Greater New York Hospital Association

555 West 57th Street / New York, N.Y. 10019 / (212) 246 – 7100 / FAX (212) 262 - 6350

Kenneth E. Raske, President

COMMENTS OF THE GREATER NEW YORK HOSPITAL ASSOCIATION

ON CERTIFICATE OF NEED REFORM

AT A SPECIAL MEETING OF THE

PLANNING COMMITTEE OF THE

NEW YORK STATE HOSPITAL REVIEW AND PLANNING COUNCIL

SEPTEMBER 18, 2008

NEW YORK CITY

Comments of the Greater New York Hospital Association
On Certificate of Need Reform
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Good afternoon. I am Susan C. Waltman, Executive Vice President for Legal, Regulatory, and Professional Affairs and General Counsel for the Greater New York Hospital Association (GNYHA). GNYHA represents the interests of 250 hospitals and continuing care facilities concentrated in the New York City region but also located throughout New York State, New Jersey, Connecticut, and Rhode Island. All of GNYHA's members are either not-for-profit, charitable organizations or publicly-sponsored institutions that provide services that range from state-of-the-art, tertiary services to basic primary care needed by their surrounding communities, many of which are medically underserved. GNYHA members and their related medical schools also provide extensive medical education and training and undertake cutting-edge medical research that benefits patients all over the world.

GNYHA and its members are exceptionally pleased that the New York State Department of Health (DOH) and the Planning Committee in particular are evaluating the State's certificate of need (CON) process in an effort to ensure that it facilitates the appropriate alignment of health care resources with community needs and avoids another forced downsizing of the delivery system. We agree that the goal should be the development of a patient-centered, high performing health care delivery system, which the State defines as one that offers accessible, affordable, and effective care. We also believe that the specific questions that you pose are on target.

Overview of Comments—GNYHA firmly believes that the State's CON program, much like the CON programs that remain across the country, no longer effectively furthers the State's goals of promoting cost control, access, and quality, and in some cases, actually undermines those goals, due in great part to the dynamics of today's health care environment. Within this context, the current CON process can only be viewed as unnecessarily complicated and expensive, it is

over- and under inclusive at the same time, it is dated, and it is unreasonably lengthy and burdensome. And that is exactly why the State of New York is so wise to be reviewing the process. In brief, GNYHA recommends that the State significantly increase the program's cost thresholds, exempt non-clinical projects from the application process, and streamline the process that remains. GNYHA also recommends that the State stop the proliferation of freestanding, non-hospital based ambulatory surgery centers that threaten the ability of hospitals to meet the needs of their communities. Finally, GNYHA calls on the State of New York to develop meaningful financing mechanisms that will enable hospitals to access the capital they need to deliver high quality, accessible patient care.

I. The Pressing Need to Reduce Costs and Promote Efficiencies

The State's timing in terms of reviewing its CON process is of course perfect. We are in the process of a "forced" downsizing of hospitals across the State resulting from the Berger Commission's recommendations. The economy is facing extraordinarily turbulent times, which has in turn placed severe constraints on Federal, State, and local budgets. Hospitals in particular face severe financial pressures as the payers, both private and public, look for ways to reduce health care expenditures, while the cost of the component parts of delivering high quality health care, such as the costs of new technologies, energy, or medical malpractice coverage, spiral out of control. Yet, all the while, hospitals must remain committed to their mission of meeting their communities' health care needs and doing so in a safe, transparent, accountable way. Indeed, their patients and the public deserve and expect nothing less.

GNYHA Collaboratives—Precisely because of these factors, GNYHA and its members have been earnestly pursuing ways in which to enhance their quality, safety, and efficiency and at the same time to reduce their costs. Perhaps most significant among these initiatives have been member efforts to create and maintain a culture of safety such that every employee and staff member works together to implement best practices and ensure safe patient care. GNYHA has supported these efforts through a number of successful quality and patient safety collaboratives that enable hospitals to share resources and expertise in order to speed and sustain their progress. GNYHA and its members have undertaken similar collaborative efforts with respect to

compliance, preparedness, and other operational and regulatory areas, all with the goal of promoting efficiencies, reducing costs, and ensuring compliance with operational and financial requirements.

GNYHA Regulatory Reform Initiative—As part of its focus on efficiency and cost reduction, GNYHA is also embarking on a broad-based regulatory reform initiative. GNYHA believes strongly that the current regulatory environment, many aspects of which are of course essential, adds greatly and often unnecessarily to the costs of and the inefficiencies in the delivery of care. In some cases, this is due to the multitude of agencies and organizations having jurisdiction over the operation of hospitals, each with their own well intended, but often overlapping and sometimes inconsistent regulatory or accreditation requirements.

In other cases, the regulatory environment adds to hospital costs due to the immense number of regulatory and law enforcement agencies that can and do inquire into hospital operations and finances, particularly in this day and age in which governmental budgets are often balanced by identifying "fraud targets." Indeed, one GNYHA member that is undergoing what is probably a "typical" number of audits, investigations, and surveys recently inquired whether it had been targeted in some fashion. Our answer? No, you are not at all alone.

In still other cases, the regulatory environment contributes to hospital costs and inefficiencies due to the immense number of reporting requirements that run the gamut from outcome measures, to process measures, to data on every part of hospital operations imaginable. Again, many of these requirements are important. Taken together, however, they amount to an extraordinary amount of effort in terms of documenting, tracking, and reporting.

As a result, GNYHA is launching a major initiative under which it will, together with its members and the agencies involved, review the regulatory environment to identify ways in which regulations, surveys, audits, and reporting obligations can be minimized and/or reconciled without undermining the quality of care or hospital operations. The goal is of course to reduce unnecessary costs, enhance efficiency, and thereby be able to devote more resources to what our hospitals are all about: delivering patient-centered, high quality health care.

II. The Importance of Reforming New York State's CON Program

The State's review of its CON program falls squarely within the regulatory reform process that GNYHA believes should be undertaken across the board: a review designed to determine whether a regulatory process accomplishes its goals, whether the goals can be accomplished more efficiently and effectively through other means, and whether it requires adjustments moving forward. We are therefore very appreciative of the State's efforts in this regard as well as the opportunity to provide input.

Questions About the Efficacy of CON Programs in General—Many other states have undertaken or are undertaking similar reviews of their CON programs, precisely because significant questions have been raised about their efficacy and value. As presumably the State is aware, there are conflicting studies on whether CON programs have accomplished their historical goals of promoting cost control, quality, and access. Some studies indicate that CON programs may have initially helped control costs, while others indicate that CON programs may have actually increased costs. At least one, *still often-quoted* study indicates that, even though CON programs may have historically helped control costs, there is no indication that providers increase their capital expenditures following elimination of a program. See Conover and Stone, "Does Removing Certificate of Need Regulations Lead to a Surge in Health Care Spending?" Journal of Health Politics, Policy and Law, June 1998. In short, there are significant questions whether, in today's environment, CON programs play any positive role in controlling costs.

There seems to be more agreement on the fact that CON programs may have a favorable impact on promoting quality in terms of controlling services or equipment for which volume and quality are linked. But beyond that, the continuing value of CON programs seems to be subject to significant dispute. In fact, the State of New Jersey recently went through its own form of Berger Commission, chaired by Princeton University's Uwe Reinhardt. One of the reports to the Commission was on the subject of New Jersey's CON program and recommended that New Jersey's CON program (which New Jersey calls its "CN program") be eliminated entirely and that the State of New Jersey pursue other ways to promote access and quality. Although the New Jersey Commission did not embrace total elimination of New Jersey's CON program, the

Commission called for a comprehensive review of its requirements and stated "While the evidence is mixed on the ability of CN programs to contain health care spending, proven relationships between volume and quality for certain clinical services argue for the continuation of the CN program for certain services." See Final Report of the New Jersey Commission on Rationalizing Health Care Resources, January 24, 2008, p. 132.

Reforming New York State's CON Program—Against the backdrop of these studies that question the value and efficacy of CON programs in general, GNYHA will now turn to answering New York State's questions about reforming its CON program. The State's questions in this regard are divided into four key areas. Two of the key areas of questions—projects that should be subject to review (or not subject to review) and the CON submission process—are intertwined and therefore GNYHA will answer them together. In general terms, GNYHA believes that New York State's CON cost thresholds should be increased significantly, that non-clinical projects should be exempt from CON review, and that the CON process should be streamlined, in each case for the benefit of not just the applicants involved, but for the State and the goals it hopes to achieve.

As reflected in the various studies regarding CON programs, the fundamental questions in assessing a CON program are whether the process is fulfilling its goals, what costs are associated with the process, and whether there are other effective mechanisms or forces that fulfill these goals without the costs or regulatory burdens associated with the existing process. GNYHA will follow this analysis in discussing New York's program.

New York State's Goal of A Patient-Centered Environment—As New York State undertakes a review of its CON program, the State's articulated goal is the development of a patient-centered, high performing health care delivery system that offers accessible, affordable, high-quality and cost effective care. Embedded in this goal are precisely the historical goals of most CON programs: quality, access, and cost control. As discussed, studies seriously question whether CON programs effectively accomplish the goal of cost control *in today's environment* although there seems to be a consensus that CON programs can play a role in ensuring quality with respect to those services where there is a relationship between volume and quality.

With respect to whether these same goals can be met through other means in New York, GNYHA believes strongly that, in today's health care environment, these goals are being met and/or certainly can be met through a variety of different means and methods, without the necessity of having the comprehensive CON program that currently exists in New York. First, New York State certainly has the capability and authority to encourage and require providers to meet many aspects of these goals through its extensive regulatory and licensing authority over the facilities and individuals that deliver care as well as through its payment systems and methodologies. Indeed, the State has taken bold steps over the last several years to identify and encourage best practices of care, to clarify its authority over health care facilities and practitioners alike, to promote transparency and accountability, to create financial incentives (and disincentives) for models and standards of care, and to encourage providers to better meet the needs of their communities. The State's CON process plays an important role in this regard, in that it can restrict, if it chooses, the types of providers permitted to provide certain services or impose conditions on the way those providers may enter the field or begin to provide certain services. However, the CON process is by definition a one-time review as opposed to the day-to-day oversight and control that New York State can and already does exercise with respect to many providers, particularly hospitals.

In addition to the State's regulatory, licensing, and payment authorities, there are of course many external factors that encourage the basic goals of quality, access, and cost control. There are broad societal, governmental, and payer expectations and requirements regarding the delivery of safe and high quality care. There are the similarly broad-based pressures to control health care costs, with the result that payers of all sorts continuously look for ways to reduce payments to providers. At the same time, the costs that affect the ability of providers to deliver care have escalated tremendously. Finally, there remains limited capital reimbursement from payers, thereby creating even more pressure on providers <u>not</u> to incur costs, unless necessary.

Quite simply, there are many forces at play that drive quality, efficiency, and cost control so that a comprehensive CON program such as New York State's program is no longer needed.

The "Cost" of the CON Process—I will now turn to the corresponding burdens and costs of the current CON program, which are excessive in any event and particularly so given that many of the goals of the program can be met through other means. Everyone here today, including those from DOH's Division of Health Facility Planning, recognizes that many aspects of the current CON process are labor-intensive, time-consuming, and expensive. The State's CON application requests extensive information about each project, its financing, its applicant, its applicant's finances, its need, and its overall plans. Indeed, many applications require the completion of anywhere from 13 to 15 different schedules. The applications must be filed, for the most part, in hard copy format (together with eight copies). It takes many months (and it can take years) for the State to process the applications. (And, yes, I recognize that the State will say that some applicants could do a more complete job as they submit their applications, but it is a complicated process indeed and more technical assistance would be welcomed.)

It often takes many different bureaus in Albany to review and approve the projects. It takes, at the very least, the Commissioner of Health to provide final approval, and in many other cases, it also takes the valuable time and attention of this committee, the full State Hospital Review and Planning Council, the Establishment Committee of the Public Health Council, and the full Public Health Council itself to finally move forward. And the applicant still needs approval to undertake construction as well as approval (and a survey) to open!

The Specific "Costs" Involved—It is not surprising then that this process consumes considerable time and resources within both the applicant organizations and DOH and that many applicants hire outside consultants and attorneys to assist them. The State itself recognized the considerable costs of the CON process as it undertook to add more flexibility to the process nearly a decade ago. The following statements by DOH are excerpted from the August 19, 1998, *New York State Register*:

> **Cost of Application:** Many applicants incur considerable costs in staff time and in consultant and legal fees in the preparation and submission of an application…..
>
> **Lost Revenue:** Although the time required for review and approval of applications has been reduced significantly…, many applicants still lose potential revenues while awaiting

CON approval of a new facility or service. This opportunity cost can be considerable for some providers.

Limits in Competitive Capacity: The need to seek CON approval and await review of an application can deprive providers of the flexibility they need to respond to rapidly changing market conditions and may erode their individual competitive positions in local markets.

There is one cost that the State did not reference in listing the cost of the CON program in 1998: the increase in construction costs while a CON application is pending. GNYHA members indicate that, in planning a project that requires CON approval, *their costs of construction will increase 12 percent each year as they await CON approval*. This is confirmed by a recent publication by the New York Building Congress, which states that overall construction costs have gone up at an extraordinary rate in recent years, with the cost of new hospital construction up 12 percent per year and renovation and alteration costs escalating at roughly 6 percent per year. The publication indicates that volatile material prices, not labor, are considered to be the major cause of escalating hospital construction costs. See "New York's Rising Construction Costs: Issues and Solutions," New York Building Congress and New York Building Foundation, June 2008.

The question is therefore whether the CON process is worth these costs and burdens, particularly when its goals can be met, in great part, though other mechanisms. The answer is perhaps yes, in certain cases, but in others, definitely not. GNYHA therefore recommends, as discussed below, increasing the cost thresholds overall, removing some projects from the process, and streamlining the process that remains.

Increasing the Thresholds—First, with respect to increasing the cost thresholds, it has been a full ten years since the State of New York increased the program's overall cost thresholds, which are currently, in general terms, $3 million for administrative reviews and $10 million for full reviews, with many exceptions. At the time that the State increased the cost thresholds a decade ago, it did so in two steps, in each case in recognition of the fact that the health care environment called for a less stringent CON process. First, in 1996, the State increased the thresholds from $400,000 to $1 million for administrative reviews and from $4 million to $6 million for full reviews.

The State quickly recognized, however, that the 1996 increases affected only a "modest portion of the CON applications." The State therefore increased the thresholds again in 1998 to the current $3 million administrative and $10 million full review thresholds and exempted certain applications unrelated to patient care. According to the State, the 1998 threshold increases and other changes were made "to bring additional flexibility to the CON program as well as reduce the… costs and limitations for affected applicants." *New York State Register,* August 19, 1998. In increasing the thresholds, the State cited the historical goal of the CON program as to promote judicious use of publicly funded capital and to ensure access to quality health care. However, the State noted that "the changing health care system, the growth of managed care, and the passage of the Health Care Reform Act have made it possible to achieve these goals with a CON program that is less stringent and more supportive of today's more market-oriented health care environment." See *New York State Register*, August 19, 1998.

Today's Increased Pressures to Reduce Costs and Promote Efficiencies—Since the State concluded that it needed a more flexible CON program due to the changing health care environment nearly a decade ago, the health care system has changed even more, with much broader and more varied cost pressures on providers; more intense efforts by all payers to reduce payments to providers through varied payment mechanisms, incentives, and disincentives; and more initiatives to enhance quality and efficiencies. Therefore, whatever environmental factors served to reduce costs and enhance quality and efficiency in 1998 (and thereby required a more flexible CON program) have only multiplied and intensified in their impact over the last decade. At the same time, there is even less reimbursement for capital costs today, thereby creating an even greater disincentive to incur capital costs, regardless of need. And, as noted, the cost of construction has grown exponentially, thereby making what might have been a modest project in 1998, a more expensive project today, thus quickly tripping the ten-year-old cost thresholds while not really being "substantial" among the array of provider projects.

Recommended Cost Thresholds—Taken together, these factors—the costs of the CON process, the many incentives to reduce costs and enhance quality and efficiency that come from factors other than the CON process, and the increased cost of construction—dictate a material increase in the cost thresholds. For this purpose, GNYHA proposes at a minimum, *that the thresholds be*

increased so that administrative reviews are not triggered until the project cost is $10 million and full reviews are not triggered until the project cost is $25 million. GNYHA also recommends that the current threshold of $25 million for projects that qualify for administrative review if the total project costs do not exceed 10% of the facility's operating costs for the two previous fiscal years (and none of the facility's debt is financed by instruments that are State-supported) *should be increased to $40 million*. Finally, in order to ensure that the thresholds keep pace with inflation and changing times, GNYHA recommends inclusion of an "inflation" or price increase factor to be applied to the thresholds over time.

Exempting Non-Clinical Projects—In addition, GNYHA proposes that certain types of projects be entirely exempt from the CON process, regardless of the project costs. In general, any project that is not clinical in nature and therefore will not raise concerns about the quality of care or competency of the operator should not be subject to CON review. Providers simply do not undertake projects, particularly non-clinical ones, unless the project is needed. As noted, if anything, the current health care reimbursement and cost environment acts as a *disincentive* for hospitals to undertake such projects. Non-clinical projects should unquestionably be left to the judgment and discretion of management, who must budget for such projects in the same way they budget for basic operating costs, and who are unable to do so as effectively as possible, given the delays and burdens of the current CON process. To the extent there may be concerns about the projects being built to code(s), sufficient safeguards are already in place through existing local, State, and Federal codes, regulations, certifications, and other requirements. Moreover, for any meaningful projects, outside and certainly in-house architects and engineers are involved as well in order to safeguard the integrity and quality of the project.

The State clearly recognizes these considerations as evidenced by its publication of proposed rulemaking on the "Approval of Nonclinical Projects" in the August 20, 2008, *New York State Register*. Those proposed rules reflect, as noted, consensus rulemaking in that GNYHA, together with the Healthcare Association of New York State, put forward and agreed upon the approach proposed in the rule. However, GNYHA is today proposing a more expansive approach to the handling of non-clinical projects by recommending that they be exempt from the CON process, regardless of cost, in light of the considerations outlined earlier in our comments.

GNYHA is appreciative of the State's proposed rulemaking and the flexibility it proposes to provide. However, given the State's current broad-based review of its CON program, GNYHA respectfully urges adoption of its more expansive recommendation to exempt all non-clinical projects.

Undertaking A Thorough Review of the Remaining Projects—GNYHA proposes that the State, in coordination with interested stakeholders, undertake a methodical review of the various types of projects and equipment that would remain under the CON process (once non-clinical projects are exempt) to determine whether they should require review, under what circumstances, and under what levels of review. For example, many types of equipment replacements should not require more than the replacement letter process. While GNYHA knows that this committee is very familiar with CON requirements, GNYHA attaches to these comments a chart that GNYHA has prepared to assist its members sort out the many types of reviews required under New York's CON program. GNYHA notes that there are a significant number of permutations of projects listed in the chart, most of which should at least be reconsidered in light of today's health care environment.

Streamlining the Process—Finally, GNYHA believes that the CON process itself should undergo significant streamlining. While those who work in the Division of Health Facility Planning are expert at what they do and put in very long hours, the current system for processing applications should go through a review to determine whether some of the steps could be deleted, combined, or expedited in some fashion. GNYHA perfectly understands how certain systems become embedded and are hard to roll back. But we believe the process should be reengineered and thus become more beneficial and less costly to both the applicants and the State.

As part of the streamlining process, GNYHA members have specifically recommended that:

- Applicants be able to file their applications electronically via the State's Health Provider Network (HPN).
- The applicant should be able to check on the status of its application as well as ask questions via the HPN.
- One point of contact at DOH should be assigned for each application.

- In many cases, an approval or position taken by DOH personnel in Albany should be sufficient and therefore the State should examine whether and when area office involvement is also needed.
- Where there is a need for area office involvement, the State should examine whether there can be better coordination between DOH personnel in Albany and the area offices.

Involvement in Financing Terms—On a somewhat separate but related note, bankers and attorneys for GNYHA members have raised questions about the appropriateness and necessity of the State's dictating the form of the transaction that hospitals might enter to finance a particular project. They strongly recommend that the State leave to the hospital, its bankers, and its attorneys the determination of the most prudent transaction for the hospital. GNYHA understands that more specific recommendations in this regard are being shared directly with DOH.

Summary of Recommendations Regarding Review Process—GNYHA believes that the foregoing recommendations will reduce the unnecessary costs and burdens of the CON program without undermining the program's ability to review what it should review, namely, projects and acquisitions that may affect the quality of care provided either because quality may be correlated with volume or the competency of the operator is critical. In the current world of cost pressures, reductions in payments to providers, and intense scrutiny of the quality, safety, and efficiency of care through myriad means, there is no need to subject non-clinical projects to CON review nor is there the need to subject most clinical projects to the CON application process, unless they fall into certain categories or surpass certain substantial thresholds. Finally, regardless of what projects remain for review, the CON application process should be reengineered and streamlined for the benefit of the State and the applicants alike.

III. Out-Migration of Services

The State also raises questions about the migration of services to settings outside of hospitals and what role the CON process should play with regard to such situations. GNYHA has long been on record regarding its concerns about this issue and in particular the severe negative impact that

free-standing, non-hospital based ambulatory surgery centers (ASCs) have on hospitals. Indeed, GNYHA has for many years called for a moratorium on these ASCs, given their impact on the ability of hospitals to meet the needs of their communities.

The contrasts between the demands on, and characteristics of hospitals on the one hand, and ASCs on the other, are stark, and GNYHA outlines these differences below:

Caring for the Underserved and Uninsured—Many hospitals serve large numbers of Medicaid and uninsured individuals. In fact, many hospitals are the only source of care in their communities, particularly for many individuals who are otherwise medically underserved and uninsured. As a result, hospitals provide a significant amount of uncompensated or charity care. In contrast, freestanding ASCs often do not participate in Medicaid or they participate in a limited way, and they also do not provide significant uncompensated or charity care.

Providing the Full-Array of Services—Hospitals also provide the full array of services required by their communities, such as emergency department and trauma services, many of which result in significant losses for hospitals. In contrast, freestanding ASCs do not provide these needed, but "unprofitable" services, choosing instead to provide those services that will generate profits for their owners.

Needing to Cover "Unprofitable" Community Services—Hospitals often need to rely on those services that are "profitable," relatively speaking, such as orthopedics and ophthalmology, to cover the cost of "non-profitable" services like emergency and burn care. In contrast and as stated above, freestanding ASCs concentrate primarily on providing such profitable services, thereby skimming these types of cases from hospitals without providing the concomitant community benefits that hospitals provide.

Preparing for Disasters—Hospitals must be prepared to respond to all sorts of possible emergencies and disasters in their service areas, all at a considerable cost to the hospitals. In contrast, freestanding ASCs have no such obligations or corresponding cost.

Struggling with the Problem of Access to Capital—Hospitals in New York State are constrained by their ability to access needed capital for renovations and expansion of specialty units in order to attract and retain physicians who might otherwise wish to establish freestanding ASCs. GNYHA addresses this lack of access to capital in more detail later in these comments.

Berger Commission Concerns About ASCs—In its 2006 report, New York State's Berger Commission expressly recognized that freestanding ASCs deprive hospitals of much-needed revenue and correspondingly undermine their ability to serve their communities:

> Hospitals face increasing competition from niche providers such as ambulatory surgery centers, who often provide services that are well reimbursed and deprive hospitals of revenues that were historically used to cross-subsidize less profitable services. (Berger Commission Report, p. 6.)

The Berger Commission also described how this negative phenomenon unfolds:

> A significant amount of health care services has migrated out of the hospital to other settings. Ambulatory, "niche" providers are unburdened by the large overhead costs borne by hospitals and so can be less costly for payors and users…. The movement of services out of large institutions is likely to continue. This would not be problematic except for the fact that hospitals treat a disproportionate share of complex and difficult high-risk cases, while other providers effectively "cherry pick," profiting more from specializing in lower-risk cases utilizing high value services. In today's health care environment, hospitals rely on high value services to subsidize less-profitable services that are critical to the community. Examples of these less profitable "public goods" are emergency departments, trauma centers, burn care services, and non-income generating services like disaster preparedness. (Berger Commission Report, p. 84.)

Quite clearly, the State's Berger Commission recognized the precarious position of the State's hospitals and how freestanding ASCs negatively affect them by stripping off the most profitable cases and leaving hospitals with materially fewer resources to deliver the care needed by their communities.

The State's Authority and Responsibility to Consider The Negative Impact on Hospitals— GNYHA understands that questions have been raised with respect to the authority of DOH, SHRPC, and the Public Health Council to consider the negative impact of ASCs on hospitals when reviewing an ASC's application. In the case of *South Shore SC, LLC v. The New York State Public Health Council, et al.*, GNYHA filed an *amicus curiae* brief taking the position that the State has not only the authority, but, in fact and in law, the responsibility to take into account the impact that new freestanding ASCs might have on surrounding hospitals and the essential services the hospitals are able to provide to their communities. This authority has been given to DOH, SHRPC, and the Public Health Council by the New York State Legislature, is reflected in regulations and related guidelines governing the establishment of ASCs, and is inherent in the overall purposes and goals of health planning prescribed by the State of New York.

Indeed, the essence of health planning is the presence of a deliberate process for determining the public need for a new facility, which includes reviewing whether there will be a negative impact on the quality, availability, and cost of existing health services should the new facility be approved. To ignore the potential impact that new freestanding ASCs might have on surrounding hospitals and correspondingly their ability to continue to provide services needed by their communities is contrary to health planning principles as well as to New York State law, regulation, and public policy.

By their terms, the ASC regulations require a review of how the applicant may affect access to services, referral patterns, and the availability of services to those in need, regardless of their ability to pay. Each of these criteria requires a review of the impact of the entry of a particular ASC on the health care system. It would make little sense if the criteria were read to require a review of only the positive aspects of the ASC while expecting the State to ignore the negative impact of the applicant's services with respect to each of these criteria.

GNYHA's Continued Opposition to ASCs—GNYHA wishes to clarify that its position regarding freestanding ASCs remains the same: it opposes each and every such ASC that undermines the ability of a hospital to deliver needed services to its community. At last week's Public Health Council meeting, GNYHA chose not to file a written opposition to an ASC that

came before the Public Health Council and to which GNYHA had objected in the past. The reason? According to the affected hospital, the damage had already been done by the time of the Public Health Council's meeting last week. The physicians proposing to establish the ASC had apparently already diverted from the hospital a substantial portion of the patients who were projected to become patients of the ASC, presumably by providing services to those patients in the physicians' office-based practices while awaiting approval of their ASC.

As a result, the hospital opted not to file a letter in opposition, and GNYHA therefore declined as well. But the point is that damage to the hospital had definitely occurred, which is precisely the reason that GNYHA opposes the establishment of any such freestanding ASCs that threaten the ability of hospitals to deliver needed health care services to their communities.

IV. Assessment of Community Health Needs

Supporting Collaborative Planning—The State also asks how the State and others can support collaborative efforts to assess community health needs and make recommendations to develop and/or deploy resources needed to address these needs. GNYHA believes that the State's Prevention Agenda and approach to encouraging hospitals to partner with local health departments and other stakeholders to both assess and address specified health goals is an excellent one. As reflected in their Community Service Plans, hospitals already undertake extensive health education, outreach, and promotion activities, often in partnership with community organizations. However, there is no question that broader-based initiatives to assess community needs, identify health priorities, and develop and implement public health and promotion programs would be valuable.

Correspondingly, as more data become available, hospitals and other providers can undertake even more meaningful reviews of their communities' health needs and fashion their efforts to meet those needs. Already, in New York City, hospitals routinely use the New York City Department of Health and Mental Hygiene's Community Health Profiles as part of their needs assessment process. Similarly, the release of the Community Health Assessment Initiative and the Prevention Quality Indicator data base will be of value to providers across the State.

GNYHA points out that, in addition to their community and outreach services, hospitals in New York State of course also provide approximately $1.6 billion of uncompensated care to the uninsured and underinsured, only half of which is eventually reimbursed; services to their communities 24 hours a day, including emergency department and trauma care; readiness to protect and care for their communities in the event of a disaster; and significant primary and ambulatory care in many communities.

Preserving New York State's Academic Medical Centers and Teaching Hospitals—As the State looks at how it can best meet community needs, GNYHA requests that the State take into account (and not lose sight of) the significant value that academic medical centers and our most tertiary teaching hospitals bring to our health care system, our region, and the world. Their expertise and state-of-the-art services are sought by individuals far and wide and not just by those located in their immediate geographic areas. Their cutting edge research brings health and hope to people no matter where located. And their medical education, graduate and otherwise, trains the physicians of our future. These centers have unique attributes and needs, and GNYHA requests that the State preserve and protect their immense value as it undertakes health planning now and in the future.

V. The Critical Need for Access to Capital

One last, but critical point: New York State's hospitals have long suffered from extraordinarily limited access to capital. This is due to, among other factors, the poor financial condition of New York State hospitals, the large number of uninsured and underinsured individuals in the State, the State's requirement that hospitals below a certain credit rating obtain credit enhancement in order to secure bonds issued through New York State authorities, and the sheer size of the capital needs. This situation has meant that many facilities can obtain access to capital only through the use of mortgage insurance issued through the Federal Housing Administration's (FHA's) Insured Health Facilities Program, a valuable, yet lengthy and exacting program. Still other facilities cannot even meet the requirements for participation in the FHA's mortgage insurance program.

Today's turbulent economic times and correspondingly the pressure being placed on Federal, State, and local budgets are expected to lead to even more restricted access to capital for New York State hospitals. GNYHA therefore calls upon the State of New York to develop creative and meaningful financing mechanisms to provide access to capital for New York State hospitals. This is the logical next step flowing from the Berger Commission's recommendations, which were designed to strengthen New York State's hospital system, and it is essential for the future of New York State's health care system. Only through improved access to capital can the health care system be strengthened, and we look forward to working with you in this regard.

VI. Conclusion and Summary

GNYHA appreciates the State's leadership in undertaking this review of its CON process. As stated, GNYHA believes that New York State should overhaul its CON program and specifically recommends that the State significantly increase its cost thresholds, exempt non-clinical projects, and streamline the process for those applications that remain. These recommendations recognize the pressures and factors in today's health care environment that drive quality, cost control, and access; will eliminate much of the cost and inefficiency of the current CON program; and yet will still ensure that those projects that may significantly affect quality will be reviewed. We strongly recommend that the State protect the ability of hospitals to serve the needs of their communities by limiting the proliferation of freestanding, non-hospital based ASCs. Finally, we call upon the State to work with GNYHA to develop meaningful access to capital for hospitals in order to protect and preserve the State's health care system. Thank you, and we look forward to working with the State as it undertakes this much-needed reform of its process.

CERTIFICATE OF NEED (CON) REQUIREMENTS FOR ARTICLE 28 FACILITIES

REVIEW DEFINITIONS (Beginning with most extensive level of review)

Full Review – entails a review by New York State Department of Health (DOH) staff and a review by and recommendation of the State Hospital Review and Planning Council (SHRPC), which meets six times a year, prior to review by and decision of the DOH Commissioner. The full review application fee for Article 28 projects proposing construction is $1,250 plus, if approved, 0.45% of the total capital value of the application.

Administrative Review – entails a review by DOH staff prior to review by and decision of the DOH Commissioner. The DOH Commissioner may choose to subject applications that are eligible for administrative review to review by SHRPC. Facilities are limited by 10 New York Code Rules and Regulations (NYCRR) 710.1 (c)(3)(ii)(a) as to the extent to which projects may be approved administratively. The administrative review application fee is $1250 for Article 28 projects, only.

Prior Limited Review – proposals are made directly to the Deputy Director of the Division of Health Facility Planning of DOH in Troy, New York. If the proposal is acceptable, the applicant is notified in writing within 30 days and an amended operating certificate is issued. If the proposal is unacceptable, the applicant is notified within 30 days of such determination and the bases thereof. If it is unacceptable due to broader planning issues, the application is subject to full or administrative review.

Prior Review Limited to Architectural and Engineering Matters – entails the submission of information and documentation as is required to determine the acceptability of the proposal. Proposals (utilizing the "AEP application") are made directly to the DOH Bureau of Architectural and Engineering Review in Albany. If the Bureau of Architectural and Engineering Review certifies that the proposal complies with all pertinent statutory and regulatory requirements, the Director of the Bureau notifies the applicant in writing. If the Bureau determines that the proposal is not acceptable, the Director of the Bureau notifies the applicant in writing of such determination and the bases thereof. If the applicant does not submit an acceptable proposal within 30 days of such determination, the proposal is subject to full review by SHRPC with a staff recommendation for disapproval.

Notification Letter – submitted to the DOH Division of Health Facility Planning and Division of Healthcare Financing at least 30 days prior to the proposed equipment replacement with a statement indicating when the original equipment to be replaced was purchased or otherwise acquired and that 90% of its useful life has been exhausted.

Prepared by GNYHA April 2005
Reviewed by New York State Department of Health

Category	Type of Project	Type of Application	Project Cost[1]	Regulation Source
GENERAL				
	Proposals not eligible for administrative review.	Full Review	Greater than $10,000,000, or other specified projects, regardless of cost	10 NYCRR 710.1 (c)(2)(i)(d)
	Proposals that are otherwise eligible for administrative review but that were recommended for disapproval.	Full Review	Regardless of cost	10 NYCRR 710.1 (c)(2)(i)(f)
	Proposals over $10,000,000 that are otherwise eligible for administrative review provided that: (1) total project costs do not exceed 10% of the facility's operating costs for the two previous fiscal years; (2) total project costs do not exceed $25,000,000; and (3) neither the facility nor any part thereof, nor the project, is currently or is proposed to be financed by bonds or any other debt instruments insured, enhanced, or guaranteed by any state or municipal governmental agency or public benefit corporation.	Administrative Review	Greater than $10,000,000 and less than $25,000,000.	10 NYCRR 710.1 (c)(3)(i)

Category	Type of Project	Type of Application	Project Cost[1]	Regulation Source
BEDS				
ADDITION				
	Addition of beds (other than AIDS beds described below).	Full Review	Regardless of cost	10 NYCRR 710.1 (c)(2)(i)(a)
	Addition of AIDS beds.	• Administrative Review • Full Review	$10,000,000 or less Greater than $10,000,000	10 NYCRR 710.1 (c)(2)(i)(a)
	Skilled Nursing Facility Beds – addition of beds specifically designated for persons with AIDS by a residential health care facility (RHCF).	Administrative Review	Regardless of cost	10 NYCRR 710.1 (c)(3)(i)(n)
	Temporary addition of beds to a facility's certified capacity for a specified amount of time (no more than a year) required to address high priority health care needs for which there is a demonstrated acute shortage.	Administrative Review	$10,000,000 or less	10 NYCRR 710.1 (c)(3)(i)(s)
CONVERSION OF BEDS				
	AIDS Center – change in bed capacity that does not result in a net increase in the certified bed capacity of the facility.	Administrative Review	$10,000,000 or less	10 NYCRR 710.1 (c)(3)(i)(k)
	Conversion of beds that establishes a different level of care.	Full Review	Regardless of cost	10 NYCRR 710.1 (c)(2)(i)(a)
	Conversion of beds where a facility is not already certified to provide the service, that does not establish a different level of care.	Administrative Review	$10,000,000 or less	10 NYCRR 710.1 (c)(3)(i)(c)
	Conversion of acute care beds in one of the following categories to another, provided that the hospital is already certified to provide such services: medical/surgical, intensive care, coronary care, pediatric, pediatric intensive care, neonatal intensive care, neonatal intermediate care, neonatal continuing care, maternity, alcohol detoxification, and drug detoxification.	• Prior Limited Review • Administrative Review • Full Review	$3,000,000 or less Greater than $3,000,000, but $10,000,000 or less Greater than $10,000,000	10 NYCRR 710.1 (c)(6)(iv)

Category	Type of Project	Type of Application	Project Cost[1]	Regulation Source
REALLOCATION / MOVEMENT OF BEDS				
	Reallocation, relocation, or redistribution of acute care beds from one hospital to another hospital within the same established Article 28 network (as defined in 10 NYCRR 401.1(j)).	• Prior Limited Review • Administrative Review • Full Review	$3,000,000 or less Greater than $3,000,000, but, $10,000,000 or less Greater than $10,000,000	10 NYCRR 710.1 (c)(6)(vi); 10 NYCRR 401.1 (j)
DECERTIFICATION OF BEDS/SERVICES	Decertifying certain beds or services.	Prior Limited Review	Regardless of cost	10 NYCRR 710.1 (c)(6)
EQUIPMENT	Addition, updating or modification of equipment utilized in the provision of services listed in 10 NYCRR 710.1 (c)(2)(i)(b)[3], with the exception of cardiac catheterization services.	• Administrative Review • Full Review	$10,000,000 or less Greater than $10,000,000	10 NYCRR 710.1 (c)(2); 10 NYCRR 710.1 (c)(3)(i)(f)
	Cardiac catheterization equipment: • Initial purchase. • Additional purchase. • Replacement purchase, if 90% depreciated or no longer meets generally accepted operational standards.	• Full Review • Full Review • Notification letter to DOH as long as no construction is required. 4	• Regardless of cost • Regardless of cost • Regardless of cost	• 10 NYCRR 710.1 (c)(2)(i)(b) • 10 NYCRR 710.1 (c)(2)(i)(b) • 10 NYCRR 710.1 (c)(4)(iii)

Category	Type of Project	Type of Application	Project Cost[1]	Regulation Source
EQUIPMENT (cont'd)	CT scanners:			
	• Initial and additional purchases.	• Administrative Review	• Greater than $3,000,000, but $10,000,000 or less	• 10 NYCRR 710.1 (c)(3)(i)(p)
		• Full Review	• Greater than $10,000,000	• 10 NYCRR 710.1 (c)(4)(iii)
	• Replacement purchase, if 90% depreciated or no longer meets generally accepted operational standards.	• Notification letter to DOH (even if higher capacity) as long as no construction is required[4]	• Regardless of cost	• 10 NYCRR 710.1 (c)(5)(i),(ii); 10 NYCRR 401.1 (j)
	• Relocation within the same established Article 28 network (as defined in 10 NYCRR 401.1 (j)).	• Prior Review Limited to Architectural and Engineering matters[4]	• $3,000,000 or less	
		• Administrative Review	• Greater than $3,000,000 but, $10,000,000 or less	
		• Full Review	• Greater than $10,000,000	
	Extracorporeal shockwave lithotripters			
	• Initial and additional purchases.	• Administrative Review	• $10,000,000 or less	• 10 NYCRR 710.1 (c)(3)(i)(q)
	• Replacement purchase, if 90% depreciated or no longer meets generally accepted operational standards.	• Notification letter to DOH (even if higher capacity) as long as no construction is required[4]	• Regardless of cost	• 10 NYCRR 710.1 (c)(4)(iii)

Category	Type of Project	Type of Application	Project Cost[1]	Regulation Source
EQUIPMENT (cont'd)	• Relocation within the same established Article 28 network (as defined in 10 NYCRR 401.1 (j)).	Prior Review Limited to architectural and engineering matters (as long as no construction is required)[4]	Regardless of cost	10 NYCRR 710.1 (c)(5)(i),(ii); 10 NYCRR 401.1 (j)
	Ionizing radiation/magnetic resonance equipment, for which a CON is not otherwise required	Prior Review Limited to Architectural and Engineering Matters	$3,000,000 or less	10 NYCRR 710.1 (c) (5)(i)(a)
	Linear accelerators: • Replacement of cobalt unit with a linear accelerator by a facility that has been licensed by DOH to provide therapeutic radiology or radiation oncology.	• Administrative Review	• $10,000,000 or less	• 10 NYCRR 710.1 (c)(3)(i)(r)
	• Replacement purchase, if 90% depreciated or no longer meets generally accepted operational standards.	• Notification letter to DOH (even if higher capacity, as long as no construction is required[4])	• Regardless of cost	• 10 NYCRR 710.1 (c)(4)(iii)
	• Relocation of linear accelerator as replacement for cobalt unit within the same established Article 28 network (as defined in 10 NYCRR 401.1 (j)).	• Prior Review Limited to Architectural and Engineering matters (as long as no construction is required[4])	• Regardless of cost	• 10 NYCRR 710.1 (c)(5)(i),(ii); 10 NYCRR 401.1 (j))

Category	Type of Project	Type of Application	Project Cost[1]	Regulation Source
EQUIPMENT (cont'd)	Magnetic Resonance Imagers (MRIs):			
	• Initial purchase.	• Full Review	• Regardless of cost	• 10 NYCRR 710.1 (c)(2)(i)(b)(7)
	• Additional purchase.	• Administrative Review	• $10,000,000 or less	• 10 NYCRR 710.1 (c)(2)(i)(b)
	• Replacement purchase, if 90% depreciated or no longer meets generally accepted operational standards.	• Notification letter to DOH (even if higher capacity, as long as no construction is required[4])	• Regardless of cost	• 10 NYCRR 710.1 (c)(4)(iii)
	• Relocation within an established Article 28 network (as defined in 10 NYCRR 401.1 (j)).	• Prior Review Limited to Architectural and Engineering matters (as long as no construction is required[4])	• Regardless of cost	• 10 NYCRR 710.1 (c)(5)(i),(ii); 10 NYCRR 401.1 (j)
	Therapeutic radiology (other than replacement of a cobalt unit with linear accelerator by a facility that has been licensed by DOH to provide therapeutic radiology or radiation oncology):			
	• Initial purchase.	• Full Review	• Regardless of cost	• 10 NYCRR 710.1 (c)(2)(i)(b)(1)
	• Additional purchase.	• Administrative Review	• $10,000,000 or less	• 10 NYCRR 710.1 (c)(2)(i)(b)
	• Replacement purchase, if 90% depreciated or no longer meets generally accepted operational standards.	• Notification letter to DOH (even if higher capacity) as long as no construction is required[4]	• Regardless of cost	• 10 NYCRR 710.1 (c)(4)(iii)

Category	Type of Project	Type of Review	Project Cost[1]	Regulation Source
NETWORK REALLOCATION				
	Reallocation or redistribution of the following equipment or services within the same established Article 28 network (as defined in 10 NYCRR 401.1 (j)): • Magnetic resonance imagers (MRI). • CT scanners. • Extracorporeal shockwave lithotripters. • Linear accelerators as replacements for cobalt units.	Prior Review Limited to Architectural and Engineering matters	Regardless of cost	10 NYCRR 710.1 (c)(5)(i)(b); 10 NYCRR 401.1 (j)
	Reallocation, relocation, or redistribution of acute care beds from one hospital to another hospital within the same established Article 28 network (as defined in 10 NYCRR 401.1(j)) provided the hospital receiving the beds is already certified to operate the category of beds being moved.	Prior Limited Review (as long as no construction is required[4])	Regardless of cost	10 NYCRR 710.1 (c)(6)(vi); 10 NYCRR 401.1 (j)
OUTPATIENT SITES/SERVICES				
	Adult day health care services: • Initial.	• Administrative Review • Full Review	• $10,000,000 or less • Greater than $10,000,000	• 10 NYCRR 710.1 (c)(3)(i)(a)
	• Addition of services provided either in a residential health care facility (RHCF) or offsite by an RHCF that has been approved to provide the services on-site.	• Administrative Review	• Regardless of cost	• 10 NYCRR 710.1 (c)(3)(i)(m)
	• Expansion of an existing service.	• Administrative Review • Full Review	• $10,000,000 or less • Greater than $10,000,000	• 10 NYCRR 710.1 (c)(3)(i)(m)

Category	Type of Project	Type of Application	Project Cost[1]	Regulation Source
OUTPATIENT SITES/SERVICES (cont'd)	Extension clinic – operation/relocation	Administrative Review	$10,000,000 or less	10 NYCRR 710.1 (c)(3)(i)(h); 10 NYCRR 401.1
	Methadone maintenance treatment program – addition of service to the facility's main site or an extension clinic	Administrative Review	$10,000,000 or less	10 NYCRR 710.1 (c)(3)(i)(o)
	Part-time clinics: • Addition or deletion of approval to operate part-time clinics • Approval to operate each site once licensed to provide part-time clinic services, or to relocate a site • Closure of a specific site	• Administrative Review • Prior Limited Review (with specific application form) • Notification letter to DOH with closure plan at least 15 days prior to closure	• Regardless of cost • Regardless of cost • Regardless of cost	• 10 NYCRR 710.1 (c)(1)(i); 10 NYCRR 710 (c)(3)(i)(g) • 10 NYCRR 703.6 (b)(1),(2) • 10 NYCRR 703.6 (b)(3)
	Primary care sites meeting certain criteria – addition	Administrative Review	$15,000,000 or less	10 NYCRR 710.1 (c)(3)(i)(w)
PHYSICAL PLANT				
	Corrections of patient safety deficiencies, ordinary repairs and maintenance, and energy conservation	• Administrative Review • Full Review	• $10,000,000 or less • Over $10,000,000	• 10 NYCRR 710.1 (c)(3)(i)(e) • 10 NYCRR 710.1 (c)(2)

Category	Type of Project	Type of Application	Project Cost[1]	Regulation Source
PHYSICAL PLANT (cont'd)	Maintenance or repair of a medical facility that does not otherwise require a CON application, Prior Limited Review, or Prior Review Limited to Architectural and Engineering Matters, including routine purchases and the acquisition of minor equipment in the course of inventory control functions if the proposal "will not result in increased costs or expenses other than for lease costs, amortization, depreciation, interest, or return of or on equity."	No application	$3,000,000 or less	10 NYCRR 710.1 (c) (4)(i)
	Modernization of a medical facility or a portion of a medical facility that does not substantively change the capacity or type of services and does not involve issues of public need.	Administrative Review	$10,000,000 or less	10 NYCRR 710.1 (c) (3)(i)(e)
	Projects that do not exceed $3,000,000 and for which a CON application is not otherwise required involving the following: (i) facility areas relating to surgical or other invasive procedures; (ii) inpatient units, relating to other than routine maintenance and repairs or routine purchase of equipment; or (iii) heating, ventilating, air conditioning, plumbing, electrical, water supply, fixed dietary, solid waste and/or sewage disposal, and fire protection systems, other than routine maintenance and repairs or routine purchases affecting such systems.	Prior Review Limited to Architectural and Engineering Matters	$3,000,000 or less	10 NYCRR 710.1 (c) (5)(i)(a)

Category	Type of Project	Type of Application	Project Cost[1]	Regulation Source
SERVICES – ADDITION/MODIFICATION/CHANGE IN METHOD OF DELIVERY				
	AIDS center designation, except for provisions regarding AIDS beds[2].	Full Review	Regardless of cost	10 NYCRR 710.1 (c)(2)(i)(b)(6)
	Addition, modification, or change in the method of delivery of licensed service, other than set forth in 10 NYCRR 710.1 (c)(2)(i)(b)[3] (that require full review).	Administrative Review	$10,000,000 or less	10 NYCRR 710.1 (c)(3)(i)(a)
	Addition of services (other than those set forth in 10 NYCRR 710.1 (c)(2)(i)(b)[2] and 10 NYCRR (c)(3)(i) or for which a CON application is not otherwise required).	Prior Limited Review	$3,000,000 or less	10 NYCRR 710.1 (c)(6)(iii)
	Burn care.	Full Review	Regardless of cost	10 NYCRR 710.1 (c)(2)(i)(b)(5)
	Cardiac catheterization.	Full Review	Regardless of cost	10 NYCRR 710.1 (c)(2)(i)(b)(3)
	Chronic renal dialysis stations – addition by facility approved and operating stations.	Administrative Review	$10,000,000 or less	10 NYCRR 710.1 (c)(3)(i)(v)
	Emergency department – expansion or modernization.	Administrative Review	$10,000,000 or less	10 NYCRR 710.1 (c)(3)(i)(i)
	Epilepsy.	Full Review	Regardless of cost	10 NYCRR 710.1 (c)(2)(i)(b)(8)
	Existing services – additions not involving an additional site or beds	Administrative Review	$10,000,000 or less	10 NYCRR 710.1 (c)(3)(i)(d)
	Kidney, heart, liver, and bone marrow transplantation.	Full Review	Regardless of cost	10 NYCRR 710.1 (c)(2)(i)(b)(4)
	Open heart surgery services.	Full Review	Regardless of cost	10 NYCRR 710.1 (c)(2)(i)(b)(2)
	Swing Bed Demonstration Program.	Administrative Review	$10,000,000 or less	10 NYCRR 710.1 (c)(3)(i)(u)
	Therapeutic radiology (other than the replacement of a cobalt unit with a linear accelerator by a facility that has been licensed to provide therapeutic radiology or radiation oncology services).	Full Review	Regardless of cost	10 NYCRR 710.1 (c)(2)(i)(b)(1)

Category	Type of Project	Type of Application	Project Cost[1]	Regulation Source
	Ventilator dependent service – addition	Administrative Review	$10,000,000 or less	10 NYCRR 710.1 (c)(3)(i)(t)
	Proposals eligible for administrative review but that exceed the facility's administrative review limitation set forth in 10 NYCRR (c)(3)(ii)(a).	Full Review	Regardless of cost	10 NYCRR 710.1 (c)(2)(i)(e); 10 NYCRR 710.1 (c)(3)(ii)(a)

1. Certain projects over $10,000,000 may be eligible for administrative review, assuming certain conditions are met. See the last item under "other" above.
2. See "BEDS" above, for description of provisions regarding AIDS beds.
3. 10 NYCRR 710.1 (c)(2)(i)(b) – The following services are listed in this subsection: therapeutic radiology; open heart surgery; cardiac catheterization; kidney, heart, liver, and bone marrow transplantation; burns care; AIDS centers (with certain exceptions); magnetic resonance imagers (MRIs); and epilepsy services.
4. In those circumstances, if construction is required, either Prior Review Limited to Architectural and Engineering Matters or Administrative Review may be required.