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Brief Review of State Certificate of Need (CON) Processes

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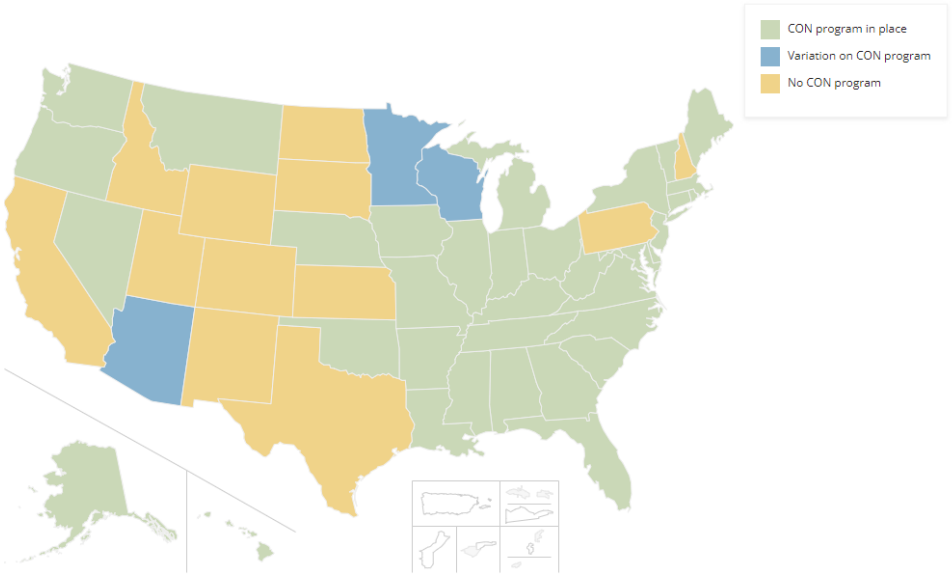
Introduction

This deliverable summarizes the research and findings conducted by HMA (Health Management Associates, Inc.) on state Certificate of Need (CON) programs and their legislation, regulations, policies, and procedures. HMA conducted a state comparison of five eastern region states to Washington, DC. The scan included review of health services required from CON submission; the activities regulated under the provision of the CON; and the decision-making bodies, processes, and criteria for approval. In addition, HMA conducted broader research on current trends (e.g., legislative reform) seen amongst state CON programs.

Currently, thirty-five states operate and maintain CON processes (**Figure 1**). Many states require submission of CONs for certain service types, settings, and activities.[1] Within recent years, several states have reformed their processes by either carving out services that previously required a CON, or revising the activities regulated under a CON law (e.g., allowing temporary expansion of services, exempting certain services, and expanding capital expenditure thresholds).

Figure 1. CON Laws by State



Source. National Conference of State Legislatures. Note: In the Legend, Variation on CON Program, means the state does not a CON program but may require a similar application process for a certain services.

[1] National Conference of State Legislatures. Certificate of need state laws. www.ncsl.org. Published December 20, 2021. https://www.ncsl.org/health/certificate-of-need-state-laws

As of 2020, the number of regulated services per state ranged from a low of one in Indiana to a high of twenty-eight in Hawaii.[2] In 2020, Washington, DC was ranked third highest in number of regulated services, at twenty-five.[2]

This brief review of CON laws and processes was conducted in response to specific questions posed by the Washington DC Statewide Health Coordinating Council (SHCC) regarding how the DC CON processes and procedures could be strengthened. The SHCC was especially interested in understanding how similar jurisdictions were operating their CON programs, and if there were opportunities to strengthen their processes and procedures to eliminate waste, improve efficiency, and promote long-term positive health outcomes.

Methods

Following discussions with JSI and the SHCC, HMA helped to define a set of key research questions to be addressed in this CON review. The questions were grouped into two primary categories related to 1) CON processes and procedures, and 2) trends in CON reforms. Below are the specific questions that were addressed.

CON Processes and Procedures

Through a review of the legislation, policies, and regulations that support and govern development of CONs, this research seeks to better understand approval criteria, implementation processes and procedures, and monitoring and evaluation processes of the CON (e.g., audit, outcomes, etc.) across different states and jurisdictions. The research questions include:

1. What are the major similarities or differences between DC's current CON process and procedures and those of other states?
2. Who are common stakeholders involved in the CON review processes, and in what ways are they engaged?
3. What are the predominant measures used in CON processes?

Trends in CON Reforms

In 1986, the federal government repealed the CON mandate, and many states immediately began retiring their CON programs. Since then, there have been repeals of state programs as well as various reforms. Through a review of these reforms, this research seeks to better understand the types of reforms taking place. The research questions include:

1. Are there trends in how states or jurisdictions are modifying or redefining their CON processes or procedures over the past five years? What are the types of CON reforms being implemented by states?
2. Are there any pending litigations to change or modify a state's current CONs process?

HMA identified a set of five states to focus on for this review. These states are Connecticut, Maryland, New York, Virginia, and Vermont. = Maryland and Virginia were chosen due to their proximity and

[2] Matthew D. Mitchell, Anne Philipot, and Jessica McBirney. (2020, November). How CON laws Effect Spending, Access, and Quality of Healthcare across the States. Mercatus. Retrieved from https://www.mercatus.org/publication/con-laws-2020-about-update#0

demographic similarities to Washington, DC, as well as an explicit request from the SHCC to include them. New York was selected because of its new Health Equity Impact Assessment (HEIA) that was effective June 22 of 2023.[3] Currently, New York is the only state that requires a HEIA submission. Connecticut and Vermont were selected as two east coast states with recent CON reform efforts.

Findings

The following section provides an overview of HMA's findings relevant to each of the research questions outlined above.

Question 1: What are the major similarities or differences between DC's current CON process and procedures and those of other states?

Though many states have common processes for approving a CON, there are important differences among states that should be considered. For our review, we focused on four elements included in most CON processes:

- Services requiring CONs
- Process timelines and procedures
- CON approval criteria
- Monitoring and evaluation

Services Requiring CONs

Among the five selected states and DC, HMA found that the most common services that required CON submission were hospitals, ambulatory surgical facilities (see **Appendix A** for definitions), diagnostic treatment centers, and home health agencies. Other common services that required CON submission included rehabilitation facilities, nursing home facilities.. See **Appendix B** for a detailed list of services requiring a CON for each state reviewed. The most common activities requiring the submission of a CON application typically fall under one or all of the following categories: (1) the expansion, opening, or closure of a new facility, (2) capacity changes to the number of beds, and (3) acquisition of major medical equipment. The selected states, including DC, have stipulations that specify that if there is a purchase or capital expenditure above a certain amount, a CON application must be submitted.

Given the increased role of telehealth services within the healthcare industry, HMA conducted a rapid review of how telehealth services were considered under states CON processes. HMA found that there are currently no CON review requirements on telehealth or telemedicine across the states reviewed. However, each state has different regulations and policies around telehealth and telemedicine services, which may include requirements for licensure, reimbursement policies, and standards. See **Appendix C** for details on state telehealth regulations and requirements for each state reviewed.

[3] Crowell, Chipetine MLM, Mourning P, Singh T. New York's CON Law Amended to Require Health Equity Impact Assessment. Lexology. Published January 27, 2023. https://www.lexology.com/library/detail.aspx?g=d0b927aa-94eb-46e1-b883-be05c37b642d

Process Timelines and Procedures

Across the states reviewed, most processes included 1) a review of an applicant's CON letter of intent, 2) a formal submission of the CON application, 3) a CON application review, 4) a public comment or hearing, and 5) a formal decision from a Board or Commission. Many CON processes also include standard procedures for appeals, which can be sought following a formal application decision being made. Process timelines and procedures can differ by state.

Application Review

- Washington, DC allows for what is known as a **pre-application conference**, where the applicant can meet with State Health Planning and Development Agency (SHPDA) staff to receive consultation on their application prior to its submission. In these conferences, applicants receive feedback to ensure their application meets criteria and standards required for the application to be approved, and that the applicant is aware of and adherent to the necessary timelines throughout the application process.

Process Differences Depending on CON Application Type

- In Maryland, a hearing to **review project evidence is prohibited** for ambulatory surgical facilities or for the expansion of one's services, if owned or controlled by a hospital.
- Connecticut **activities regulated under the state's CON law differ** depending on whether the facility is classified as a General Health Facility or a long-term care facility.[4]

Application Filing and Timelines

- Virginia and Washington DC both have a **batching process**, meaning that there are only two times during the year (every six months) when an application may be filed.[5]

Request for Independent Assessments

- New York requires an **independent health equity assessment** be submitted with the CON for general hospitals, nursing homes, birthing centers, ambulatory surgical centers, and all diagnostic and treatment centers, except diagnostic and treatment centers whose number of uninsured and Medicaid patients is over 50% of their total population.

Stakeholder Participation

- Though all states identified allow for **stakeholders to intervene in the application process** (including a competing stakeholder, advocacy group, or concerned citizen), the Vermont Office of Health Care Ombudsman or the Long-Term Care Ombudsman office may file a notice of intervention to the board.

CON Approval Criteria

Criteria for CON approval was found to differ across states (**Table *1***). Many of the states reviewed used different criteria than DC in their CON processes. In Washington, DC, a CON application must include an

[4] Certificate of Need Guidebook.; 2020. https://portal.ct.gov/-/media/OHS/CONfolder/CON-Guidebook-2020.pdf

[5] District of Columbia. CODE OF D.C. *MUNICIPAL REGULATIONS*. https://dchealth.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/SHPDA%20Regulations%20DCMR%2040-46.pdf.

explicit connection to a public need and a description of how the establishment or expansion of services proposed by the application will increase the accessibility, quality, acceptability, and continuity of care. In other states, this demonstration of how a project will increase coordination of care was not seen in their overarching criteria. In all the states reviewed, demonstrating a public need and financial feasibility is required criteria for inclusion in CON applications. All states reviewed require applicants to provide financial data, including history and projected expenditures of the facility the applicant is looking to open. Exemplifying "public need" includes providing evidence of the medical necessity of the applicant's service within their projected catchment area. Additional criteria used by states include contribution to health education (Virginia), competence based on an applicant's experience and past performance (Maryland and New York), correlation of the project to the State's health improvement plan (Vermont, Connecticut, Maryland, and Virginia), impact on health system (Maryland, Connecticut, Vermont, and Virginia), and construction requirements (New York). For further detail on the states criteria see **Appendix D**.

Table 1. Criteria Used by States to Assess CON Applicants

State	Public Need	Financial Feasibility	Access-ability	Accept-ability	Quality of Care	Continuity of Care
Washington, DC	X	X	X	X	X	X
Virginia	X	X	X	X		
Maryland	X	X		X		
Vermont	X	X				
New York	X	X				
Connecticut	X	X	X		X	

Application Questions and Specifications around Criteria

A review of the publicly available applications for hospitals were identified, leading to the discovery of similarities and differences in questions and measures, used to determine if an application had met the specified criteria **(Appendix E)**.[6,7,8,9]Applications for Virginia and Maryland required more granularity in an applicant's responses when compared to Vermont, which had broader and open-ended questions, especially around access and how services would help serve a public need. Only New York and Vermont included specific questions about how the applicant would improve quality of care. This contrasts with what is shown in **Table 1** above: that criterion under the Connecticut CON requires demonstration of quality of care.

Conditional Approvals

All five states included in the review had a process for "conditional approvals", which would allow the state decision makers to approve an application "contingent on specific conditions". However, no information was found to identify those conditions.

[6] https://www.vdh.virginia.gov/licensure-and-certification/applications-and-forms/
[7] https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/documents/con_hospital_application_201412.pdf
[8] https://gmcboard.vermont.gov/sites/gmcb/files/documents/Application%20for%20CON_1.pdf
[9] https://portal.ct.gov/OHS/Pages/Certificate-of-Need/CON-Forms

Monitoring and Evaluation

The five states reviewed are not consistently monitoring and/or evaluating the impact of CON projects with the measures described in **Table 2** below, as it is also unclear what criteria is being used when conditions are put on the approval of a CON. Both Virginia and Vermont include some form of annual reporting. Modifications to a CON require proactiveness of the CON project staff, to alert the authority about necessary modifications. Vermont and Connecticut are two states for which a formal modification form submission is made publicly available. See **Appendix F** for additional detail on each state's monitoring and evaluation processes.

Question 2: What are the predominant measures used in CON processes?

Historically, CON was enforced by the concern of disallowing Medicare or Medicaid payment for facilities or services that had not undergone CON approval. Since repeal of these provisions, states have adopted a variety of mechanisms for enforcing CON regulations. States can generally enforce CON requirements by denying, suspending, or revoking the license or certification of a facility not in compliance. Some states impose sizable administrative penalties (e.g., $5 million) for specific violations of CON statutes.[10]

The stated goals of CON regulation are to contain costs, ensure adequate and equitable access to care, and improve overall quality. Applications are approved based on the extent to which the projects align with these goals. Researchers have tried to assess whether these goals are achieved. The measures used by researchers to assess CON impact are described in **Table 2**.

Table 2. Example Measures to Assess CON Goals and Impact

CON Goal	Example measures
Cost Containment	• Costs per unit costs • Total expenditures
Access	• Proximity to care, including number of facilities (e.g., hospitals, hospice care facilities, dialysis clinics, ambulatory surgery centers), number of beds, and Medical imaging devices • Distribution of care, including number of facilities, beds, and medical imaging devices in rural, frontier, and urban geographies (e.g. travel distance to care)
Equity	• Amount of charity care (e.g., healthcare services delivered where no payment was expected)
Quality	• Mortality rates from heart attacks, heart failure, and pneumonia • Readmission rates following heart attack or heart failure • Post-surgery complications • Prevention quality indicators (PQIs) • Lower patient satisfaction levels

Source: Blase, B.C. (2021). "Don't Wait for Washington: How States Can Reform Health Care Today. Paragon Institute. Retrieved from https://paragoninstitute.org/wp-content/uploads/2021/12/Chapter-4-PDF.pdf

[10] https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-020-05563-1

Question 3: Who are common stakeholders involved in the CON review processes, and in what ways are they engaged?

HMA reviewed the stakeholders decision-making bodies involved in the CON review process for each state in this analysis and found that they differed in approach (**Table *3***). In general, Maryland, Vermont, and New York leverage an elected or appointed Board as their CON decision-making body, while Virginia and Washington, DC leverage a process that relies on one final decision-maker.[11,12] In Virginia, despite the application review process being conducted by the Virginia Department of Health, the State Health Commissioner has sole decision-making authority. This is similar to the DC process, where the SHCC committee reviews and makes recommendations to the SHPDA commissioner, who then makes the final decision.

Table 3. CON Application Decision Maker by State

State	CON Application Decision Maker
Washington, DC	SHPDA Director
Virginia	State Health Commissioner
Maryland	Board comprised of fifteen members, appointed by the Governor, who represent hospitals, specialty services, plans, legal, and consumer advocacy groups[13]
Vermont	Green Mountain Board of five state employees, nominated by a committee of senators, representative and gubernatorial members, and the Governor
New York	Commissioner of Health and the Public Health & Health Planning Council, consisting of twenty-five members appointed by the Governor, representing the BH services Advocacy Council, General Hospitals, healthcare payers' specialty service (such as home care agencies, diagnostic and treatment facilities), employee labor organizations, and consumer advocacy groups
Connecticut	Director of the Office of Health Strategy, Office of Health Strategy Planning Unit

Question 4: Are there trends in how states or jurisdictions are modifying or developing CON processes or procedures over the past five years? What are the types of CON reforms being implemented?

A review of legislative changes related to CON policies among the five identified states identified several common reforms. **Table 4** shows the most common reform types seen across the five states. Of note, the common reforms listed do not represent a detailed account of all reforms that took place since 2019.

[11] GREEN MOUNTAIN CARE BOARD RULE 4.000: CERTIFICATE of NEED 4.100 GENERAL PROVISIONS 4.101 Authority.
https://gmcboard.vermont.gov/sites/gmcb/files/files/resources/rules/12%2012%2014%20CON%20Rule.pdf

[12] Pages - COMAR Search. Maryland.gov Enterprise Agency Template. Accessed January 24, 2024.
https://dsd.maryland.gov/Pages/COMARSearch.aspx#k=10.24.01#l=1033

[13] MHCC Commissioner's Bio. mhcc.maryland.gov.
https://mhcc.maryland.gov/mhcc/pages/home/commissioners/commissioners.aspx

The first common reform was the exemption of a CON for the expansion of the number of beds in a facility. In 2022, Connecticut temporarily exempted the need for mental health facilities to submit a CON when increasing the number of licensed beds in a facility. Similarly, in 2022, Virginia exempted the need for CON submission for the expansion of temporary beds.

Another common reform is the revision of CON regulation to exclude previously required facilities from needing to submit a CON. In 2019, Maryland revised CON regulation to exempt the need for "continuing care at home" arrangements from needing to submit a CON application.[14] Similarly, in 2019, Vermont extended their moratorium on home health agencies and home health services until 2025. A moratorium, though practiced by very few states, is a hold on any CON applications for a specific services area.

Another reform seen across states is related to changes to capital expenditure thresholds. In April of 2023, Vermont voted to expand the capital expenditure threshold required for CON across both hospital and non-hospital services.[14] Though still awaiting public comment, this expansion will be a part of a similar trend seen across other states not listed here.

In 2023, New York DOH announced the adoption of the Health Equity Impact Assessment, an independent health equity audit that would need to be submitted along with the CON. New York is the first and only state to adopt such legislation around their CON process.[15] This is a new concept not currently adopted by other states, and is completed by an independent auditor, typically consultants based on predetermined DOH questions and data forms. As of December 8, 2023, an amendment was established to expand the scope of the HEIA to include impacts on reproductive health services and maternal healthcare. Applicants will be required to demonstrate how a proposed project will impact the availability, provision, and delivery of reproductive health services and/or maternal healthcare in the applicant's facility and service area. In addition, there has been additional clarification from the DOH that there will be no redaction of information in the HEIA, meaning that the agreement between the auditor and the facility must be made public. Subsequently, this allows for CON applicants who must submit an HEIA to research pricing on previous HEIAs submitted, allowing for transparency and containment of HEIA costs. As this is a new requirement from the DOH, it is unclear what the pros and cons are of this process. Careful monitoring is advised, as there are perceived benefits and perceived barriers to this process being successful.

Table 4. CON Reforms Since 2019, by Type

State	Expansion of the number of beds in a facility	Exclude previously required facilities	Changes to capital expenditure thresholds	Extension of a moratorium for specific services or activities	Independent Audit
Virginia	X				
Maryland		X	X		

[14] Certificate of Need | Green Mountain Care Board. gmcboard.vermont.gov. Accessed February 2, 2024. https://gmcboard.vermont.gov/certificate-need

[15] Certificate of Need. www.health.ny.gov. https://www.health.ny.gov/facilities/cons/

State	Expansion of the number of beds in a facility	Exclude previously required facilities	Changes to capital expenditure thresholds	Extension of a moratorium for specific services or activities	Independent Audit
Vermont			X	X	
New York					X
Connecticut	X				

Question 5: Are there any pending litigations to change or modify a state's current CON process?

Within the last few years, there has been discussion around the repeal of CON processes in many states. The federal mandate that required CON laws was repealed in 1986, leading several states to repeal or modify their CON laws. Since then, states have been assessing the need to keep a CON process. As of 2022, twelve states fully repealed their CON programs or allowed the program to expire.[16] Many of these states cited concerns with market isolation to a select few providers and health systems.[16] Ongoing discussions around a mass overhaul of the CON process continue in states such as Georgia and North Carolina.[17]

In Virginia, litigations in the case of *Chesapeake Regional Medical Center v. State Health Commissioner* made headlines when, in 2021, Chesapeake Regional Medical Center sued their competitor Sentara Heart Hospital, citing that Sentara was trying to cripple their cardiology program, leading to a subsequent denial of their Certificate of Public Need (COPN).[18] The case went to the Supreme Court, who upheld the decision of the State Health Commissioner's denial. Another example includes *Singleton v. N.C, Dep't of Health & Human servs* in North Carolina, where a submission was made for medical equipment for a Singleton vision center. That claim was ultimately denied.[19]

Questions around the validity of the CON process are well-documented. The American Medical Association released an article citing evidence for CON repeal, including that CON laws have failed to achieve their intended goal of containing costs, CON laws may be a barrier to entry for new facilities and a source of anticompetitive behavior, that CON laws could impede patient choice. [20]

These reasons aside, strong advocates for state CON laws remain, with the intention of helping avoid the expansion of unnecessary healthcare services or duplicative services within a specific region of any given state. CON laws have been designed to prevent unnecessary investment in infrastructure that can

[16] https://www.ncsl.org/health/certificate-of-need-state-laws

[17] National Conference of State Legislatures. Certificate of need state laws. www.ncsl.org. Published December 20, 2021. https://www.ncsl.org/health/certificate-of-need-state-laws

[18] Chesapeake Hospital Authority v. State Health Commissioner. Justia Law. Accessed February 1, 2024. https://law.justia.com/cases/virginia/supreme-court/2022/201510.html

[19] Singleton v. N.C. Dep't of Health & Hum. Servs. | North Carolina Judicial Branch. www.nccourts.gov. Accessed February 1, 2024. https://www.nccourts.gov/documents/appellate-court-opinions/singleton-v-nc-dept-of-health-hum-servs

[20] Certificate of Need: evidence for repeal. *American Medical Association*. 2015. https://www.ama-assn.org/media/14736/download.

lead to inflation of costs and help avoid extraneous expenses.[20] Moreover, CON processes enable quality assurance efforts, given CON processes typically require applicants meet quality criteria.[21] Published studies are mixed, and do not come to a definitive conclusion, on how CON laws drive cost effectiveness within the healthcare system.[22,23] These processes force state officials to be held accountable for the allocation of services and offer assurance that all members within the state can receive accessible care.

[21] Palmer E. Everything you need to know about Certificate-of-Need Laws for ASCs. HST Pathways. https://www.hstpathways.com/blog/everything-you-need-to-know-about-certificate-of-need-laws-for-ascs/#:~:text=Here%20are%20the%20pros%3A,cost%2Deffective%20allocation%20of%20resources. Published July 14, 2023.

[22] Conover CJ, Bailey J. Certificate of need laws: a systematic review and cost-effectiveness analysis. BMC Health Serv Res. 2020 Aug 14;20(1):748. doi: 10.1186/s12913-020-05563-1. PMID: 32795295; PMCID: PMC7427974.

[23] Rosko MD, Mutter RL. The Association of Hospital Cost-Inefficiency With Certificate-of-Need Regulation. Medical Care Research and Review. 2014;71(3):280-298. doi:10.1177/1077558713519167

Appendix A: State Definitions of Ambulatory Surgical Centers and Facilities

State	Definition
Washington, DC[24]	"Ambulatory Surgical Treatment Center" means any institution, place, or building devoted primarily to the maintenance and operation of facilities for the performance of surgical procedures on an outpatient basis. This includes facilities where family planning procedures are performed. Such facilities cannot provide beds or other accommodations for the overnight stay of patients. Individual patients should be discharged in an ambulatory condition without danger to the continued well-being of the patient(s), or should be transferred to a hospital. "Center" means an Ambulatory Surgical Treatment Center.
Maryland[25]	"Ambulatory surgical facility" means any center, service, office, facility, or office of one or more health care practitioners (or a group practice) that: (a) Has three or more operating rooms; (b) Operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization; and (c) Seeks reimbursement from a third-party payor as an ambulatory surgical facility.
Vermont[26]	"Ambulatory surgical center" means a facility or portion of a facility that provides surgical care not requiring an overnight stay. The office of a dentist in which activities are limited to dentistry and oral/maxillofacial surgical procedures is not deemed an ambulatory surgical center for purposes of this subchapter. In order to be considered an ambulatory surgical center, a facility shall meet all the following criteria: (a) charge, or intend to charge, a facility fee in addition to professional fees for the services performed; (b) have an operating room or recovery room in the facility; (c) use an anesthesiologist or nurse anesthetist; and (d) provide one or more outpatient services for which Medicare coverage is provided.
Virginia[27]	"Hospital outpatient (ambulatory care)" means any specialized center or clinic or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery.[28]

[24] D.C. Law 2-66. D.C. Ambulatory Surgical Treatment Center Licensure Act. | D.C. Law Library. D.C. Law Library. https://code.dccouncil.gov/us/dc/council/laws/2-66.

[25] Laws - Statute text. https://mgaleg.maryland.gov/mgawebsite/Laws/StatuteText?article=ghg§ion=19-114&enactments=false.

[26] Vermont Laws. https://legislature.vermont.gov/statutes/section/18/221/09432.

[27] https://law.lis.virginia.gov/admincodefull/title12/agency5/chapter410/

[28] https://ij.org/report/conning-the-competition/state-profile/virginia/

New York[29]	"Ambulatory surgery service" is a service organized to provide those surgical procedures which need to be performed for safety reasons in an operating room on anesthetized patients requiring a stay of less than 24 hours' duration
Connecticut [30]	Outpatient surgical facility is defined as operated by a corporation other than a hospital which provides ambulatory Surgical care in addition to the provision of medical care for diagnosis and treatment of persons with acute or chronic conditions or to the provision of surgical care to well persons. Ambulatory surgical care is defined as surgical care not requiring overnight stay but requiring a medical environment exceeding what is normally found in a physician's office. This medical environment may include any or all of the following: (a) The pathological process for which the operation is to be performed shall be localized and not conducive to systemic disturbance; (b) The patient shall not, in the opinion of the attending physician, have other significant physiological, biochemical, or psychiatric disturbance which might be worsened by the operation; (c) The preoperative work to be done following admission shall not be such as to extend the admission beyond the normal period of clinic operation during one day; (d) The postoperative recovery period anticipated shall not require skilled medical or nursing care such as to extend the admission beyond the normal period of clinic operation during one day; (e) Anesthesia requirement, which may render the patient unconscious and unable to walk, but which will not prohibit discharge during the normal period of clinic operation during the day on which the operation is performed.

[29] Title: Section 755.1 - Ambulatory surgery definition | New York Codes, Rules and Regulations. https://regs.health.ny.gov/content/section-7551-ambulatory-surgery-definition.

[30] State of Connecticut Department of Health. Licensure of Out-patient Surgical Facilities. https://portal.ct.gov/-/media/departments-and-agencies/dph/dph/public_health_code/sections/1913d56outpatientsurgicalfacilitiespdf.pdf.

Appendix B: Services By State

Requirements	Washington DC [31]	Virginia[32]	Maryland[33]	Vermont[34]	New York[35]	Connecticut[36]
General Hospitals	X	X	X	X	X	X
Psychiatric Hospitals	X	X	X	X	X	X
Specialty Hospitals	X	X	X	X	X	X
Rehab Facilities	X	X	X			
Skilled Nursing Facilities (SNFs)	X	X		X	X	X
Intermediate Care Facilities	X	X			X	
Ambulatory Surgical	X	X	X	X	X	X
Ambulatory Care Center or Clinic	X					
Home Health Agencies	X		X	X	X	
Hospice Facilities	X		X		X	
Diagnostic Treatment Facilities	X	X		X	X	X
Freestanding Hemodialysis Facility	X					
Kidney Disease Treatment Centers	X	X		X		
Other comparable healthcare facility with an	X	*		X		

[31] D.C. Health. www.dchealth.dc.gov. Certificate of Need. Available at: https://dchealth.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/2023-02-SHPDA-CertOfNeed-FAQs.pdf. Accessed February 27, 2024.
[32] Virginia Law. Code of Virginia. Available at: https://law.lis.virginia.gov/vacode/32.1-102.1:3/. Accessed February 27, 2024
[33] Maryland Division of State Documents. 10.24.01.01. Available at: https://dsd.maryland.gov/regulations/Pages/10.24.01.01.aspx. Accessed February 27, 2024.
[34] Justia US Law. Title 18 Health Chapter 221 Health Care Administration. Available at: https://law.justia.com/codes/vermont/2012/title18/chapter221/section9434. Accessed February 27, 2024/
[35] New York Department of Health. How to Determine if CON Submission is required. Available at: https://www.health.ny.gov/facilities/cons/more_information/#project_types. Accessed February 27, 2024.
[36] Connecticut Office of Health Strategy. Certificate of Need Guidebook April 2023. Available at: https://portal.ct.gov/-/media/OHS/CONfolder/CON-Guidebook-2020.pdf. Accessed February 27, 2024.

annual operating budget of at least $500,000						
Other	X	X	**	X	X	X

** Any capital expenditure above an annual, inflation adjusted threshold ($20,961,758 in 2021)*

*** A freestanding medical facility, as defined in Health-General Article, §19-3A-01, Annotated Code of Maryland*

Appendix C: Telehealth Services Regulations

	Washington, DC	Virginia	Maryland	Vermont	New York	Connecticut
Payment Parity?[37]	No	No	Yes	Yes	Yes	Yes
Private Payer Law?[38]	Yes	Yes	Yes	Yes	Yes	Yes
Interstate Medical Licensure Compact[39]	Yes	No	Yes	Yes	No	Yes
Requirements for Telehealth Services[40]	Must meet program requirements	No further authorization process	No further authorization process	Telehealth registration and licensing	No further authorization process	Telehealth Registration
State License Required?[41]	Yes	No	Yes	Yes	Yes	No
Telehealth License Required?[42]	No	No	No	Yes	No	No

[37] CCHP. Private Payer Parity. Available at: https://www.cchpca.org/topic/parity/. Accessed on March 7, 2024.
[38] CCHP. Private Payer Requirements. Available at: https://www.cchpca.org/topic/requirements/. Accessed on March 7, 2024.
[39] CCHP. Professional Requirements Licensure Compacts. Available at: https://www.cchpca.org/topic/licensure-compacts/. Accessed March 7, 2024.
[40] CCHP. Professional Requirements Cross-State Licensing. Available at: https://www.cchpca.org/topic/cross-state-licensing-professional-requirements/. Accessed March 7, 2024.
[41] CCHP. Professional Requirements Cross-State Licensing. Available at: https://www.cchpca.org/topic/cross-state-licensing-professional-requirements/. Accessed March 7, 2024.
[42] CCHP. Professional Requirements Cross-State Licensing. Available at: https://www.cchpca.org/topic/cross-state-licensing-professional-requirements/. Accessed March 7, 2024.

Appendix D: Criteria By State

State	Criteria Summary
Washington, DC	• **Need:** Applicants shall demonstrate unmet need among the proposed target population. • **Accessibility:** Applicants must demonstrate how the proposed project will lower barriers to accessibility. • **Quality of Care:** Applicants shall demonstrate how the proposed project will provide quality care to patients. • **Continuity of Care:** Applicants shall demonstrate how the proposed project will ensure appropriate care is provided on a continuous basis across one or more care settings. • **Acceptability:** Applicants must demonstrate how the proposed project will be acceptable to the proposed target population and the public. • **Financial Feasibility:** Financial impact is defined as the full breadth of financial and economic consequences resulting from the provision of healthcare services.
Virginia	• **Need:** The level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served. • **Accessibility:** The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care. • **Acceptability:** The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served, while improving access to essential healthcare services for all persons in the area to be served. • **Impact on existing health systems (including utilization and efficiency):** The relationship of the project to the existing healthcare system of the area to be served, including the utilization and efficiency of existing services or facilities. • **Financial Feasibility:** The feasibility of the project, including the financial benefits of the project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital. The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of healthcare services; (ii) the potential for provision of services on an outpatient basis; (iii) any cooperative efforts to meet regional healthcare needs; and (iv) at the discretion of the Commissioner, any other factors as may be appropriate.

	• **State Plan:** The extent to which the application is consistent with the State Medical Facilities Plan. • **Contribution to health education*:** In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served, (i) the unique research, training, and clinical mission of the teaching hospital or medical school, and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of healthcare for citizens of the Commonwealth, including indigent or underserved populations.
Maryland	• **Need:** The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served and established that the proposed project meets those needs. • **Correlation to State Health Plan:** An application for a CON shall be evaluated according to all relevant State Health Plan standards, policies, and criteria. • **Availability:** The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review. • **Viability of the Proposal ("Financial Feasibility"):** The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project. • **Impact on existing health system:** An applicant shall provide information and analysis with respect to the impact of the proposed project on existing healthcare providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the healthcare delivery system. • **Health Equity:** The Commission shall consider how a proposed project will address healthcare disparities in availability, accessibility, and quality of care among different populations within the service area. The Commission shall consider how social determinants of health within the service area of the proposed project create disparities in the delivery of healthcare. • **Competence of applicant:** The Commission shall assess the character and competence of an applicant based upon experience and past performance, including any records of violation in operating a healthcare service or facility.

Vermont	• **Need:** Whether the project will help meet the needs of medically underserved groups and the goals of universal access to health services. • **Facilitate implementation of Vermont Blueprint**:** Whether the project will help facilitate the implementation of the Blueprint. • **Care Coordination:** Whether the applicant has demonstrated it has analyzed the impact of the project on the Vermont healthcare system and the project furthers effective integration and coordination of healthcare services. • **In compliance with state and federal reform efforts:** Whether the project is consistent with current healthcare reform initiatives, at the state and federal level. • **Financial Feasibility:** Except where circumstances support approval of an emergency Certificate of Need, whether the project was identified prospectively as needed at least two years prior to the time of filing in the hospital's four-year capital plan. • **Impact on existing health system:** Whether, and if so to what extent, the project will have an adverse impact on the ability of existing facilities to provide medically necessary services to all in need, regardless of ability to pay or location of residence.
New York	• **Need:** Determination of public need is based upon a variety of factors, including population demographics, service utilization patterns, epidemiology of selected diseases and conditions and access to services. • **Financial Feasibility:** Financial feasibility is based on expenses, projected revenues, current financial status, and capacity to retire debt. • **Character and Competence:** Assessment of the character and competence of an applicant is based upon experience and past performance in operating a healthcare service including records of violations, if any, and whether a substantially consistent high level of care was maintained. Applicants without experience in healthcare services are evaluated based on compliance with laws and practices pertinent to their professional experience. • **Construction (Building Compliance):** Buildings must comply with Title 10, Chapter V, Article 2 (Parts 710-717) of the Official Compilation of the Rules and Regulations of the State of New York. • **Health Equity:** demonstrate how a facility's proposed project affects the accessibility and delivery of services, and whether the project will enhance health equity and contribute to mitigating health disparities in the project's service area, specifically for medically underserved groups.*
Connecticut	• **Need:** It is the Applicant's responsibility to demonstrate public need for the proposed project. Although benefits to the Applicant may intersect with those of the public, please be sure to focus on the latter.

	• **Correlation to State Health Plan** • **Impact on existing health system (including utilization and efficiency):** Utilization of existing healthcare facilities and services in the service area. Whether the Applicant has satisfactorily demonstrated that the proposal will not result in unnecessary duplication of services or facilities in the area. • **Accessibility, Quality, Cost Effectiveness:** Whether the Applicant has satisfactorily demonstrated how the proposal will improve quality, accessibility, and cost effectiveness of healthcare delivery in the region. The analysis takes into consideration, in part, any changes in access to services for Medicaid and indigent persons. • **Cost and Accessibility:** Whether the Applicant has satisfactorily demonstrated that any consolidation resulting from the proposal will not adversely affect heathcare costs or accessibility to care. • **Financial Feasibility:** Whether the Applicant has satisfactorily demonstrated how the proposal will impact either: the strength of the healthcare system or that the proposal is financially feasible for the Applicant.

Appendix E: Examples of Application Standard Metrics by Criteria

	Virginia	Maryland	Vermont	New York	Connecticut
Public Need	• Geographic **Location** • **Access** in Relationship to Transportation • How the project will **fill unmet needs** and solve geographic barriers	• Geographic **location** • Volume of service provided by all other existing healthcare providers that are likely to experience some impact as a result of this project • How will the project increase **access** in the service area • Cost on the healthcare system • Community support for the project • Alignment with MD State plan	• Geographic **location** • Specification around **need** • Any adverse impacts • Improvement of **access** to healthcare for residents	• Identify **demographics** of relative shortage areas (street boundaries, Zip codes, shortage area) • Projected demand (number of patients the project projects to serve) • Aligned with facilities Community Service Implementation Plan • Ratio of physicians to population	• Alignment with Healthcare Facilities and Service Plan • Alignment with CLAS standards • Promotion of health equity • Impact on primary care • **Demographic** breakdown in service area • Improving coordination of care • Charity care • **Access** to Medicaid recipients or indigent care • Average Cost year over year by payment type (self-pay, commercial)
Availability	• Total Licensed **Beds** • Total Patient Days	• Physical **Bed** capacity	• Availability of affordable, accessible		• Utilization by service type

	Virginia	Maryland	Vermont	New York	Connecticut
	• Total Occupancy % • **Total Discharges** • Total Discharge Day • **Average Length of Stay** • Same metrics above by major Inpatient Services • Show how the method and assumptions used in determining the need for additional beds, new services or deletion of service in the proposed project's service area.	• Expected and actual (last to years) number of **discharges** • Expected to actual **patient stays**	transportation services to facility		• Patient volumes by payer mix • Population race/ethnicity age groups or persons with specific conditions
Quality			• Quality of healthcare for residents	• Evidence of accreditation, certification, or awards obtained proving high quality services	
Finance	• Per diem rate for all existing negotiated reimbursement contracts and proposed contracts	• Expenses and revenues • Statistical financial projections for new facilities	• Cost • Feasibility		• Cost • Feasibility • Operational performance • Liquidity

	Virginia	Maryland	Vermont	New York	Connecticut
	for patient care with state and federal governmental agencies • Estimated Capital Costs: Direct Construction Costs (e.g., material and labor costs), equipment, acquisition costs etc., • Impact the proposed capital expenditure will have on the cost of providing care in the facility • Estimated income, expense and capital budget for the first two years of operation after the proposed project is completed.	and expansions • Audited financial statements			• Leverage and Capital Structure • Income of operations • Available bed occupancy • Annual operating revenue • Annual expense growth rate • Capacity and Utilization • Community benefit • Charity Care

Appendix F: Monitoring and Evaluation of CON Projects by State

Virginia

Virginia's monitoring of CON projects includes several components, including:

- **Project Timeline.** A certificate of public need is valid for a twelve-month period and may be extended by the commissioner for additional time periods which shall be specified at the time of the extension.
- **Demonstration of progress.** Applicants provide reports to demonstrate progress made towards the implementation of an authorized project in accordance with the schedule of development which shall be included in the application.[43]
- Annual Reporting: Reports of indigent and primary care provided in compliance with CON conditions are reported annually based on the CON holder's fiscal year or the calendar year[44].
- Inventory of CON-regulated equipment and services: In accordance with the fourth enactment clause of Virginia Acts of Assembly 2020 Reconvened Session Chapter 1271, Virginia Department of Health (VDH) provides an inventory of authorized CON-regulated equipment and services. As new equipment and services are authorized, and known to be discontinued, the inventory is updated on at least a monthly basis. People are asked to provide errors of inclusion or omission with supporting evidence to VDH.

Maryland

Maryland Health Care Commission (Commission) requires status reports on the approved project to the Commission every three months from the date of a CON, and continuing, at three-month intervals, until the completion of the project.

Eligibility also may speak to monitoring. Eligibility to apply for a CON or to expand an authorized service area must meet a set of performance requirements, as shown in **Table F1**. Performance is determined based on the data publicly reported on the applicable CMS Care Compare websites and, for Maryland nursing homes, the Maryland-specific patient/family satisfaction or experience of care survey on the Maryland Quality Reporting website.

Table F1. Maryland Performance-Related Qualifications by Type of Applicants

	Performance-Related Qualifications by Type of Applicants
Nursing homes	(1) Quality of Patient Care (QOPC) Overall Nursing Home star rating equal to or better than the Maryland State average as follows: 4 stars in CY 2017; 3 stars in CY 2018; and 3 stars in CY 2019 (2) Maryland-specific Experience of Care Survey equal to or better than the Maryland State average rating on scale of 1 to 10 as follows: 8.1 in CY 2016; 7.7 in CY 2018; and, 7.6 in CY 2019 (3) A nursing home which has been cited by CMS for resident abuse has been excluded from the list of qualifying nursing homes, even if that nursing home met the performance-related qualifications

[43] https://www.vdh.virginia.gov/content/uploads/sites/96/2016/07/COPN-regs-2011.pdf

[44] https://www.vdh.virginia.gov/content/uploads/sites/96/2016/07/Condition_Compliance.Guidance.revision.4.07.pdf

Performance-Related Qualifications by Type of Applicants	
Health home agencies (Both Maryland and non-Maryland HHAs)	(1) QOPC Overall star rating equal to or better than the Maryland State average of 4.0 stars (2) Home Health Consumer Assessment of Health Care Providers and Systems (HHCAHPS®) Survey Summary Overall star rating equal to or better than the Maryland State average of 4.0 stars
Hospitals	(1) QOPC Overall star rating equal to or better than the Maryland State average of 3.0 stars for all three years (2) Hospital Consumer Assessment of Health Care Providers and Systems (HCAHPS®) Survey Summary star rating equal to or better than the Maryland State average of 3.0 stars, for all three years
Residential Service Agency (RSA)	Demonstrating a track record of providing good quality of care. • Documenting that it has operated and provided skilled nursing services for at least three years • Established a system for collecting data that includes systematic collection of process, outcome and experience of care measures • Maintained accreditation through a deeming authority recognized by the Maryland Department of Health for at least the three most recent years of operation, consistent with COMAR 10.24.16.07D(1). • RSA applicants must submit data to the Commission to document ability to monitor the required quality measures and performance levels.

Source: 2022 Home Health Agency Certificate of Need (CON) Review
https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_homehealth/documents/2022_HHA_Guidelines.pdf

Vermont

The Green Mountain Care Board (GMCB) manages the CON process, including monitoring and enforcement. As stipulated in Chapter 221 of Title 18 of the Vermont Statutes and in GMCB Rule 4.000[45], the CON itself may include an implementation report schedule and reporting requirements if any exist. It is expected that the CON holder provides requested implementation reports to all interested parties, unless such parties elect to not receive such reports.

Additionally, the CON recipient is required to notify the GMCB of any changes in the scope or cost of an approved project. A "material change" means:

1. A change that constitutes a new healthcare project as defined by statute or rule; or
2. A change in project cost that exceeds 10% of the total approved cost of the project. All project costs are included, including capital, operating, or other expenses, to determine whether the 10% threshold has been exceeded.

The GMCB may (on its own initiative and based on information contained in the implementation reports or any other relevant information) determine that a project has changed in kind, scope, or capacity, based on a material or non-material change to a new healthcare project authorized under a previously issued CON.

[45] https://gmcboard.vermont.gov/sites/gmcb/files/files/resources/rules/12%2012%2014%20CON%20Rule.pdf

New York

Monitoring of facility-based CONs requires the submission of an architect's letter, certifying that either new construction or existing structures are compatible programmatic requirements and features of the approved CON. Specifically:

- Architect's Letter of Certification for Completed Projects, which states that an architectural firm was hired to conduct periodic site observation visits, and ensure that the necessary standard of care was met. This would be documented through noting progress and quality, and ensuring conformance of the work with documents provided for all regulatory approvals associated with the aforementioned project.[46]
- The Architect certifies that the completed structure was designed and constructed in accordance with the programmatic requirements for the referenced construction project, based on design development drawings, and in accordance with any project definitions, modifications, and/or revisions approved or required by the New York State Department of Health.[47]

Ramifications of a neutral or negative health equity impact assessment are not immediately clear, as the law merely notes that the DOH Commissioner and the Public Health and Health Planning Council will "consider" the health equity impact statement in each application review and approval.

Connecticut

Compliance, pursuant to Conn. Gen. Stat. §19a-639, per the Final Decision Order or Agreed Settlement, is monitored and enforced by Office of Health Strategy (OHS) staff, specifically designated to OHS Compliance. All conditions in a CON Decision or Agreed Settlement are healthcare-related and may incorporate conditions related to work from other units of OHS, such as Health Information Technology (HIT). For the CON recipient, meeting these expectations includes document filing and data reporting at varied timeframes, commencing on the date of approval. It is the role of OHS Compliance Staff to review all documents filed and data received for completeness and clarity, and determine whether the intent of the condition or stipulation within the authorization order has been met.

OHS is also notified of any needed modifications to the CON through a modification request form. A modification is required to adjust a service or project that was originally authorized under the CON process. They are requested when there is a change in condition, such as an extension of timeline or a change to the project that is not substantial enough to warrant a new CON application. Example modifications include:

- Change in the scope of the Authorized Certificate of Need project
- Extension of CON expiration date
- Change in a CON order condition (other than to extend expiration date)

[46] https://www.health.ny.gov/facilities/cons/more_information/docs/3-alc_for_completed_projects.pdf
[47] https://www.health.ny.gov/facilities/cons/more_information/docs/4-alc_for_inspecting_existing_bldgs.pdf