July 7, 2010

Subject: Revisions to CON Process for Threshold Levels

Dear Administrator/Operator:

The purpose of this letter is to advise operators licensed under New York State Public Health Law Articles 28, 36 and 40 of upcoming changes made to State regulations (Title 10 NYCRR) governing the Certificate of Need (CON) process. The CON process is an effective health care planning tool that helps to improve access to and distribution of health care resources, enhance health care quality, and control health care costs.

The proposed changes in the CON review process are needed to respond to changes in the health care environment, maximize the effectiveness of the CON process, and use Department of Health (DOH) resources most effectively. In addition, the proposed regulations eliminate obsolete provisions, clarify provisions that were difficult to understand, and make appropriate changes to other regulatory provisions that reference Parts 705 and 710.

I) Regulatory Revisions

Demonstration Projects

The DOH is updating Part 705 to provide more flexibility to accommodate capital intensive demonstration projects necessary to evaluate new technologies and services that demonstrate the potential to improve outcomes, and reduce morbidity and mortality. Part 705 was written in the early 1980's to assess and approve MRIs -- an emerging technology at that time. Medical technology has evolved since Part 705 was originally adopted, and flexibility is needed to support large scale, capital-intensive projects. The new regulation provides flexibility to authorize demonstration projects beyond the two years currently authorized and to approve innovative financing arrangements, in order to fully assess the technologies in terms of efficacy, safety, cost-effectiveness, the ramifications of the financing approaches deployed, and any additional statewide need for these projects.

Increasing Cost Thresholds

The DOH proposes to raise the capital cost thresholds that determine the level of review of most projects, in order to keep pace with the increasing cost of construction and medical equipment, to expedite the processing of less complex projects, and to allow the Councils and DOH staff to focus their attention and resources on the more significant projects. By streamlining and expediting CON reviews, these proposed regulations will help to reduce the regulatory burden on health care providers and will reduce project cost increases that are sometimes attributed to CON processing delays.

Increasing the cost thresholds will mean that some projects formerly subject to full review would be subject to administrative review; while some projects that were subject to administrative review would be subject to lesser levels of review depending on their scope. Even with this shift, projects in excess of $6 million would continue to require review of public need, financial feasibility, current compliance, architectural/engineering and legal issues. However, many lower cost projects would be subject only to a limited review comprised of architectural and engineering or programmatic considerations.

Non-Clinical Projects, Health Information Technology, and Limited Reviews

In 2009, regulatory revisions adopted to Part 710 shifted non-clinical projects with a total cost of up to $10 million to prior review, while non-clinical projects with a total cost in excess of $10 million remained subject to full review. In implementing the revised regulation, it became apparent that most non-clinical projects require construction and some architectural review. Similarly, many service additions and decertifications currently covered under prior review also involve construction.

In order to better address hybrid projects under the limited review process, the DOH is now combining the two levels of review into a single "limited review" category in regulation. By removing non-clinical projects from State Hospital Review and Planning Council review entirely, and raising the monetary threshold for non-clinical projects eligible for limited review, the Council and DOH staff may focus their attention on the projects that involve medical services and have a greater impact on the health care delivery system.

In addition, growing numbers of health care facilities are moving to adopt electronic health records and other forms of health information technology. Recognizing the important role that health information technology can play in supporting health care quality, patient safety and efficiency, the regulatory amendments provide an explicit and streamlined review process for health information technology projects.

Medical Equipment

Over the past decade, the use of MRI and CT scanners for diagnostic purposes has become the standard of care in general hospitals. The majority of general hospitals in New York operate at least one MRI and CT scanner. MRI and CT scanners are minimally invasive imaging tools and are available at prices that are affordable to most hospitals. Accordingly, a rigorous CON review of these types of equipment in general hospital settings is no longer necessary, and the goals of CON can be accomplished by a less intensive review. Moreover, by reducing the level of review of this equipment to limited review, the DOH will facilitate these acquisitions, while assuring that the equipment is installed in a setting that meets State architectural and engineering safety standards.

Under the new regulatory revisions, the initial purchase of an MRI or CT scanner by a diagnostic and treatment center would remain subject to administrative review. These devices have not become the standard of care in diagnostic and treatment centers and are supply-sensitive. Accordingly, the acquisition of this type of equipment outside of a hospital setting should be scrutinized for community need.

The DOH has determined that the acquisition of lithotripters should no longer be regulated by the CON process. Lithotripters do not raise the cost and patient safety concerns that once justified review under the CON process. They are now recognized as an affordable, minimally-invasive, first-

line treatment for renal stones. Because they are used to treat a specific condition, utilization of lithotripters does not appear to be supply-sensitive. Thus, eliminating CON review for lithotripters is not likely to generate a significant increase in utilization or associated health care costs. However, the addition of lithotripsy as a service on a facility's operating certificate will remain subject to a limited review.

Project Amendments

By reducing the number of projects that must come before the Councils repeatedly due to cost increases or other non-substantive changes, the DOH seeks to target staff and Council resources more effectively. Specifically, the proposed regulatory revisions will allow administrative review of amendments to projects that are substantively unchanged, but experience:

- a change in financing, where the project is no more costly on a present value basis over the expected life of the project than 10% of approved costs or $15 million, whichever is less;
- an increase in total construction costs of up to $6 million and up to 10% or $15 million, whichever is less; or
- a reduction of scope of construction which accounts for 15% or more of projected costs, if there is a corresponding reduction in construction costs, which may include consideration of fixed costs.

The revisions will increase the existing dollar thresholds that trigger a Council review to reflect the increases in construction costs and to conform to proposals to raise the administrative and full review thresholds.

The elimination of a second Council review of these types of amendments should reduce costly delays in construction and would allow staff and the Councils to focus resources on projects that have not previously been approved.

II) Consolidated Limited Review Application

As explained, the DOH is combining the "limited architectural review" and "prior review" classifications into a single "limited review" category in the regulations. However, in doing so, staff realized that the application and review processes for the two former categories were very different from one another. Therefore, to parallel implementation of the revised regulation, the DOH has also established a consolidated *Limited Review Application* for use under the new "limited review" classification.

In addition to the regulatory changes, combining these categories into a single application will eliminate long-standing confusion between the two categories. The consolidated *Limited Review Application* will provide a more explicit process for projects that involve the addition or decertification of a service, implementation of health information technology, and/or involve construction requiring an architectural review.

Consolidating and streamlining the *Limited Review Application* to reflect all "limited review" categories created via recent regulatory reform initiatives will allow the DOH staff to better coordinate the input of reviewers, as well as provide for easier tracking for applicants. As a result, the DOH anticipates enhanced CON transparency, improved public understanding of the CON and limited

review processes, greater support for local planning, improved quality of applications, and a more streamlined review and approval process.

III) Implementation

With the Notice of Adoption published in the New York State Register today, and provision of a 30-day implementation period, the regulations will not technically be effective until August 6, 2010. However, the new consolidated *Limited Review Application* form is now available on the DOH website (www.nyhealth.gov/nysdoh/cons/index.htm) and applicants are asked to begin using it immediately, as staff will begin reviewing applications under the new regulations.

In accessing the *Limited Review Application* on the DOH website, you will notice that the application is comprised of a cover sheet and twelve (12) schedules – though, not all of the schedules will need to be completed for a given project. The responses given on the cover sheet will determine which schedules to complete.

In addition, "limited review" applications will now be processed using the standard 6-digit CON numbering system – for example, 102###. Applicants will notice this as a change from how limited architectural review applications (AEP-####) and prior limited review applications (5#####) were numbered in the past. The change to the numbering system went into effect on July 1, 2010, and applicants may have already witnessed such on acknowledgement letters since received.

If you have any questions regarding implementation of the new regulatory revisions to the CON process for threshold levels, please do not hesitate to contact Jeffrey Rothman, Director of Project Management, at (518) 402-0911.

Sincerely,

Thomas M. Jung
Acting Director
Division of Health Facility Planning

Enclosures