group

Following the Working Group's extensive outreach to stakeholders, the members coalesced around a vision for the eventual elimination of CON by replacing it with enhanced quality standards for entry into the marketplace.

Since CONs are effectively permanent once an applicant has become licensed, the program lacked ongoing regulatory authority to ensure that applicants fulfilled the promises they made regarding quality of care and charity care once their CON was approved. Licensure regulation, on the other hand, could establish uniform standards that all licensees would be required to adhere to.

During the initial stakeholder outreach, the Working Group observed that introducing a novel regulatory scheme based on quality could be costly to Tennessee taxpayers due to the expense of additional clinical staff to review patient outcomes. The Working Group also determined that such a scheme might be redundant if not aligned with existing requirements from the private sector (e.g., insurers, federal programs, private payers, accrediting bodies). To resolve both issues, the Working Group decided to leverage existing private sector resources that have a demonstrable record of improving the quality of patient care: accrediting bodies.

Accreditation has long been a valuable means of improving quality of care among health facilities. Many facilities are already accredited though it is not required by state law. The Working Group concluded that certain accreditation standards could be made into requirements for initial licensure, such as certain written policies on medical staff and provision of care and systems and processes standards on information and environment management. In addition to these requirements for initial licensure, licensees would be given a reasonable amount of time to become accredited.

Leveraging the proven benefits of accreditation instead of establishing a new quality standard scheme would thus save taxpayer dollars and avoid imposing a potentially duplicative or contradictory system of quality standards while improving the care received by Tennesseans.

Public Chapter 557 (2021)

In 2021, the Working Group successfully made CON cheaper, quicker, and easier. Within months of passage, CON application fees were reduced by more than 50%, the length of the process was reduced by 55%, and the application itself was reduced by 57%. Importantly, PC 557 also continued to move down the path begun by Speaker Sexton's 2016 legislation by replacing the CON criteria "orderly development of the health care" with "consumer advantage". This formally redirected attention from the impact of a proposed CON project from existing providers and toward their patients.

The legislation also eliminated the CON requirement for mental health hospitals, home health agencies limited to pediatric patients or patients covered under the Energy Employees Occupational Illness Compensation Program (EEOICPA) and reduced the county population thresholds for PET and non-pediatric MRI from 250,000 to 175,000 (adding Montgomery, Sumner, and Williamson counties).

Public Chapter 557 also set up the next phases of reform by requiring the executive director of the Health Services and Development Agency (HSDA) to draft a plan to combine HSDA with the Board for Licensing Health Care Facilities (BLHCF). A single consolidated board with both approval and monitoring functions would be better suited for performing continuing oversight.

Public Chapter 1119 (2022)

Although the plan for merging the two boards was not due until January 1, 2023, HSDA staff discovered early on that it would be logistically advantageous to combine the staff of the two boards in advance of merging the boards themselves. In 2022, the General Assembly passed Public Chapter 1119, which moved the Office of Health Care Facilities from the Department of Health to HSDA and renamed HSDA the Health Facilities Commission (HFC). This plan completes the work by setting a timeline to consolidate the boards and incorporate CON into the licensure process.

Industry Impact of CON Reform Legislation

PET and Non-Pediatric MRI Exemption under PC 1043

From 2015 (the last full year of data prior to enactment of the carve-out) to 2022, the number of MRI providers in the affected counties increased by only 5.21%. The number of PET providers in those counties increased by only 4.35% over the same period. See sttachments A and B for detailed data.

Mental Health Hospital Exemption Under PC 557

There were 20 licensed mental health hospitals in Tennessee in 2016, when the exemption went into effect. Since then, four new mental health hospitals opened, and one has closed. There are now 23 mental health hospitals licensed in Tennessee.

Home Health Exemption Under PC557

There are currently 157 home health agencies licensed in Tennessee. Of those, 24 have filed under the pediatric and/or Energy Employees Occupational Illness Compensation Program (EEOICPA) PC557

exemption since October 1, 2021. Eleven (11) agencies have filed under the EEOICPA exemption, eight (8) under the pediatric exemption, and five (5) agencies under both the EEOICPA/pediatric exemption.

Eleven home health agencies, or 46%, of the 24 actively licensed home health agencies seeking exemption have successfully satisfied statutory requirements of achieving the required accreditation within two years. Of the eleven agencies that are currently accredited, eight (8) are accredited by the Accreditation Commission for Health Care (ACHC), two (2) by The Joint Commission, and one (1) is accredited by the Community Health Accreditation Partner (CHAP). The remaining actively licensed thirteen home health agencies under the accreditation exemption are on track to reach accreditation requirements within two years.

Of the eleven agencies that have satisfied statutory accreditation requirements, four (4) agencies serve EEOICPA patients, three (3) serve pediatric, and four (4) serve both EEOICPA and pediatric.

Home Health Agency (HHA) Licensure Pre and Post Exemption Under PC557

The year end 2020 licensed HHA total was 145; by year end 2023 the licensed HHA total was 157 an 8.28% increase. Closure of licensed HHAs during this time have under-paced application submission and licensure of HHAs. There has been a total of seven HHAs to close since October 1, 2021.

23 HHAs have been licensed since October 1, 2021. This includes those HHAs which sought CONs as well as those licensed under the PC557 exemption. There are currently nine HHA applications in process – three under the EEOICPA exemption, two under the pediatric exemption, and four under a Certificate of Need (CON).

2023 CON Reform Proposal and Stakeholder Outreach

The CON Reform Working Group began meeting in the summer of 2023 to prepare for the next phase of reform. A draft plan was shared with all stakeholder groups and the Working Group members pledged to hear from everyone who wanted to speak on it. The plan provided a timeline for the implementation of the vision previously articulated by the Working Group [see Attachment C].

Over the course of three meetings in late 2023, the Working Group heard from Ascension St. Thomas Health, Ballad Health, the Beacon Center, the Center for Individual Freedom, Community Health Systems, the Group Practice Coalition, HCA Healthcare, LifePoint Health, National Healthcare Corporation (NHC), Tennessee Ambulatory Surgery Center Association, Tennessee Association for Home Care, Tennessee Health Care Association, Tennessee Hospital Association, Tennessee Oncology, Tennessee Orthopedic Society, Tennessee Radiological Society, Vanderbilt University Medical Center, West Tennessee Health Care, and Williamson County Medical Center.

2024 Proposed CON Reform Legislation

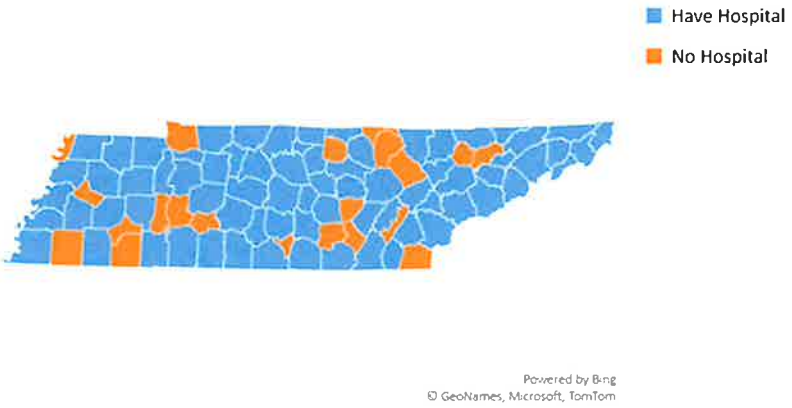
Service Type	Support	Oppose
Eliminate CON		
Burn Units	The investment required to provide these services and their low profit margins dissuade most providers from offering them	Concerns about impact to quality if utilization is split between providers
NICU		
Organ Transplantation		
FSED	Increase access to care, within 35 miles of affiliate hospital, subject to EMTALA	Potential impact on current systems
ICF/IID	Licensed by DIDD	No opposition expressed
Eliminate CON (>100k county pop)		
Acute Care Hospital	Increase access, promote competition, could assign charity care requirements, impacts 14 counties High capital cost already constrains new builds and expansions, create competition in monopolistic markets	Potential impact on rural hospitals attached urban/suburban systems, competition by for-profit systems could create stress on safety net systems
ASTC	Increase access, promote competition, could assign charity care requirements, impacts 14 counties High capital cost already constrains new builds and expansions, create competition in monopolistic markets	Hospital concerns about cherry picking
Linear Accelerator		
PET		
MRI		

Keep CON As Is	Support	Oppose
Rehabilitation Hospitals	Not enough understanding of potential impact to current providers	No opposition was expressed
Home Health Hospice Methadone Clinics Nursing Homes	Enhanced risk of fraud, waste, and abuse.	Reduces competition
Long Term Hospitals Open Heart Surgery Cardiac Cath	Not enough understanding of potential impact to current providers	Reduces competition

2024 CON Reform Plan Summary

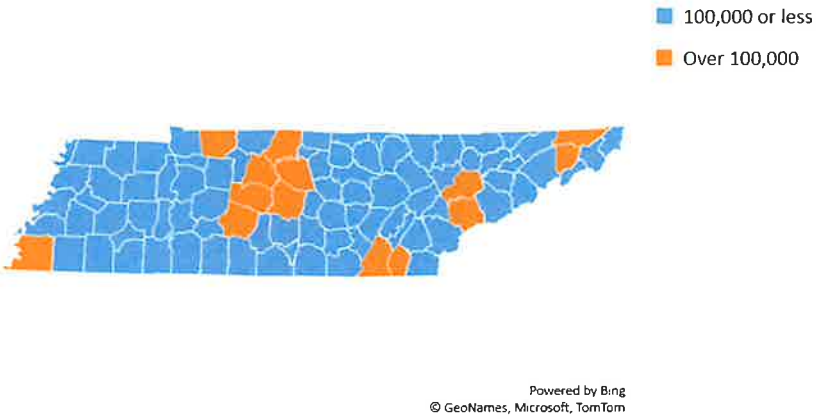
1. Eliminate CON requirement for the following effective July 1, 2025 (will require accreditation within two years):
    a. Freestanding Emergency Departments
    b. IDD Habitation Facilities (licensed by DIDD)
    c. Burn Units
    d. NICU
    e. Organ Transplantation
2. Reduce threshold for county population-based CON carve-out from 175k to 100k
3. Expand county population-based CON carve-out to include:
    a. Acute Care Hospitals
    b. MRI
    c. PET
    d. Megavoltage Radiation Therapy (Linear Accelerators)
    e. ODCs (with charity care requirements)
    f. ASTCs (with charity care requirements)
4. Expand distressed county carve-out to include any county that doesn't have an actively-licensed hospital (will require accreditation within two years of licensure)
    a. Remove Home health, hospice, nursing homes, and methadone clinics from this carve-out
5. Project types left alone for time being:
    a. Cardiac Catheterization
    b. Home Health
    c. Hospice
    d. Long-Term Care Acute Hospitals/Beds
    e. Methadone Clinics (licensed by Mental Health)
    f. Nursing Homes
    g. Open Heart Surgery
    h. Rehabilitation Hospitals/Beds

Counties Without Actively Licensed Hospital



Counties That Do Not Need a CON for Most Project Types:	
• Chester	• Meigs
• Crockett	• Moore
• Decatur	• Morgan
• Fayette	• Perry
• Fentress	• Pickett
• Grainger	• Polk
• Grundy	• Sequatchie
• Jackson	• Stewart
• Lake	• Union
• Lewis	• Van Buren
• McNairy	

County Based on 100,000 Population



Counties That Do Not Require a CON for Acute Care Hospital Beds, MRI, PET, Linear Accelerators, ODCs, or ASTCs	
• Blount	• Rutherford
• Bradley	• Shelby
• Davidson	• Sullivan
• Hamilton	• Sumner
• Knox	• Washington
• Maury	• Williamson
• Montgomery	• Wilson

Attatchment A

Information Related to MRI's and PET's Based on Population Carve Out

	2015	2016	2017	2018	2019	2020	2021	2022	Percent Changed from 2015 to 2022
MRI Utilization									
Statewide	694,159	719,208	714,892	735,367	753,591	686,251	721,797	767,389	10.55%
Population > 250,000	427,843	453,464	454,453	472,870	479,839	438,444	455,680	469,807	9.81%
Population < 250,000	266,316	265,744	260,439	262,497	273,752	247,807	266,117	297,582	11.74%
Population >175,000	465,806	491,288	493,007	513,904	526,609	483,028	498,605	523,210	12.32%
Population <175,000	228,353	227,920	221,885	221,463	226,982	203,223	223,192	244,179	6.93%
MRI Number of Providers									
Statewide	213	212	213	210	209	212	203	212	-0.47%
Population > 250,000	96	96	97	96	96	97	96	101	5.21%
Population < 250,000	117	116	116	114	113	115	107	111	-5.13%
Population >175,000	111	111	113	112	114	115	110	119	7.21%
Population <175,000	102	101	100	98	95	97	93	93	-8.82%
MRI Number of Units*									
Statewide	296	296	300	296	297	302	293	298	0.68%
Population > 250,000	156	157	162	159	162	164	164	163	4.49%
Population < 250,000	140	139	138	137	135	138	129	135	-3.57%
Population >175,000	173	174	180	177	182	184	181	183	5.78%
Population <175,000	123	122	120	119	115	118	112	115	-6.50%

Number of Units Added Through Carve Out since 2016 Without a CON

Attatchment B

Information Related to MRI's and PET's Based on Population Carve Out

	2015	2016	2017	2018	2019	2020	2021	2022	Percent Changed from 2015 to 2022
PET Utilization									
Statewide	33,539	36,806	40,313	42,539	45,743	44,115	47,686	55,230	64.67%
Population > 250,000	23,938	26,461	28,586	30,217	32,180	30,306	32,575	38,825	62.19%
Population < 250,000	9,601	10,345	11,727	12,322	13,563	13,809	15,111	16,405	70.87%
Population >175,000	24,379	27,224	29,411	31,255	33,643	32,094	34,367	40,910	67.81%
Population <175,000	9,160	9,582	10,902	11,284	12,100	12,021	13,319	14,320	56.33%
PET Number of Providers									
Statewide	46	45	44	43	44	48	47	48	4.35%
Population > 250,000	22	21	21	20	21	23	23	23	4.55%
Population < 250,000	24	24	23	23	23	25	24	25	4.17%
Population >175,000	24	24	24	23	24	27	27	27	12.50%
Population <175,000	22	21	20	20	20	21	20	21	-4.55%
PET Number of Units*									
Statewide	48	47	46	45	49	52	51	52	8.33%
Population > 250,000	24	23	23	22	26	27	27	27	12.50%
Population < 250,000	24	24	23	23	23	25	24	25	4.17%
Population >175,000	26	26	26	25	29	31	31	31	19.23%
Population <175,000	22	21	20	20	20	21	20	21	-4.55%

Number of Providers Added Through Carve Out since 2021

1

Based on 2022 population estimates from Bureau of the Census

Counties with Populations Greater than 250,000: Davidson, Hamilton, Knox, Rutherford, and Shelby

Counties with Populations Greater than 175,000: Davidson, Hamilton, Knox, Montgomery, Rutherford, Shelby, Sumner, and Williamson

Source: Medical Equipment Registry 2/2/2024

*Includes mobile units not adjusted to full time equivalent

Attatchment C

Health Facilities Commission

CON Reform Working Group

September 6, 2023

CON Reform Overview: Effective 2026

Eliminate the CON program.

Require all Special Health Services licensees to meet quality standards prior to licensure and to obtain accreditation within three years of licensure.

Special Health Services

Special Health Services could include:

1. Acute Care Hospitals
2. Ambulatory Surgery Centers
3. Cardiac Catheterization
4. Freestanding Emergency Departments
5. Home Health Agencies
6. Hospice Agencies
7. Imaging Equipment (linear accelerators, PET, MRI, Megavoltage Radiation)
8. Outpatient Diagnostic Centers
9. Organ Transplantation

Special Health Services could exclude:

1. Burn Units
2. Habitation Facilities for Individuals with Intellectual or Developmental Disabilities
3. Long-Term Care Hospitals
4. NICUs
5. Open Heart Surgery Services
6. Nursing Homes
7. Rehabilitation Hospitals
8. Substitution-based outpatient treatment for opiate addiction

Proposed Timeline

Sep.–Dec. 2023

CON Reform Working Group meets with stakeholders to solicit feedback on final CON Reform Plan.

Nov. 2023

HFC Staff releases draft legislation to stakeholders for review and feedback.

Jan.–May 2024

Legislation is filed by members of the CON Reform Working Group and passed by the General Assembly.

May 2024

HFC ED appoints Technical Advisory Group (TAG) members.

June 2024 – May 2025

TAGs meet and finalize recommendations to HFC for rulemaking.

July 2025

HFC staff initiate rulemaking for quality standards requirements and procedures to be effective on July 1, 2026.

1 July 2026

CON is eliminated and new quality standard-based licensure process is operational.

Technical Advisory Groups (TAGs)

- TAGs will be formed to make recommendations to HFC on the following:
  - Content of quality standards
  - Approved accrediting organizations
  - Consequences for failure to meet quality standards/obtain accreditation
- TAGs will be composed of providers (including both direct care providers and quality improvement experts in health care administration), representatives from accrediting organizations, representatives of free market and patient care advocacy groups, and other representatives relevant to the service type.
- The following TAGs will be convened depending on which services are included as Special Health Services:
  - Acute Care Services TAG (acute care hospitals and FSEDs)
  - Imaging Services TAG (ODCs and all imaging equipment)
  - Home Health and Hospice TAG
  - Organ Transplantation Services TAG
  - Ambulatory Surgical Services TAG (ASTCs and cardiac catheterization)

Quality Standards

Quality Standards are pre-licensure requirements that providers must meet for accreditation which do not require chart review. These can be categorized as required written policies, environment of care standards, and systems and processes standards. The below chart provides more specific examples.

Required Written Policies:	Environment of Care Standards:	Systems and Processes Standards:
Information management policies;	Safety;	Human resources;
Medication management policies;	Fire Safety and Life Safety;	Information management;
Medical staff policies;	Hazardous Materials and Waste;	Environment management;
Provision of care, treatment, and/or services;	Medical/Laboratory Equipment;	Leadership and communication;
Medical staff policies;	Utilities;	
Rights and responsibilities of the individual;		
Transplant safety;		
Waived testing;		

Process Maps