

NYS Implements First Phase of CON Reform

New York State is reforming its certificate of need (CON) program to increase efficiencies and reduce costs. Much-welcomed regulations updating and streamlining the State's CON program took effect August 6. In the fall, the State will unveil the first phase of its electronic CON application process, and effective December 1, the responsibilities of the State's now-separate health planning and public health councils will be combined, further streamlining the review process. This issue of *Health Care News In-Depth* examines these reforms.

The Need to Streamline

GNYHA and its members have long expressed concerns about the burdens and costs associated with the State's CON program, which had not undergone a major revision of its cost thresholds and other requirements since 1998. As a result, in 2008, the State embarked on a process to update its CON program, which included hearings

by the State Hospital Review and Planning Council's (SHRPC's) Planning Committee and extensive meetings by the State Department of Health (DOH) with providers and other stakeholders. GNYHA was an active participant in this process, taking the position that the State's CON program, as then constructed, no longer effectively promoted the State's goals of cost control, access, and quality. In some cases, the process actually undermined those goals. At the same time, the process had become unnecessarily cumbersome, lengthy, and expensive for providers and the State alike. As an example, GNYHA pointed to the fact that construction costs increased 12% per year while applications wended their way through the all-too-slow approval process. During this time, GNY-

HA worked extensively with its members to provide DOH with concrete, detailed input on how the CON application process could be updated, streamlined, and less costly.

State Makes CON Changes

Last week, revised regulations that streamline the State's CON process went into effect, reflecting the State's efforts to incorporate stakeholders' extensive input. The regulations increase project thresholds that establish the level of review, reduce the level of review for the acquisition of certain medical equipment, and combine limited architectural review and prior review into a single category called simply "limited review." Among the more notable changes are that all non-clinical projects, as well as all health information technology projects, will no longer require SHRPC approval, regardless of cost. Such projects under \$15 million will need to undergo only the new limited review process, and those projects that are \$15 million and over must go through only the administrative review

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GNYHA MEMBER BRIEFING

GNYHA Briefing on NYS CON Reform

Date: Wednesday, September 15, 2010

Time: 2:00 p.m.–4:30 p.m.

Location: GNYHA Conference Center

Representatives of the NYS Department of Health (DOH) will provide information regarding the State's recent amendments to its CON program, implementation of its NYSE-CON application system, merger of the responsibilities of the State Hospital Review and Planning Council and Public Health Council, and proposed changes to health care facility construction standards. DOH will also discuss recommendations and plans for further streamlining and improving its CON program. To register, please contact Linda Tam, ltam@gnyha.org. ■

CON PROGRAM PROJECT COST THRESHOLDS AND LEVELS OF REVIEW: PRIOR AND NEW

The following chart lists prior and new, as of August 6, 2010, cost thresholds broken out by level of review. Exceptions exist at each level of review (e.g., certain equipment requires review regardless of cost).

Type of Application/ Review	Prior Regulations	New Regulations
No Application Required	\$3M or less for repair and maintenance	\$6M or less for repair and maintenance Acquisition of lithotripters (need methodology repealed)
Level I or Prior Review (for addition of services, conversion of certain beds, decertification of beds and services, and non-clinical and HIT projects)	\$3M or less \$10M or less for non-clinical and HIT projects	The new regulations combine the categories of Level I or Prior Review and Limited Architectural and Engineering Review into one category called Limited Review. \$6M or less \$15M or less for non-clinical and HIT projects Acquisition of MRIs or CT scanners by general hospitals (elimination of need methodology)
Limited Architectural and Engineering Review (for construction projects and certain equipment other than routine repair or maintenance)	\$3M or less \$10M or less for non-clinical and HIT projects	The new regulations combine the categories of Level I or Prior Review and Limited Architectural and Engineering Review into one category called Limited Review. \$6M or less \$15M or less for non-clinical and HIT projects Acquisition of MRIs or CT scanners by general hospitals (elimination of need methodology)
Administrative Review	Over \$3M but not exceeding \$10M Initial acquisition of MRIs, CT scanners or lithotripters	Over \$6M but not exceeding \$15M Over \$15M for non-clinical and HIT projects Initial acquisition of MRIs or CT scanners (by facilities <i>other than</i> general hospitals)
Sliding Threshold for Administrative Review (for larger facilities)	Up to 10% of facility operating costs, not exceeding \$25M Not available for facilities with debt supported by state or municipal agency	Up to 10% of facility operating costs, not exceeding \$50M (for general hospitals) Elimination of exclusion for state or municipal supported debt
Full Review	Over \$10M	Over \$15M (excluding non-clinical and HIT projects)

First Phase of CON Reform *continued*

process. To accommodate the new category of limited review, DOH has developed a new application that includes schedules and instructions specific to the type of application involved. The new regulations also eliminate SHRPC review of certain project amendments, as well as update and add flexibility to the State's new medical technology and health services demonstration project authority. (For details regarding many of these regulatory changes, please see the chart on page 2.) A copy of DOH's "Dear Administrator" letter outlining the revisions, as well as information regarding the application for the new category of limited review can be found at www.nyhealth.gov/facilities/cons.

In publishing the regulations for comment, DOH characterized the changes as its initial phase of reform and stated that the changes are designed to focus the State's resources on "projects that involve the delivery of highly complex services, the investment of substantial resources, and/or the creation of new facilities or beds."

Correcting Deficiencies

CON approval is also no longer necessary for hospital construction projects triggered by the need to correct cited deficiencies, due to a provision in the health care budget bill recently passed by the Legislature and signed into law by Governor David Paterson. However, the construction must be authorized by a DOH-approved plan of correction. The hospital also must send written notice to DOH with a written architect and/or engineering certification that the project meets applicable statutes, codes, and regulations. Finally, the hospital must

implement a plan to protect patient safety during construction.

Electronic Filing to Come

In response to GNYHA's repeated requests to allow providers to file CON applications electronically, DOH will be unveiling in the fall the initial phase of its new electronic application system, which it calls NYSE-CON. When fully implemented, the system will offer several ways for providers to input information, including a function to guide providers through application questions and a function for more sophisticated users to input information directly. The system is ultimately slated to include error checks, logic edits, and guidance on which schedules to complete. The system will also allow providers to track the status of their applications, receive and respond to questions and contingencies, and schedule site surveys online. In developing the system, DOH convened a large number of stake-

holder groups, including GNYHA, to understand user needs and frustrations with the current paper application system. System costs are being covered by the increased CON fees imposed for this purpose by the State's 2009–2010 budget.

Councils to Merge

To create additional efficiencies, the recently enacted health care budget also amends the Public Health Law to merge, effective December 1, 2010, the responsibilities of SHRPC and the Public Health Council (PHC) within a single entity that will be known as the "Public Health and Health

Planning Council" (the Council). The composition of the new Council will build upon the membership of the current 14-member PHC and will expand to 24 members as of December 1. New and reappointed members of the Council will be appointed by the Governor with the advice and consent of the State Senate. As with the current PHC, the Commissioner of Health will also be a member of the new Council. For a breakdown of the statutory requirements regarding the composition of the new Council, please see the box on page 4.

The Council will be responsible for, among other things, considering applications for the establishment and construction of health care facilities, home care agencies, and hospices licensed under Articles 28, 36, and 40. It is also charged with reviewing regulations and procedures governing the establishment and construction of these facilities and submitting recommendations for revising such regulations to the State Commissioner of Health every five years.

CON REGULATIONS AND PROPOSED CONSTRUCTION REVISIONS AVAILABLE ON-LINE

The revised CON regulations are available on the New York State Department of Health Web site at: http://www.health.state.ny.us/regulations/recently_adopted/docs/2010-07-07_revisions_to_con_process_for_threshold_levels.

To view the proposed construction revisions, visit: http://www.health.state.ny.us/facilities/state_hospital_review_planning_council/meetings/2010/2010-07-22/codes_agenda.pdf.

Finally, contrary to the Executive Branch's initial proposal, the Council will continue to have a role in the process of promulgating regulations. The Executive had proposed that exclusive authority for promulgating regulations be vested in DOH.

Construction Standards Next

DOH has also proposed to update its construction standards for health care facilities to align them with more current National Fire Protection Association standards; national codes addressing radiation protection, facility heating, cooling, ventilation, and gas and vacuum standards; and the

2010 edition of *Guidelines for Design and Construction of Health Care Facilities*. DOH has not updated its health care construction guidelines since 1998, and the proposed revisions, which were discussed in detail at the July 22 meeting of SHRPC's Codes Committee, reflect input from a DOH advisory group comprising hospital engineers and architects, among others. DOH hopes to present the revisions for adoption at the SHRPC Codes Committee's November 18 meeting and to require provider compliance with the new standards for all CON applications approved January 1 or after.

Proton Beam Therapy Demo

Pursuant to DOH's expanded demonstration project authority contained in the CON reform regulations, DOH is currently reviewing three CON applications for a demonstration project to bring proton beam therapy to New York State. Proton beam therapy is a form of radiation treatment for certain types of cancers that can better target doses to the tumor and thus spare surrounding healthy tissue. According to a press statement released by Governor Paterson, "The high cost of proton beam therapy devices and the ethical issues surrounding randomized clinical trials that involve life-saving interventions have ... inhibited rigorous scientific research on PBT." The demonstration project is intended to "advance research on proton beam therapy while opening access to treatment for people af-

flicted with diseases for which the therapy has been shown to be effective." According to a memorandum submitted by DOH to SHRPC, there are only eight PBT facilities in operation in the United States, and the development of a five-gantry PBT facility is estimated to cost about \$200 million. To encourage the sharing of resources and expertise, DOH will



To view Susan Waltman, Executive Vice President, Legal, Regulatory, and Professional Affairs and General Counsel at GNYHA, discuss CON Reform, visit <http://wms29.streamhoster.com/gnyham/conreform.wmv>.

tation of the NYSE-CON application, proposed revisions to construction standards, and the merger of the responsibilities of the SHRPC and the Public Health Council. See the box on page 1 for more information on the briefing. DOH views the briefing as an opportunity to solicit input on additional

PUBLIC HEALTH AND HEALTH PLANNING COUNCIL'S REQUIRED MEMBERSHIP

Effective December 1, 2010, the State's new Public Health and Health Planning Council becomes operational. Building on the State's existing 14-member Public Health Council, the Governor will appoint 10 new members for a total of 24, plus the State Commissioner of Health. The new Council is required to have:

- Representatives that reflect the diversity of the State's population
- Representatives of the public health system
- Health care providers who compose the State's delivery system
- Individuals with expertise in:
 - Clinical and administrative aspects of health care delivery
 - Issues affecting health care consumers
 - Health planning
 - Health care financing and reimbursement
 - Health care regulation and compliance
 - Public health practice

The Council must also represent different aspects of the health care industry. At least:

- Two members must be on the mental health services council
- Four members must be representatives of general hospitals or nursing homes
- One member must be representative of each of the following groups:
 - Home care agencies
 - Diagnostic and treatment centers
 - Health care payers
 - Labor organizations for health care employees
 - Health care consumer advocacy organizations

give preferential treatment to applications that involve active collaboration among multiple health care facilities.

CON Reform Ongoing

To provide members with detailed information regarding the State's reform of its CON program, GNYHA will host a briefing on September 15 at which DOH will discuss its new CON regulations, implemen-

tation of the NYSE-CON application, proposed revisions to construction standards, and the merger of the responsibilities of the SHRPC and the Public Health Council. See the box on page 1 for more information on the briefing. DOH views the briefing as an opportunity to solicit input on additional ways to streamline and improve the State's CON program for the benefit of both providers and the State. GNYHA is appreciative of DOH's efforts to date and looks forward to providing input on additional reforms of the State's CON program. ■

For additional information on CON reform issues, contact Susan Waltman (waltman@gnyha.org) at GNYHA.