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**Report of the Public Health and Health Planning Council:
Administrative Streamlining Recommendations for New York State's Certificate of Need Program**

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This report represents the completion of the first phase of the Public Health and Health Planning Council's effort to re-design the State's certificate of need (CON) process. This phase focused on administrative streamlining of the process. It began last fall with the solicitation and receipt of recommendations from stakeholders. Over the course of six meetings, which included joint meetings with the Public Health Committee, the Planning Committee reviewed background papers on CON and health planning in New York, discussed recommendations submitted by stakeholders, developed its own recommendations, and heard from members of the public who spoke at each meeting. The Committee also developed a mission and vision for CON in New York and adopted a set of principles to guide its work (see attached).

The next phase of the PHHPC's CON redesign work will begin with the adoption of this report and will involve a more fundamental re-thinking of CON. Over the next six to nine months, the Committee will undertake a more thorough examination of the role and structure of CON in the context of health care reform. Based on the mission and vision for CON adopted by the PHHPC, this effort will seek to re-design New York's certificate of need (CON) program to promote the alignment of health care resources with community health needs and the development of high-quality, integrated and coordinated systems of care. It will examine the role and appropriate scope of CON and will identify policy levers other than CON (such as licensure, surveillance and payment) to promote positive change in the delivery system, where CON is ill-suited to do so. Finally, to promote the effectiveness of CON and healthy communities, PHHPC's work will include recommendations concerning the future role, funding and organization of regional or local health planning activities.

Accordingly, the following recommendations lay the groundwork for the next phase of the PHHPC's work by focusing the review process on appropriate projects and narrowing the scope of certain aspects of the review. They represent initial steps to streamline the CON process. Most of these initiatives can be implemented, at least partially, without legislation. Some require changes in regulation, which often take six months or more from inception to adoption, but others can be implemented immediately.

- **Eliminate “certificate of need” review of certain construction projects, while retaining oversight of compliance with construction standards for licensure purposes.**

This proposal would limit certificate of need (CON) to a core set of projects for which control of supply and distribution of health care is an accepted objective and for which a needs assessment is relevant. Accordingly, public need reviews and many financial reviews would be eliminated for construction projects that do *not* involve:

- Additions, decertifications, or re-purposing of beds,
- New extension sites,
- Changes in ED or surgery capacity,
- Major new medical equipment ;
- Major new service,
- Facility replacement or relocation; or
- Closing facilities, extension sites, or services.

Projects that involve changes in capacity, services, location of a facility, or major medical equipment, such as an increase or decrease in beds, the addition of transplant services, or the purchase of an MRI or CT scanner in a diagnostic and treatment center would continue to be subject to CON.

Projects exempt from CON review under this proposal would include physical plant modernization and reconfiguration projects, such as renovations to shift from double rooms to single rooms or to consolidate pediatric or women’s health services in a single building or wing. These projects, although exempt from CON, would continue to be subject to licensure reviews, in the same way that such projects are reviewed in states without CON. This would include reviews or other oversight to ensure that projects are constructed in compliance with physical plant standards such as the Life Safety Code and the FGI Guidelines.

The PHHPC recognizes that there are risks associated with eliminating the review of capital costs and financial feasibility for these projects. For example, there is a risk that unfettered capital investment will unnecessarily drive up Medicaid spending, putting pressure on the State’s global Medicaid spending cap. The PHHPC recommends that the Department, in consultation with stakeholders, develop and implement mechanisms to monitor and address increases in Medicaid spending due to the relaxation of CON requirements.

Further, there is a risk that, in an effort to boost thin or negative margins, facilities may attempt to attract new patients and physicians from their competitors by investing in modernization projects that they cannot afford, thereby jeopardizing their survival. In order to mitigate this risk, the PHHPC recommends that the Department take steps to ensure the feasibility of capital projects undertaken by financially fragile providers. For example, the Department could conduct a financial review of the construction projects undertaken by facilities that fail to meet financial benchmarks or metrics specified by the Department.

This initiative requires statutory change for complete implementation and regulatory change for partial implementation.

- **Reduce the number of outpatient services subject to licensure/certification.**

There are currently 60 different services which a diagnostic and treatment center (D&TC) or hospital outpatient clinic may be licensed to provide and which may appear on the facility's operating certificate.

To add or remove a service from an operating certificate requires -- at minimum -- a Limited Review Application (LRA). DHFP received 86 applications to add or decertify a service in 2011, of which approximately 60 related to outpatient services. In addition, to these LRAs, DHFP receives full and administrative review applications that include the addition or decertification of an outpatient service as one component. All applications require the applicant to dedicate time and resources and the Department to dedicate resources to processing and issuing a new operating certificate. In addition, the application requires a filing fee -- for an LRA, the fee is \$500, or \$250 for safety net D&TCs.

The PHHPC proposes eliminating approximately 40 of the 60 services eligible for outpatient certification and creating an inclusive category of "medical services." Services that are not eligible for licensure may nevertheless require an architectural review, if construction is required to create the service, in order to ensure the safety of the physical plant. For example, construction related to installing a hyperbaric chamber or lithotripter would be subject to architectural oversight, even though the service would not be subject to licensure.

In addition to eliminating the certification requirement for various services, this proposal entails creating a new category of "medical services." Currently, "primary medical care" is used as the ~~catch-all~~inclusive category and often mischaracterizes the nature of the services delivered in certain facilities. The "medical services" category would include any primary or specialty care that is not encompassed by the other services.

The following services would be subject to licensure in outpatient settings:

- Medical services
- Abortion
- AIDS adult day health care
- Ambulatory surgery – multi-specialty
- Ambulatory surgery – gastroenterology
- Ambulatory surgery – ophthalmology
- Ambulatory surgery – orthopedics
- Ambulatory surgery – pain management
- Birthing center
- Part-time clinic services
- School-based services
- School-based dental services
- Dental
- Home hemodialysis training and support
- Home peritoneal dialysis training and support
- Lithotripsy
- Therapeutic radiology

- MRI and CT scanner – D&TC only
- Podiatry
- Renal dialysis
- Upgraded D&TC services
- TBI program
- Hospital-based methadone maintenance, chemical dependence, certified mental health (these services would continue as Article 28 services only for hospital-based facilities and only on an interim basis until statutory changes are made to permit reimbursement of hospital-based facilities through licensure under the Mental Hygiene Law).

In order to track the availability of services that would no longer be listed on the operating certificate, the Department should create an on-line registration process that would be completed by providers seeking to offer or discontinue the following services:

- Audiology
- D&TC certified mental health services
- D&TC chemical dependence
- D&TC methadone maintenance
- Clinical laboratory (licensure by the Wadsworth Laboratory would continue to be required)
- Family planning
- Hyperbaric chamber
- Nuclear medicine
- County public health nursing
- Ophthalmology
- Optometry
- Pediatrics
- Pharmacy
- Prenatal care
- Primary care
- Psychology
- Diagnostic radiology (indicating X-ray, CT, MRI, or PET)
- Physical therapy
- Occupational therapy
- Respiratory therapy
- Speech therapy
- Vocational rehabilitation
- Transfusion services – full
- Transfusion services – limited
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Existing outpatient services that are neither licensed nor subject to registration would not be tracked.

- **Streamline the process for adding outpatient behavioral health services and delivering integrated behavioral health and physical health services.**

Currently, hospital outpatient clinics and diagnostic and treatment centers (D&TCs) that seek to offer services licensed by OMH or OASAS (e.g., mental health clinic services, chemical dependence services, or methadone maintenance services) must apply to both DOH and the appropriate mental hygiene agency (OMH or OASAS).

The PHHPC recommends that Article 28 providers that are not licensed by OMH or OASAS be permitted to add outpatient behavioral health services by seeking certification from the relevant mental hygiene agency only (not DOH). For D&TCs, this would entail submitting the necessary application to OASAS or OMH as appropriate. For hospital-operated outpatient clinics, Article 28 certification of behavioral health services is currently required by statute for reimbursement purposes. Accordingly, DOH would accept the decision made by OASAS and OMH on its application.

The Department should seek a change in sections 17 through 23 of Part C, of Chapter 58 of the Laws of 2009 in 2013 to permit OMH and OASAS certification of these services for reimbursement purposes. In addition, the Council supports the work of the Department, OMH and OASAS in developing a simplified process for provider organizations that are already licensed by more than one agency to add services at sites that are not currently licensed to provide those services. For example, an organization that operates an outpatient primary care clinic licensed by DOH at one site and a mental health clinic at another site could, through this streamlined process, add mental health clinic services to the primary care site and primary care services to the mental health site. Such integrated services sites should be subject to a single set of operating standards and unified surveillance to facilitate the delivery of integrated services.

- **Architecture and Engineering**

The CON process includes an architectural/engineering review that serves two purposes:

- Assuring that the proposed facility is appropriately sized for the proposed functional program. The cost review checks to ensure that the proposed capital costs are appropriate.
- Assuring that the proposed physical plant is compliant with health care facility construction standards, including among other elements fire safety and infection control.

Hospitals, outpatient facilities, and nursing homes present a number of unique physical plant safety issues, including occupants who may be unable to ambulate and evacuate in the event of a fire and infection control challenges related to communicable disease, invasive procedures, and patients with open wounds or compromised immune systems.

The architectural/engineering review spans from the receipt of a CON application through the CON approval to the completion of construction and opening of the facility or renovated space. It relates to both the CON review and the licensure of the facility.

Often, CON applicants do not submit complete architectural plans with their CON applications. Instead, they submit schematic drawings which can be used to determine whether the proposed space can be constructed in a compliant manner. Once the CON is approved, they develop complete drawings that can be used to determine whether the facility will be compliant with the State's hospital and nursing home regulations (which incorporate NFPA Life Safety Code and the Facilities Guidelines Institute standards).

Over the past decade, the number of architects and engineers in the Department has diminished. At present, the Department does not have an engineer on staff. As a result, a backlog of projects requiring architectural review has accumulated. The Department has undertaken two initiatives to reduce the backlog:

- Piloted self-certification by architects/engineers retained by applicants for certain projects under \$15 million;
- Allowed applicants to contract with DASNY for architectural reviews.

In order to reduce the workload of the architects, while maintaining appropriate oversight of the safety of health care facilities, PHHPC recommends that:

- the Department exclude the architectural review from the PHHPC exhibit;
- the Department conduct solely a cursory architectural review prior to CON approval to determine only whether the proposed building can be made compliant with Article 28 standards;
- focus efforts on the post-CON licensure aspect of the process (e.g., physical plant safety).

With respect to the post-CON process, the PHHPC recognizes the importance of providing state oversight of the design of health care facilities in order to protect the safety of patients and promote high quality health care. Given this policy imperative and insufficient staffing in the architectural unit of the Department, the PHHPC recommends that DOH continue the self-certification process with additional safeguards. It recommends that high risk projects, such as surgical suite renovations, new ambulatory surgery centers, bulk oxygen and medical gas storage facilities, locked inpatient or residential units, and new hospital and nursing home construction be ineligible for self-certification. In addition, the PHHPC recommends that the Department's architecture bureau or DASNY conduct routine audits of a percentage of the self-certified projects and identify architects and engineers who design non-compliant projects and disqualify them from self-certification. The Department should also consider disqualifying from self-certification any architect or engineer who is disqualified by New York City's Department of Buildings from self-certifying to the compliance of their projects.

The PHHPC recommends an expansion of DASNY's role in architectural reviews. DOH should contract directly with DASNY to conduct reviews of a portion of the projects that are ineligible for self-certification and, in particular, any project requiring engineering expertise. Other projects that are not subject to the DOH-DASNY contract could be reviewed by DASNY at the option of the applicant, subject to payment of the DASNY fee. The remainder of the projects should continue to be reviewed by the DOH architectural bureau.

- **Amendments to Approved CONs**

DOH regulations require that amendments of approved projects receive another full review including a recommendation by the PHHPC. Amendments are defined to include (among other changes):

- A change in the financing of the project, unless the applicant demonstrates that the change will not result in a more expensive project for third-party payors or if the change represents less than 10 percent or less than \$15M whichever is less;
- An increase in the total construction cost in excess of 10 percent or \$15 million whichever is less;
- A reduction in the scope of the project which accounts for 10 percent or more of the total costs without a corresponding reduction in construction costs.
- A substantial change in any agreement to construct, renovate, or acquire, through a purchase, lease or other arrangement, any land or building.

The PHHPC recommends that these types of amendments based be processed administratively, without PHHPC review. However, amendments that involve an increase in the scope of a project, along with an increase in cost, a change in financing or a change in an agreement, would continue to be subject to full review.

This recommendation would require changes in regulation.

- **Permit administrative conversions of operating certificates with a limited duration to an indefinite duration.**

The PHHPC has occasionally approved establishments of new operators on a time-limited basis. In those cases, typically ambulatory surgery centers or other D&TCs, the operator's authority to provide health care services expires. The operator must file a report documenting compliance with various conditions of its CON approval and apply for renewal of its establishment. These renewal applications are presented to the PHHPC.

The PHHPC recommends that when a provider is approved on a time-limited basis, the operating certificate, rather than the establishment, be assigned an expiration date. If the provider complies with the conditions of its CON (including access by Medicaid beneficiaries) and exhibits a strong compliance record, the provider's operating certificate could be renewed without PHHPC review. Any applicant that fails to satisfy its CON conditions (including its commitment to serve Medicaid beneficiaries or other special populations or geographic regions) would be required to be presented to the PHHPC for approval. The Department would retain the discretion to bring renewal applications to the PHHPC, and providers would have an opportunity to appeal a denial of renewal to the PHHPC.

The Department should report at least annually to the PHHPC on the administrative conversions of operating certificates to indefinite duration. This report should include the Department's findings with respect to compliance with the CON conditions.

This initiative would require a change in regulations and would apply prospectively to establishments approved after the adoption of the regulations.

- **Streamline process for changes in ownership of less than 10% that amount to a 25% change over 5 years.**

Under this initiative, Article 28 limited liability company and partnership operators that undergo several small changes in ownership over a 5-year period that amount a change of 25 percent or more of the ownership in the organization would no longer have to submit a full CON application, but would be able to file an abbreviated application. By statute, these applications would be presented to the PHHPC for approval. However, the Department should consider seeking statutory changes to permit administrative approval of such applications by the Department. In the event that the statutory requirement of PHHPC review is eliminated, the Department should, nevertheless, report periodically to the PHHPC on significant ownership changes that are processed administratively.

- **Rationalize character and competence reviews of proposed new operators of health care facilities and home care agencies.**

Currently, the PHHPC approves or disapproves proposed operators of health care facilities and home care agencies based on the proposed operator's experience and record of compliance with various laws. The Public Health Law precludes approval of proposed operators who have been an owner or director of a licensed facility in the past ten years, unless the PHHPC finds that a substantially high level of care has been rendered in such facility. This is known as the "ten-year lookback period."¹ The PHHPC cannot find a substantially high level of care, if there were violations that threatened to affect directly the health, safety or welfare of any patient or resident and that were recurrent or not promptly corrected.²

The ten-year lookback period has become burdensome for providers and Department of Health staff, particularly when proposed operators have affiliations with out of state facilities. Moreover, it is not clear that the ten-year lookback adds value to the review process. The fact that a facility was cited in 2002 and 2012 for two serious violations is not necessarily indicative of poor care in that facility. If the violations were promptly corrected and the facility took appropriate steps to prevent a recurrence, it may be inappropriate to disqualify its board members or owners from involvement in other facilities. Yet, the statute requires disqualification.

In addition, where a proposed operator is affiliated with facilities in other states, the Department frequently experiences difficulty in obtaining the necessary information from out-of-state regulatory agencies to assess the proposed operator's compliance record, particularly when the facilities in question are hospitals or ambulatory care facilities.

¹ The ten-year lookback is not required by statute for home care agencies licensed under Article 36 or hospices licensed under Article 40.

² N.Y. Public Health Law §2801-a(3).

The PHHPC recommends the following steps to alleviate the burden of character and competence reviews:

- Permit proposed operators of hospitals and diagnostic and treatment centers to submit affidavits concerning out-of-state compliance record, if other states do not provide requested information concerning compliance; and
 - Reduce the statutory lookback period from 10 years to 7 years.
- **Continue implementation and enhancement of NYSE-CON, incorporating performance measures and timelines for review.**

Under this continuing initiative, the PHHPC recommends that New York State Electronic Certificate of Need (NYSE-CON) system be enhanced to facilitate the CON process from application submission to the Department through operating certificate issuance and data storage. Expanding the NYSE-CON system to cover the full scope of the project approval process will improve applicant interaction with the Department and streamline business processes. This, in turn, will reduce timeframes for project completion and improve transparency of the process for all stakeholders. Specific enhancements should include project tracking data and search functionality, including project review milestones that will permit Department managers to generate a variety of reports related to workload, review time, efficiency and performance.

In addition, the PHHPC recommends that enhancements include improvements in the public access to CON, notice and licensure information. Additional information concerning proposed construction projects, service additions, and establishments should be made available to the public through NYSE-CON. This should include automated notifications of status changes in projects.