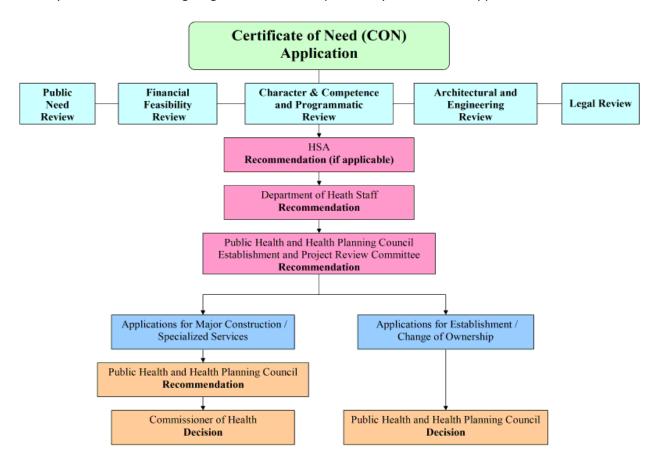
CURRENT STATUS OF New York's CON PROGRAM¹

A. The Process

New York's Certificate of Need (CON) process governs the establishment, construction, renovation and major medical equipment acquisitions of health care facilities and agencies -- namely hospitals, nursing homes, home care agencies, hospices and diagnostic and treatment centers. CON applications that involve the establishment of a new health care facility, home care agency or hospice, a change in ownership, the addition of certain specialized services, or major capital projects are reviewed by the Public Health and Health Planning Council (PHHPC or the Council). The CON program and the Council are administered by the NYS Department of Health.

Broadly stated, the following diagram indicates the process by which a CON application is acted on:



(The second row of boxes (aqua color) are the statutory and regulatory criteria which must be considered in the process of reviewing an application.)

¹ The Council would like to thank Art Streeter of the Finger Lakes Health Systems Agency for his assistance in preparing this report.

B. Need Determination and Licensure/Certification

In New York State, the CON process encompasses not only the reviews necessary to determine need and financial feasibility, it also includes the reviews necessary to certify or license facilities and services. Even in states with no CON program, health care facilities and services are subject to licensure or certification. This typically involves a character/competence review, a program review, and an architectural/physical plant review. In some states with CON, the need review and the certification reviews are conducted sequentially by different organizational units. Even if New York were to repeal Certificate of Need, it would still license health care facilities, agencies and services and as part of that function, review character and competence, program features, and physical plant safety.

C. The Public Health and Health Planning Council (PHHPC)

PHHPC was established in 2010 by the merger of two prior state councils, The State Hospital Review and Planning Council and the Public Health Council. The PHHPC makes recommendations to the Commissioner of Health on major CON construction and service addition applications and is the final decision-maker on applications to establish new operators of health care facilities and agencies. The PHHPC is intended to assure citizen and expert input into the CON process.

D. Scope of CON

A CON application is required in order to establish a new operator of, or undertake construction, add certain services, or purchase major equipment in, any of the following types of health care providers:

- Hospitals
- Diagnostic and Treatment Centers (D&TCs)
- Residential Health Care Facilities (RHCF)
- Certified Home Health Agencies (CHHA)
- Licensed Home Care Services Agencies
- Long Term Home Health Care Programs
- Hospices

Adult care facilities, under Article 7 of the Social Services Law, are subject to a separate CON process administered by the Department of Health without review by the PHHPC.

There are also separate CON processes administered by the Office of Mental Health, the Office of People with Development Disabilities and the Office of Alcoholism and Substance Abuse Services for facilities and programs that require their licensure or certification. This paper does not cover those

processes, but as the state moves to support greater integration of behavioral health and physical health care, coordination among these processes and agencies becomes increasingly important.

Notably, private physician practices are generally not covered by CON. ² Thus, a physician group (e.g., one organized as a professional corporation, professional LLC, or partnership) may typically construct a medical building, purchase and operate certain medical equipment without securing CON approval. However, the Department of Health regulations at 10NYCRR 600.8 set forth criteria that trigger licensure and CON requirements to be established as a diagnostic and treatment center, regardless of provider's legal form of organization.

E. CON Reviews

CON Reviews have been divided into three broad categories, based on factors such as cost, services proposed, and safety issues:

- Full Review;
- Administrative Review; and
- Limited Review.

Full review applications require a recommendation or decision of the Public Health and Health Planning Council. Administrative reviews require an approval of the Commissioner only, without a recommendation by the PHHPC. Limited reviews are also processed without referral to the PHHPC. They are typically reviews of the programmatic and physical plant aspects of less extensive construction projects or service additions or eliminations – similar to the types of reviews that would be done in a non-CON state to certify a facility or service. See Attachment A for a table describing the various types of review and their monetary thresholds for Article 28 facilities.

Under Article 28, projects involving the establishment of a new operator (including mergers and the establishment of an active parent) always require full review. In general, most projects with a capital cost greater than \$15 million are subject to full review. Addition of beds, changes of level of care, and certain named high technology services always require a full review. A referral to the Council is also required for projects eligible for administrative review that receive a recommendation of disapproval by Department or staff of the relevant HSA.³ The Council also provides an opportunity for public comment on CON projects.

Proposals eligible for administrative reviews typically have costs of up to \$15 million and do not require a recommendation from the PHHPC. Examples of administrative reviews include conversion of beds within the same level of care or addition of primary care sites by an established provider; certain

² Clifton Springs Sanitarium Co, Inc v. Axelrod, 115 A.D.2d 949 (1985).

³ For more detail, see 10 NYCRR 710.

amendments to approved projects are also eligible. Administrative review has been expanded over the years, so for instance health IT projects over \$15 million are eligible for administrative review; in certain specific circumstances, projects with costs as high as \$50 million may be reviewed administratively.⁴

Proposals with a total project cost up to \$6 million are eligible for a limited review. Examples include minor construction, acquisition of lower-cost medical equipment, addition of certain services, decertification of beds and services, and relocation of clinics within the same service area. Health IT projects with costs between \$6 million and \$15 million are also subject to limited review. Some limited reviews require only an architectural review to assure health and safety requirements are met.

Under Article 36 (home care agencies), establishment and transfers of ownership require PHHPC decision. In contrast to Article 28 review thresholds, construction or other capital costs in excess of \$400,000, and initiation or some increases in long term home health care programs, require PHHPC recommendations. Other projects require only an administrative review. ⁵

Under Article 40 (hospice), establishment or transfers of ownership require PHHPC decision, while addition of hospice beds, acquisition or construction of a hospice inpatient unit or residence with costs exceeding \$250,000 and most other projects with costs in excess of \$1 million require a recommendation of the PHHPC. Most equipment and construction with project costs between either \$250,000 and \$1 million (hospice facility) or \$500,000 and \$1 million (hospice administrative site) may be reviewed administratively. ⁶

Full review and administrative review projects also are reviewed by the regional Health Systems Agency, where they exist; HSAs do not participate in limited reviews. There are two remaining HSAs in New York -- the Finger Lakes Health Systems Agency and the Central New York Health Systems Agency. Under state law, the Council and the Department cannot take an action on a CON application contrary to the recommendation of the HSA without affording the HSA the opportunity to request a public hearing on that action.

Generally, CON projects result in either an approval or a disapproval decision. Under state law, if a project is not approved, it is prohibited – construction cannot occur, equipment cannot be purchased, services cannot be implemented -- and is not eligible for Medicare or Medicaid reimbursement. Projects can also be approved with "contingencies" or "conditions" attached. Contingencies require specific action on the part of the applicant to resolve, typically within 60 days, before the CON approval is completed/perfected. Conditions, on the other hand, impose on-going requirements that must be complied with during the life of the project. Recently, the Council has been approving operating

⁴ General hospital projects with a cost of up to \$50 million, and other facility projects with a cost of up to \$25 million are eligible for administrative review if the total costs do not exceed 10 percent of the total operating costs of the facility. 10 NYCRR §710.1(c)(3).

⁵ For more details, see 10 NYCRR 760.

⁶ For more details, see 10 NYCRR 790.

certificates with limited durations, often for ambulatory surgery centers, to assure fulfillment of conditions.

Both to reflect medical/construction cost inflation and to streamline the CON program, the dollar thresholds which trigger a need for a CON review have been revised over time. Cost is only one factor which determines if a project requires a particular level of review, but it is a prime factor. The table below shows the changes in Article 28 dollar thresholds over time.

Dollar Threshold Triggering CON Review, NYS*

	Administrative Review	<u>Full Review</u>
Original Legislation	\$400,000	\$4 million
Revision Effective Jan 1996	\$1 million	\$6 million
Revision Effective Nov 1998	\$3 million	\$10 million
Revision Effective July 2009	\$6 million	\$15 million

^{*}These values represent the capital cost of the project; impact on operating cost is not presently considered in eligibility for review

Comparisons to review thresholds in other states will follow later in this paper.

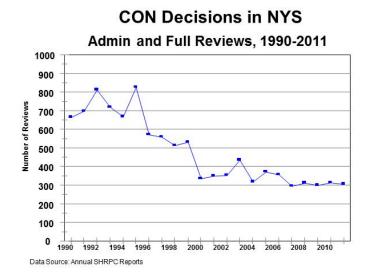
In addition to regulatory changes in the dollar thresholds that determine the intensity of the reviews, the scope of CON has recently been reduced as a result of legislative amendments. As of January 16, 2012, when Chapter 174 of 2011 takes effect, three categories of projects are exempt from prior approval subject to a notice submission requirement:

- o Repair and maintenance projects regardless of cost;
- o Nonclinical infrastructure projects; and
- o 1-for-1 equipment replacement projects.

F. CON Review Activity

Annual reports from the State Hospital Review and Planning Council, now the Public Health and Health Planning Council, provide information on activity levels. In 2010, a total of 760 projects were reviewed and approved state-wide. Of these, 446 were limited reviews. There were 187 administrative reviews and 127 full reviews, for a total of 314 such reviews. While the numbers of approved full and administrative reviews have declined since 1990, the numbers of limited reviews have climbed, in large part due to changes in the monetary review thresholds that have shifted many projects to limited review.

Limited



Limited, Admin & Full Reviews, 1990-2011 1000 900 800 700 400 400 300

1996

- Administrative

Data Source: Annual SHRPC Reports

1998

2000 2002

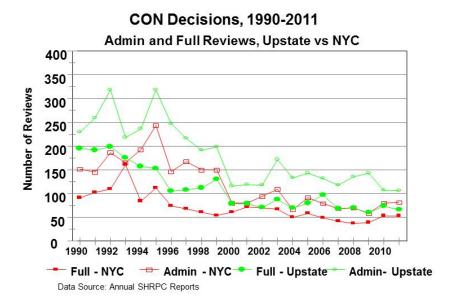
Full

CON Decisions in NYS

Numbers of Administrative and Full reviews declined in each HSA area in the state. Numerically, there were more projects reviewed in Upstate NY (NYS outside of NYC) than in New York City.

200

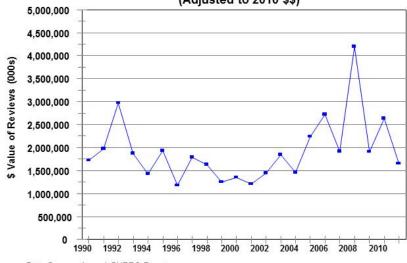
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The value of projects reviewed (administrative plus full review) has increased from about \$1.5 billion per year to around \$2.5 billion recently, on a current dollar basis. If adjusted for inflation, however, the value of projects reviewed declined through the 1990s, and then increased in recent years. A sharp peak in dollars reviewed occurred in 2008; this is thought to reflect a number of Berger Commission-related projects being processed that year. It is uncertain what generated the peak in dollars reviewed in 1992.

\$ Value of Approved CONs in NYS

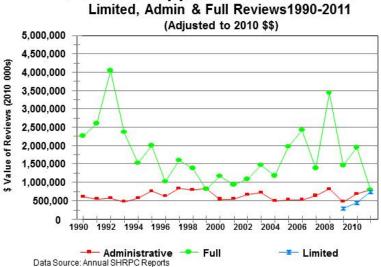




Data Source: Annual SHRPC Reports

Most of the year-to-year variations in dollars reviewed occur among full-review projects.

\$ Value of Approved CONs in NYS

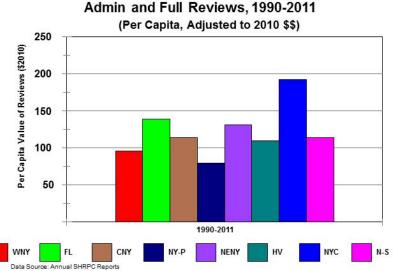


On a constant-dollar basis, New York City generally has reviews of a higher dollar value than does Upstate. Over the period 1990 to 2010, New York City also has had a higher dollar value reviewed on a per capita basis. This may be deceptive, as it does not take patient migration into account.⁷

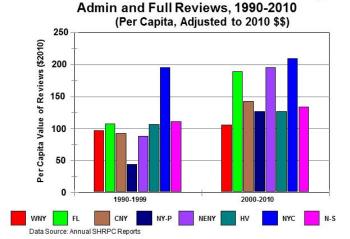
⁷ Each region's reviews are divided by its own population, but New York City provides care for residents of many other areas, including Hudson Valley, Long Island, Connecticut and New Jersey. This issue affects other regions as well, but particularly NY-Penn, which serves a substantial population from Pennsylvania.

Review volumes per capita have varied from area to area and over time, as seen in these figures.

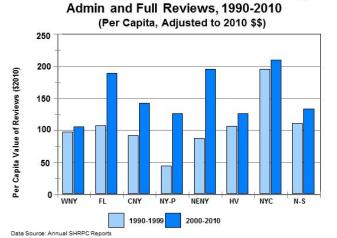




\$ Value of Approved CONs in NYS Regions



\$ Value of Approved CONs in NYS Regions



Not included in the above figures are projects that were either withdrawn by the applicant, or put into a long-term suspension/deferral due to problems, such as financing, compliance issues, or absence of public need, that were discerned during the review. Often, applicants will request that an application be deferred or suspended, when they are informed that the Department will recommend disapproval, in hopes of reaching a negotiated resolution of the problems. Nor do the figures above include projects that are suspended or deferred for policy reasons such as a moratorium on a particular service or provider-type. These figures are not easy to compile. A previous study of the NYS CON program found they may represent a substantial portion of all applications: in the period 1988 to 2000, more than 1,100 applications were withdrawn, or an average of about 86 per year. About one half of those were

withdrawn before a decision was rendered, while the other half withdrew after receiving a contingent approval. The report noted that the trend was for fewer withdrawals over time, perhaps reflecting DOH staff efforts to help applicants to submit applications consistent with regulatory requirements or otherwise perfect their applications.⁸

With the advent in late 2010 of the electronic CON system (NYSECON), the DOH staff is working to resolve deferred projects, to move them forward for positive or negative decision and to identify projects that have been abandoned.

Finally, the numbers of reviews and projects approved and disapproved do not tell the whole story of the impact of CON. The existence of the CON program is thought to provide a sentinel effect. It discourages providers from submitting applications that will not meet measures of public need, character and competence, and/or financial feasibility. This "deterrent" effect cannot easily be proven, but is understood by the CON staff at both the state and among the state's Health Systems Agencies.

G. Time Frame for Review

The duration of the review process has been a concern for both DOH and providers. According to a 2002 report, the average elapsed time from when an application is submitted until when a decision is rendered was calculated. It showed a long review period (up to a year in the mid-1990s for full reviews), including a lengthening period to review administrative projects (192 days in 2001).⁹

With the advent of NYSE-CON, DOH staff can more easily and accurately track processing time. As of early 2012, for applications submitted between December 21, 2010 and December 31, 2011, which have received a decision, the average processing time was:

- ➤ Limited Reviews (509 applications): 78 days (DOH 57, Applicant 21)
- ➤ Administrative Reviews (65 applications): 144 days (DOH 78, Applicant 66)
- Full Reviews (55 applications): 144 days (DOH 68, Applicant 76)

As indicated above, approximately half of the review time for full reviews and administrative reviews was spent waiting for applicants to respond to staff queries. Applications may be incomplete or internally inconsistent, and a series of questions may be transmitted to applicants to resolve the issues. For instance, it might take two months for the applicant to return the requested information. Again, the staff seeks to perfect the application before moving it forward for a final decision, rather than just disapprove it.

⁸ Rockefeller Institute of Government, "Certificate of Need in New York State, A Program in Transition," prepared by the American Health Planning Association, 2002.

⁹ Ibid.

There is a formal limit to how long an application can be in process. By regulation, all applications received in the January to June period must be presented to the PHHPC by the end of December of the following year, i.e., between 12 and 18 months later. Likewise, those received between July and December must be presented by June of the year hence. These provisions are to permit "batching" of like applications, so that the comparative value of the applications can be assessed. Recent examples include the batching of three major hospital expansion/renovation projects from Rochester and the batching of cardiac projects from Buffalo.

H. Public Input

As mentioned earlier, a purpose of the Public Health and Health Planning Council is to assure citizen input into the Certificate of Need process. During a review of an application, the Department of Health accepts written comments on CON proposals from interested parties. Further opportunity is given for comment on specific CONs at public meetings of the Establishment and Project Review Committee of the Council. Comments may be submitted to the Department by mail or email. When an application is on the agenda of the Establishment and Project Review Committee, interested persons may testify before the Committee.

Health Systems Agencies also provide a local recommendation to the Department and Council on CON applications, and HSA staff or committees accept comments in writing and verbally from interested parties which are considered as the HSA develops its recommendation.

I. Comparison to other states

New York is one of 36 states (plus the District of Columbia) that has a certificate of need program. After the federal requirement for CON was rescinded, a number of states discontinued their CON programs. Often, this termination was accompanied by a surge of new programs, often programs that had previously been denied by the earlier process. For instance, in mid-1985, there were nine open-heart surgery units performing a total of 2,125 surgeries per year in Phoenix, Arizona. Arizona then repealed its certificate of need law and, within a year, four additional hospitals had initiated open-heart surgeries, averaging 125 surgeries per year per hospital. Within one additional year, another three hospitals were expected to initiate open-heart surgery units.¹⁰

Pennsylvania and Indiana were the most recent states to repeal their CON requirements, in 1997. Louisiana and Wisconsin were the most recent states to initiate or re-initiate CON, in 1992.

The scope of the CON program – the number and type of services which require a CON – also vary by state. New York covers more services than many, but there are twelve states that cover more of the 30 services compiled by the AHPA.

¹⁰ American Health Planning Association, "Arizona deregulation spawns open-heart surgery units," *Today in Health Planning* 9:6:1, August 26, 1986.

The dollar thresholds triggering review -- \$6 million in the case of the NYS program – also vary by state, but there are only four state programs that have a threshold higher than New York's. A modal value is in the range of \$2 million to \$4 million.

All but one state with a CON program help fund that program with a fee for application and review. The fees tend to be related to the project cost.