Certificate of Need (CON)

September 6, 2023

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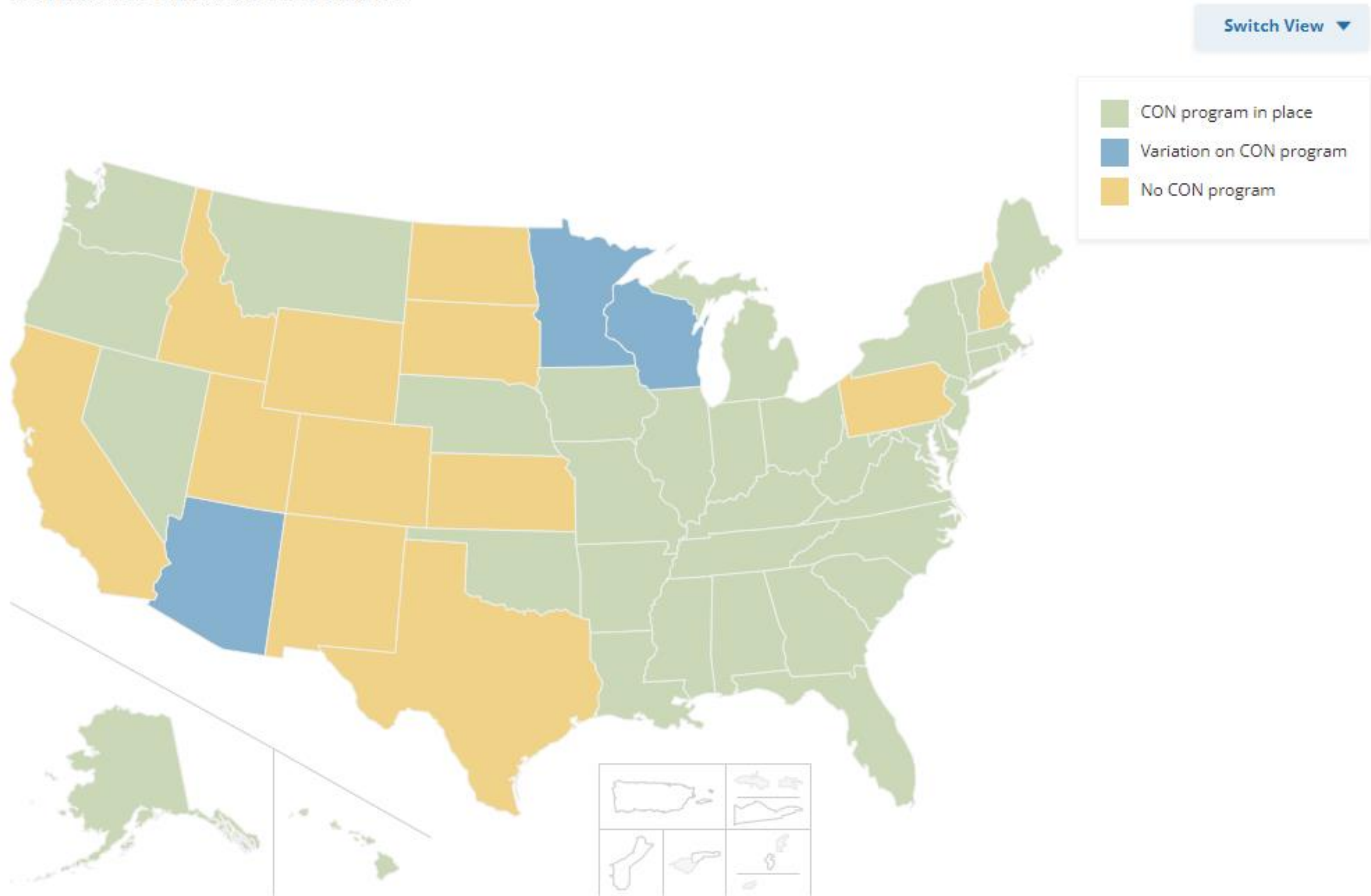
Background

- Certificate of Need (CON) is a regulatory program requiring certain types of health care providers to obtain state approval prior to making major changes in the healthcare landscape
- 35 states and Washington, D.C. operate CON programs



[Certificate of Need State Laws (ncsl.org)]

C.G.S. §§ 19a-638(a)(1)-(15)
When a CON is required

- (1) The establishment of a new health care facility;
- (2) A transfer of ownership of a health care facility;
- (3) A transfer of ownership of a large group practice to any entity other than a (A) physician, or (B) group of two or more physicians, legally organized in a partnership, professional corporation or limited liability company formed to render professional services and not employed by or an affiliate of any hospital, medical foundation, insurance company or other similar entity;
- (4) The establishment of a freestanding emergency department;
- (5) The termination of inpatient or outpatient services offered by a hospital, including, but not limited to, the termination by a short-term acute care general hospital or children's hospital of inpatient and outpatient mental health and substance abuse services;
- (6) The establishment of an outpatient surgical facility, as defined in section 19a-493b, or as established by a short-term acute care general hospital;
- (7) The termination of surgical services by an outpatient surgical facility, as defined in section 19a-493b, or a facility that provides outpatient surgical services as part of the outpatient surgery department of a short-term acute care general hospital, provided termination of outpatient surgical services due to (A) insufficient patient volume, or (B) the termination of any subspecialty surgical service, shall not require certificate of need approval;
- (8) The termination of an emergency department by a short-term acute care general hospital;

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C.G.S. §§ 19a-638(a)(1)-(15) Cont.
When a CON is required

- (9) The establishment of cardiac services, including inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery;
- (10) The acquisition of computed tomography scanners, magnetic resonance imaging scanners, positron emission tomography scanners or positron emission tomography-computed tomography scanners, by any person, physician, provider, short-term acute care general hospital or children's hospital, except (A) as provided for in subdivision (22) of subsection (b) of this section, and (B) a certificate of need issued by the unit shall not be required where such scanner is a replacement for a scanner that was previously acquired through certificate of need approval or a certificate of need determination;*
- (11) The acquisition of nonhospital based linear accelerators;*
- (12) An increase in the licensed bed capacity of a health care facility, except as provided in subdivision (23) of subsection (b) of this section;
- (13) The acquisition of equipment utilizing technology that has not previously been utilized in the state;
- (14) An increase of two or more operating rooms within any three-year period, commencing on and after October 1, 2010, by an outpatient surgical facility, as defined in section 19a-493b, or by a short-term acute care general hospital; and
- (15) The termination of inpatient or outpatient services offered by a hospital or other facility or institution operated by the state that provides services that are eligible for reimbursement under Title XVIII or XIX of the federal Social Security Act, 42 USC 301, as amended.

* Pursuant to P.A. No. 23-171, these two subsections are amended effective October 1, 2023.

C.G.S. §§ 19a-638(b)(1)-(23)
When a CON is NOT required

- (1) Health care facilities owned and operated by the federal government;
- (2) The establishment of offices by a licensed private practitioner, whether for individual or group practice, except when a certificate of need is required in accordance with the requirements of section 19a-493b or subdivision (3), (10) or (11) of subsection (a) of this section;
- (3) A health care facility operated by a religious group that exclusively relies upon spiritual means through prayer for healing;
- (4) Residential care homes, as defined in subsection (c) of section 19a-490, and nursing homes and rest homes, as defined in subsection (o) of section 19a-490;
- (5) An assisted living services agency, as defined in section 19a-490;
- (6) Home health agencies, as defined in section 19a-490;
- (7) Hospice services, as described in section 19a-122b;
- (8) Outpatient rehabilitation facilities;
- (9) Outpatient chronic dialysis services;
- (10) Transplant services;

C.G.S. §§ 19a-638(b)(1)-(23) Cont.
When a CON is NOT required

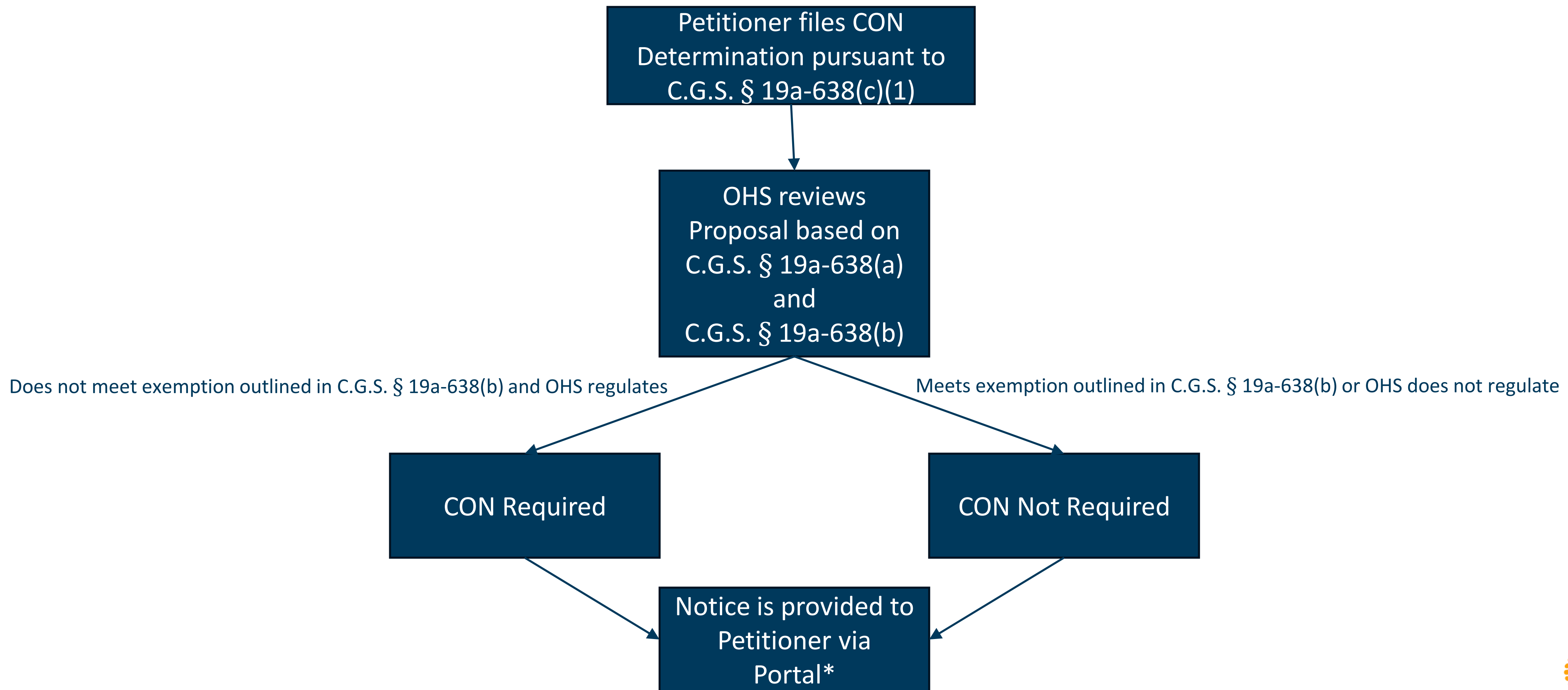
- (11) Free clinics, as defined in section 19a-630;
- (12) School-based health centers and expanded school health sites, as such terms are defined in section 19a-6r, community health centers, as defined in section 19a-490a, not-for-profit outpatient clinics licensed in accordance with the provisions of chapter 368v and federally qualified health centers;
- (13) A program licensed or funded by the Department of Children and Families, provided such program is not a psychiatric residential treatment facility;
- (14) Any nonprofit facility, institution or provider that has a contract with, or is certified or licensed to provide a service for, a state agency or department for a service that would otherwise require a certificate of need. The provisions of this subdivision shall not apply to a short-term acute care general hospital or children's hospital, or a hospital or other facility or institution operated by the state that provides services that are eligible for reimbursement under Title XVIII or XIX of the federal Social Security Act, 42 USC 301, as amended;
- (15) A health care facility operated by a nonprofit educational institution exclusively for students, faculty and staff of such institution and their dependents;
- (16) An outpatient clinic or program operated exclusively by or contracted to be operated exclusively by a municipality, municipal agency, municipal board of education or a health district, as described in section 19a-241;
- (17) A residential facility for persons with intellectual disability licensed pursuant to section 17a-227 and certified to participate in the Title XIX Medicaid program as an intermediate care facility for individuals with intellectual disabilities;

C.G.S. §§ 19a-638(b)(1)-(23) Cont.
When a CON is NOT required

- (18) Replacement of existing imaging equipment if such equipment was acquired through certificate of need approval or a certificate of need determination, provided a health care facility, provider, physician or person notifies the unit of the date on which the equipment is replaced and the disposition of the replaced equipment;*
- (19) Acquisition of cone-beam dental imaging equipment that is to be used exclusively by a dentist licensed pursuant to chapter 379;
- (20) The partial or total elimination of services provided by an outpatient surgical facility, as defined in section 19a-493b, except as provided in subdivision (6) of subsection (a) of this section and section 19a-639e;
- (21) The termination of services for which the Department of Public Health has requested the facility to relinquish its license;
- (22) Acquisition of any equipment by any person that is to be used exclusively for scientific research that is not conducted on humans; or
- (23) On or before June 30, 2026, an increase in the licensed bed capacity of a mental health facility, provided (A) the mental health facility demonstrates to the unit, in a form and manner prescribed by the unit, that it accepts reimbursement for any covered benefit provided to a covered individual under: (i) An individual or group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469; (ii) a self-insured employee welfare benefit plan established pursuant to the federal Employee Retirement Income Security Act of 1974, as amended from time to time; or (iii) HUSKY Health, as defined in section 17b-290, and (B) if the mental health facility does not accept or stops accepting reimbursement for any covered benefit provided to a covered individual under a policy, plan or program described in clause (i), (ii) or (iii) of subparagraph (A) of this subdivision, a certificate of need for such increase in the licensed bed capacity shall be required.

* Pursuant to P.A. No. 23-171, this subsection is amended effective October 1, 2023.

CON Determination Process



*Effective October 1, 2023, OHS has 30-days from the filing date to render a decision on whether a CON is required.

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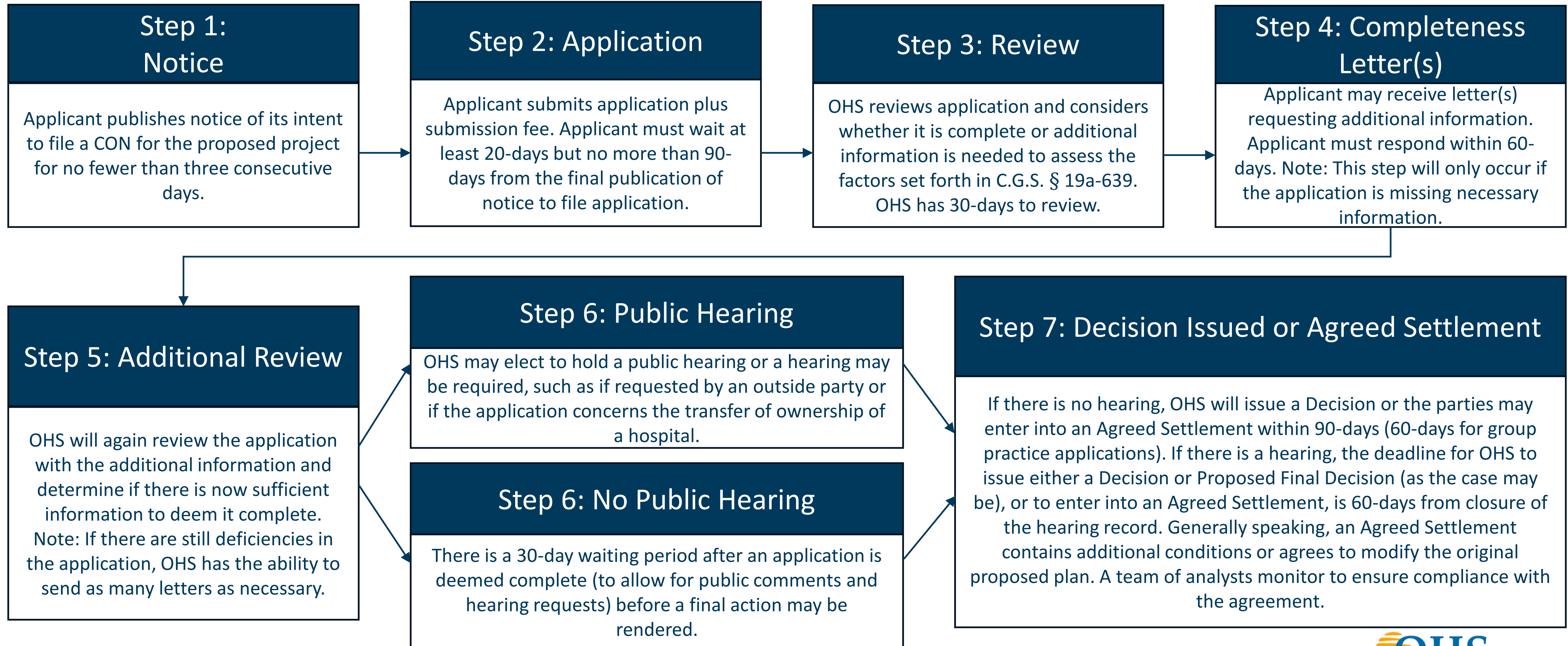
C.G.S. §§ 19a-639(a)(1)-(12)
CON Guidelines and Principles

- (1) Whether the proposed project is consistent with any applicable policies and standards adopted in regulations by the Office of Health Strategy;
- (2) The relationship of the proposed project to the state-wide health care facilities and services plan;
- (3) Whether there is a clear public need for the health care facility or services proposed by the applicant;
- (4) Whether the applicant has satisfactorily demonstrated how the proposal will impact the financial strength of the health care system in the state or that the proposal is financially feasible for the applicant;
- (5) Whether the applicant has satisfactorily demonstrated how the proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region, including, but not limited to, provision of or any change in the access to services for Medicaid recipients and indigent persons;
- (6) The applicant's past and proposed provision of health care services to relevant patient populations and payer mix, including, but not limited to, access to services by Medicaid recipients and indigent persons;
- (7) Whether the applicant has satisfactorily identified the population to be served by the proposed project and satisfactorily demonstrated that the identified population has a need for the proposed services;
- (8) The utilization of existing health care facilities and health care services in the service area of the applicant;
- (9) Whether the applicant has satisfactorily demonstrated that the proposed project shall not result in an unnecessary duplication of existing or approved health care services or facilities;
- (10) Whether an applicant, who has failed to provide or reduced access to services by Medicaid recipients or indigent persons, has demonstrated good cause for doing so, which shall not be demonstrated solely on the basis of differences in reimbursement rates between Medicaid and other health care payers;
- (11) Whether the applicant has satisfactorily demonstrated that the proposal will not negatively impact the diversity of health care providers and patient choice in the geographic region; and
- (12) Whether the applicant has satisfactorily demonstrated that any consolidation resulting from the proposal will not adversely affect health care costs or accessibility to care.

C.G.S. §§ 19a-639(b), (d)
CON Guidelines and Principles Cont.

- In addition to the twelve criteria set forth on the previous slide, certain types of CON applications require that OHS consider other concepts and criteria as well.
- For CON applications involving the transfer of ownership of a large group practice, there is a presumption in favor of approving the CON application.
- For CON applications involving the transfer of ownership of a hospital, OHS must also take into consideration:
  - Whether the applicant fairly considered alternative proposals or offers in light of the purpose of maintaining health care provider diversity and consumer choice in the health care market and access to affordable quality health care for the affected community.
  - Whether the plan submitted pursuant to section 19a-639a demonstrates, in a manner consistent with this chapter, how health care services will be provided by the new hospital for the first three years following the transfer of ownership of the hospital, including any consolidation, reduction, elimination or expansion of existing services or introduction of new services.
  - Whether the affected community will be assured of continued access to high quality and affordable health care after accounting for any consolidation in the hospital and health care market that may lessen health care provider diversity, consumer choice and access to care.
  - Whether any likely increases in the prices for health care services or total health care spending in the state may negatively impact the affordability of care.

CON Review Process



OHS Transparency Standards

- Portal access to public
  - Certificate of Need (CON)--CON Portal (ct.gov)
- Public hearings
  - Certificate of Need (CON)--Public Hearings (ct.gov)
- CON Guidebook for assisting applicants (To be updated October 1, 2023)
  - Certificate of Need (ct.gov)
- Meeting with applicants to assist with CON application process

2017 CON Taskforce Recommendations (1 of 4)

Modifying the Scope of CON. Limiting regulation that impedes market entry and exit, while preserving protections for access to services by underserved populations and enhancing oversight of health care mergers and acquisitions.

- Limit or eliminate CON review of equipment acquisitions, and address the practice of self-referral for scanners through a legislative remedy or a modification of application criteria
- Eliminate CON of new central service facilities and expansions of licensed bed capacity
- Limit CON review of terminations to only select hospital inpatient/outpatient services, and expand CON review of terminations of mental health and substance abuse treatment services to entities other than hospitals
- Apply CON review to the reduction of services by a hospital and to certain relocations of health care services
- Apply a more rigorous review (cost and market impact review, post-transfer compliance reporting) to all hospital mergers, as well as hospital acquisitions of other health care facilities or group practices
- Eliminate CON review of continuing care retirement facilities and conduct periodic reviews of the nursing home moratorium

2017 CON Taskforce Recommendations (2 of 4)

Updating the Application Criteria. Revise guidelines to reflect updated CON program goals.

- Focus on protecting access to underserved areas, ensuring provision of services to Medicaid recipients, increasing the role of state health planning, and limiting actions that adversely impact the health care market

Application Process. Increase public input, streamline application, allow advisory subject matter expert reviewers.

- ✓ Allow OHCA to charge applicants for advisory subject matter experts, including front-line caregivers from relevant fields, to assist OHCA in application review
- Require hospital transfer of ownership and acquisitions to have mandatory public hearings
- ✓ Increase current methods of informing the public about the status of CON applications without penalizing applicants who make reasonable efforts to comply
- Create expedited application processes for certain CON decisions
- Require a single CON application and cost and market impact review for the sale of all assets for hospital conversions and acquisitions

2017 CON Taskforce Recommendations (2 of 4)

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2017 CON Taskforce Recommendations (3 of 4)

Post-Approval Compliance. Expand OHCA's enforcement and monitoring authority over health care facilities outside of market entry.

- ✓ Lower the threshold needed to enforce penalties from "willful" to "negligent"
- ✓ Allow OHCA to impose civil penalties and exact other remedies from applicants who fail to comply with conditions of a CON decision or agreed settlement
- Allow OHCA to exact remedies in the case where commitments involving prices were not met, including refunding to the original bill payer (insurer, patient) of amount in excess of the "promised" price and loss of part or all of the "approvals" granted in association with the CON application
- Align OHCA and DPH licensing division inspection and monitoring activities
- Require non-compliance monitoring for any condition place on transfer of ownership applications, and adhere to strict standards for financial independence between the monitor and the applicant
- ✓ Fund additional staff at OHCA to better conduct inspection, monitoring, and enforcement

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2017 CON Taskforce Recommendations (4 of 4)

Evaluation Methods. Ensure the state's resources are being utilized effectively.

- Ensure that the Statewide Health Care Plan tracks access to and cost of services across the state
- Implement evaluation mechanisms beyond a point in time snapshot when an entity enters and exits the market to include factors that allow the state to determine CON impact on quality, access and cost

2023 CON Taskforce Recommendations (1 of 4)

Setting Standards To Measure Quality Due To A Consolidation

- The working group supports expanding the CON process to allow OHS to consider service quality, based on generally accepted, nationally recognized clinical best practices and guidelines. Quality measures should be measured against a healthcare entities baseline quality. The working group further recommends that all providers should be subject to the same rules.

2023 CON Taskforce Recommendations (2 of 4)

Enacting Higher Penalties For Noncompliance And Increasing The Staff Needed For Enforcement

- The working group recommends establishing more clarity on what triggers a fine, when the fine begins, and under what conditions it ends.
- The group further recommends that any assessed fine should continue to accrue after the fined entity has filed a CON application through the final decision by OHS.
- The group also recommends that a healthcare entity terminating its services without OHS approval bear the responsibility and costs for returning those services, if OHS determines they should have been continued.
- The group recommends closing a current loophole in which a healthcare entity can repeatedly “suspend” a service for 180 days (with brief periods of service in between) in order to delay or avoid a termination (which requires a CON process).
- The group recommends the legislature explore the Massachusetts policy model related to closing “essential services.”
- ✓ The group recommends OHS receive additional resources to carry out its enforcement and compliance activities.
- There was a group member who raised concerns with each of these recommendations from the group.

2023 CON Taskforce Recommendations (3 of 4)

The Attorney General's Authority To Stop Activities As The Result Of A CON Application Or Complaint

- ✓ The group recommends the legislature remove "willfully" from the legal standard needed to be shown in order to impose a civil penalty in CGS § 19a-653.
- The group further recommends the legislature enable OHS to issue (and the attorney general to enforce) cease and desist orders to stop a CON violation.

2023 CON Taskforce Recommendations (4 of 4)

Authorizing OHS To Require An Ongoing Investment To Address Community Need

- Group recommends strengthening OHS oversight authority regarding community health needs assessments. OHS should be able to ensure that these assessments are tied to hospital implementation plans, including transparency to ensure that resources spent on implementation are connected to a hospital's community benefit report.
- The group further recommends that OHS's authority be expanded to include healthcare provider organizations, excluding those that primarily serve Medicaid and underserved patient populations, beyond just hospitals.