PHHPC

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DRAFT

I. A HEALTH CARE DELIVERY SYSTEM IN TRANSITION

New York State is charting a new course in health care aimed at bending an unsustainable cost curve and improving population health through innovations in payment and care models. We are doing so in response to significant challenges. An epidemic of chronic disease is crippling individuals and taking an economic toll. Health care spending is almost 18 percent of the gross domestic product (GDP) in 2011 and projected to reach 20 percent by 2020.[1] At the same time, government support for health care providers is shrinking, and safety net providers are struggling to stay afloat. While we spend a disproportionate amount on health care, the quality of the care we purchase and the outcomes we experience are too often less than optimal.[2] And, health care quality, outcomes and accessibility are too often worse for racial and ethnic minorities and low-income people.[3]

Through the Affordable Care Act (ACA) and the initiatives advanced by Governor Cuomo's Medicaid Redesign Team, New York State is tackling these challenges. The ACA and the MRT have responded to the Triple Aim imperatives of bending an unsustainable cost curve, improving quality and improving population health by promoting new models of care and payment. These patient-centered care models emphasize care coordination, chronic disease management, and reduction of preventable inpatient admissions. New payment models are replacing fee-for-service payments that reward volume and expensive services with value-based and risk-based payments that reward prevention, discourage unnecessary utilization, and penalize preventable healthcare-acquired conditions.

To capitalize on innovative payment arrangements, providers and payers in New York are forging new relationships. Providers are not only forming Medicare accountable care organizations (ACOs), but also patient-centered medical homes (PCMHs), health homes for Medicaid beneficiaries with chronic conditions, and other integrated systems of care.

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[1] National Health Expenditure Projections 2010-2020, CMS Office of the Actuary, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2010.pdf .

[2] AHRQ. National Health Care Quality Report, 2011, Key Themes and Highlights, available at. http://www.ahrq.gov/qual/nhqr11/key.htm

[3] AHRQ. National Health Care Disparities Report, 2011, Key Themes and Highlights, available at http://www.ahrq.gov/qual/nhqr11/key.htm

Hospitals are expanding their regional reach and their ability to leverage beneficial payment arrangements from payers and purchasers by affiliating with facilities outside of their primary service areas. They are also partnering with physician practices to enhance their ability to coordinate care along the continuum and strengthen referral relationships. Independent physician practices are growing in size, scope and market power and organizing large IPAs. Multi-specialty physician practices that offer surgery, imaging and even radiation therapy services are emerging. The silos between behavioral health and physical health are breaking down, and behavioral health and physical health care providers are integrating and co-locating services. Long-term care systems are coalescing to link nursing home care with home care, hospice, and assisted living. Hospitals, nursing homes, and home care agencies are creating linkages to strengthen post-discharge care and prevent readmissions.

Collection, analysis and exchange of individual and population health information are critical elements of these models. Interoperable electronic health records (EHRs) support communication and coordination among providers, electronic alerts promote adherence to evidence-based practices, and patient registries support public health initiatives, chronic disease management and performance improvement.

New models of care and payment are creating tremendous opportunities for health care consumers, providers and payers in New York. The movement toward horizontal and vertical integration holds promise in improving quality and outcomes through better care coordination, robust data analysis, systematic performance improvement, and the ability to align incentives and manage risk. Payment arrangements that reward health have the potential to reduce fragmentation in the delivery system and preventable and unnecessary utilization, while improving population health. The scale of integrated systems may produce administrative efficiencies and enable providers to spread fixed costs. Together, all of these factors have the potential to bend the cost curve and improve the quality of life for New Yorkers.

At the same time, the new alignments and payment arrangements face challenges and pose significant risks. Large integrated systems and physician practices that accept risk-based reimbursement raise financial, quality and access concerns for New York State and its health system, including:

- **Cost and Quality:** Vertically- and horizontally-integrated health systems and large physician practices may absorb or overwhelm their competitors and exercise market power to drive up prices, without improving quality or access. They may reduce options for consumers who should have the opportunity to choose among high-quality health care providers.
- **Managing Risk:** Health systems and physician practices may manage payment risk unwisely. If they become dominant in a region and fail, they may bring down the entire delivery system in that region.
- **Access to Medically-Necessary Care:** In an effort to manage payment risk, providers may become over-zealous in their efforts to control costs and institute practices that restrict access to necessary care.

- **Viability of Essential Providers and Disparities:** Essential and safety net providers may be destabilized by the growth of physician practices and integrated systems. As physician practices grow in size and scope, they may attract lucrative patients and eliminate an important source of revenue for safety net providers, while declining to serve Medicaid beneficiaries and uninsured. In addition, essential providers that serve rural or low-income communities may be left behind in the race to create integrated systems. They may lack the capital, administrative depth, or patient volume to attract partners and may be forced to close their doors.

The recommendations in this report seek to strengthen CON and regional planning to mitigate the risks posed both by today's delivery system and tomorrow's. As a regulatory tool that *directly* impacts only the supply and distribution of health care resources, CON is not well-suited to addressing most of these risks. However, it can be used as a tool to promote access to services and protect the viability of essential providers. Other tools, such as the antitrust laws or the emerging certificate of public advantage process, insurance laws, the incipient accountable care organization (ACO) certification regulations, grants, and physician discipline process may provide more effective responses to the above risks. Regional planning, in particular, can help to ensure that the transformation of the delivery system proceeds in the best interests of all New Yorkers.

II. ADVANCING THE TRIPLE AIM THROUGH REGIONAL PLANNING

A. <u>Recommendation #1:</u>

Regional planning can be an effective tool to bring together a broad range of stakeholders to advance the Triple Aim. In this time of rapid change, health planning should be reinvigorated on a regional basis through multi-stakeholder collaboratives to promote improvements in the patient experience of care (including quality) and the health of populations and reductions in the per capita cost of care.

The Council endorses the following principles for collaborative regional planning:

- Regional health planning should focus on both health and healthcare, including behavioral health, and should be coordinated with the local planning process for mental hygiene services.
- New York's regional health planning policies should permit diverse governance structures, based on regional circumstances and stakeholder interests, in order to promote stakeholder buy-in.
- Regional planning activities must include representation, formal engagement and meaningful participation of all affected stakeholders.
- Regional planning entities must collect, analyze, and display data in a neutral manner.
- The State must be engaged in overseeing the strategic direction and high-level goals of regional planning. It should establish benchmarks for performance and

evaluate outcomes. It should also encourage participation in regional planning through policy levers, such as grant awards.

- The State should develop a common data set to support regional planning activities and to permit comparisons among regions.
- Planning should address the financial stability of the health care delivery system.

B. Recommendation #2:

PHHPC recommends the creation of multi-stakeholder Regional Health Improvement Collaboratives (RHICs) to conduct regional planning activities.

The RHICs should have the following characteristics:

- They should be a neutral and trusted entity. They should not be controlled by any single stakeholder or type of stakeholder. The governance structure of the RHICs should be representative of a variety of stakeholders and sectors that impact, or are impacted by, health and health care issues.
- Key stakeholders that should be actively engaged and included in the governance of a RHIC include: consumers, local public health officials, health and behavioral health care providers across the continuum, payers, business, unions and community-based organizations. Other interested parties that should be engaged include schools and institutions of higher education, local governments, transportation-related entities, and housing-related entities.
- RHICs should be supported, at least in part, by State grants.
- RHICs should have capable executive leadership with sufficient experience and expertise to assume the responsibilities set forth below.

C. Recommendation #3:

PHHPC recommends the creation of 11 geographic planning regions.

- The PHHPC recognizes that no regional map will perfectly reflect all of the factors relevant to health planning. Health care consumers, disease, and public health emergencies will cross regional boundaries.
- The regions pictured on the attached map take into account existing health planning infrastructure, including local health department collaborations, regional planning organizations, and rural health networks. Although not identical to the Governor's Economic Development Council (EDC) regions, the RHIC regions attempt to minimize the number of EDC regions to which any RHIC would relate.
- Consistent with the RHICs' charge to address both population health and health care issues, and the increasing emphasis on ambulatory care in our evolving health care delivery system, the proposed planning regions are not based exclusively or principally on inpatient referral patterns or migration for high acuity care.
- Given the permeability of state, county, and regional boundaries, sub-regional and inter-regional activities, as well as consideration of interstate issues, will be important to optimize the impact of the RHICs.

D. Recommendation #4:

Each RHIC should be responsible for advancing each dimension of the Triple Aim in its region.

RHICs should convene and actively engage stakeholders, analyze data, and develop a consensus around strategies to promote:

- Improvements in population health that advance at least two State Health Improvement Plan (SHIP) priorities selected by community stakeholders based on community needs. RHICs should measure performance against SHIP metrics and report on them transparently and publicly, commit to improvements in these metrics in a defined time period, and use evidence-based strategies to achieve stretch goals.
- Improvements in the patient experience of care. Some examples of activities that might be pursued in this area include:
    i. Measurement of health system performance and publication of quality data based on specified metrics;
    ii. Leading a quality collaborative;
    iii. Technical assistance in support of development of PCMH;
    iv. Identifying evidence-based patient and community engagement activities and supporting implementation.
- Reductions in the per capita cost of care. Some examples of appropriate activities include convening, analytics, and technical support for:
    i. Strategies to reduce preventable utilizations of services, such as implementation of evidence-based practices concerning use of diagnostic imaging, or PQI admissions;
    ii. Health and health care needs assessments;
    iii. Development of multi-payer, value-based payment and benefit design initiatives;
    iv. Publication of quality, cost, and spending data;
    v. Collaborations that improve efficiencies in health care delivery and the financial stability of essential providers.

Within each of the dimensions, RHICs will be expected to incorporate strategies to reduce health and health care disparities, whether racial, ethnic, socioeconomic or disability-based. RHICs may also choose to address workforce issues, including recruitment, retention, and training of health care workers. RHICs should work with the Regional Economic Development Councils to address health and health care issues that impact the economy, business and employment.

RHICs may also make recommendations in connection with state grants, including the 1115 waiver funding. They may be consulted concerning regional needs that could be addressed through State grants and/or the development of requests for applications and the criteria that should be applied in making awards. They may also choose to submit letters of support in relation to grant applications from their regions. Notably, the State's 1115 waiver amendment repeatedly indicates that applicants for funding that have the support of regional planning entities will be given preferential treatment.

E. Recommendation #5:

The PHHPC should consult with the RHICs concerning the regional health and health care environments, unmet needs, and effective planning strategies and interventions that could be disseminated statewide to advance the Triple Aim and eliminate health and health care disparities.

II. DRIVING HEALTH SYSTEM PERFORMANCE THROUGH CERTIFICATE OF NEED AND LICENSURE

CON is one of several regulatory tools that can be used to drive health system performance. It seeks to impact the supply and distribution of heath care resources with the goals of curbing the development of excess capacity (especially in supply-sensitive services); consolidating the volume of highly-specialized services in a limited number of facilities in order to promote quality; and channeling the development of services where they are needed. It has been used to protect safety net providers and community hospitals from destabilizing competition that could jeopardize essential services and access. It has also been used as an all-purpose lever to condition market entry or expansion on actions that support policy goals (e.g., Medicaid access or charity care). This is a controversial use of CON programs, but is credited with protecting access for low-income individuals.

However, CON is a blunt instrument – an on/off switch – that does not ensure that an approved facility or home care agency will operate efficiently, will be accessible to low-income patients, will realize its projected revenues, or will provide high quality care. It can curb development in saturated markets, but cannot effectively promote development in under-served areas without capital and ongoing operational funding. Nor can it effectively prevent the closure of a service or facility without a source of revenue or workforce to preserve it.

The current CON process exhibits several shortcomings in relation to health care trends and the risks posed by those trends:

- It impacts only supply and distribution of health care services; not demand. It does not affect the health status of populations nor the delivery system failures that may generate preventable utilization and excess spending;
- It does not cover services provided by physician practices that may destabilize essential providers or drive up health care spending;
- It may delay the development of licensed primary care sites that may be needed to address the needs of newly-insured New Yorkers and support new systems of care;
- Its process for reviewing the character and competence of health care facility and agency operators is misaligned with the growing complexity of health care organizations, the need to develop integrated systems, and the authority exerted by non-established entities.

The recommendations in this report seek to mitigate those shortcomings.

Licensure is another tool that can address health system risks – principally risks associated with quality and safety. In New York, CON and licensure are intertwined, with the license or operating certificate representing the final product of CON decisions. As discussed in more detail below, the Council recommends that where CON is rolled back through this redesign process, the State retain its licensure responsibilities where appropriate. In addition, the State should strengthen its ongoing monitoring and surveillance to promote quality and financial stability. It should have the authority it needs to respond effectively when quality and financial stability deteriorate.

A. Recommendation #6:

PHHPC recommends eliminating CON for primary care facilities, whether D&TCs or hospital extension clinics.

An expansion of primary care is necessary to serve New Yorkers who will be newly-insured under the ACA and to implement the new models of care envisioned under the ACA and the MRT initiatives. Furthermore, primary care does not exhibit the qualities that typically trigger the need for CON review -- is not supply- or volume-sensitive or capital intensive. Few states cover primary care facilities in their CON programs. The value of imposing a CON review on primary care facilities in light of the need for primary care capacity appears limited.

In order to qualify for this exemption, applicants would have to employ a physician practicing in the specialty of internal medicine, family medicine, pediatrics, obstetrics or gynecology. They would have to commit to provide one or more of these services on-site. Facilities that provide or are intended to provide imaging, radiation therapy, dialysis, or surgery services, however, would not be eligible for this blanket exemption. These services are capital-intensive and, in some cases, supply-sensitive, and require review.

Although exempt from CON, primary care facilities would be required to obtain a license (operating certificate). The licensing process would proceed like the process in States without CON:

- New operators would have to be approved based on character and competence and quality as described in Part IV below.
- Applications by established operators to create new D&TCs or extension sites would also be subject to review based on compliance and the quality of care provided by the operator. A sub-standard operator should not be permitted to expand its operations.
- Physical plants would have to be reviewed for compliance with health care facility construction standards.
- It has been brought to the Council's attention that access to primary care in under-served areas has, on occasion, been threatened when hospital and FQHC acquisitions of physician practices have been delayed by CON, and in particular

by the need to comply with the construction standards. The Council understands that licensed health care facilities receive higher rates of payment from Medicaid and Medicare, in part due to their compliance with these standards. The Council urges the Department to work with stakeholders to create a process by which access to primary care can be preserved when a physician seeks to retire or transfer his/her practice, without compromising patient safety or paying inflated rates for non-compliant facilities.

B. Recommendation #7:

Projects funded with time-sensitive State Department of Health grants should be exempt from public need review and subject to limited financial review.

Health care facility projects approved in their entirety through a request for applications (RFA) issued by the Department of Health should not be subject to a full-blown CON process. Through the award process, they have been determined to fulfill a public need, and their financial plan has been deemed reasonable. Regional health planning considerations can be captured through the award criteria set forth in the RFA or through endorsements or recommendations submitted by the RHICs along with the applications.

Some financial review may be necessary in relation to issues that were not reviewed as part of the grant award process. These projects will also require a construction application for purposes of physical plant oversight and issuance of an operating certificate, if applicable.

Projects that include both components approved through an RFA process and components that were not part of the RFA should not be eligible for this exemption.

C. Recommendation #8:

The Department of Health should enter into a contract with a research institute to evaluate emerging medical technologies and services that might be appropriate for CON.

New York State's health care delivery system should be at the forefront of innovation in medical care. However, the Council is concerned about the broad dissemination of capital-intensive, emerging technologies before they have demonstrated their value. Premature adoption of emerging medical technologies may drive up health care spending without improving outcomes. In particular, the Council notes that utilization of advanced imaging technologies has grown dramatically over the past decade and has raised concerns not only about associated costs, but also about unnecessary radiation exposure. Similarly, the use of robotic surgery appears to be growing despite limited evidence concerning its impact on quality, safety and outcomes.

The Council recognizes that it is difficult for the State to remain on top of the latest developments in medical technology and to update its regulations as new and expensive technologies emerge. The Council also recognizes that other specialized services, in addition to cardiac and transplant, might be appropriate for CON due to a strong volume-

quality association. The Council recommends that the Department contract with an academic or research institution to identify capital-intensive technologies and volume-sensitive services that might be appropriate for CON. The Department should consult with the PHHPC concerning the recommendations of the research institute and the adoption of policies in response to those recommendations.

D. <u>Recommendation #9:</u>
CON for hospital beds should be retained at least in the short run and reconsidered in the next three to five years.

The Health Planning Committee discussed whether review of public need for hospital beds should be continued, given the growth of payment incentives that discourage admissions. It reviewed data on hospital occupancy and staffed bed rates and noted that in most counties, occupancy rates of certified beds are below 75 percent and less than 75 percent of the certified beds are staffed. In many counties, less than 50 percent of beds are staffed. This suggests that hospitals are voluntarily taking beds out of service in response to diminished demand.

The Council has concluded that, in the future, payment incentives may eliminate the supply-sensitivity of hospital beds. However, the penetration and impact of new payment mechanisms have not yet been fully realized. As hospitals transition from an inpatient-centered system to a patient-centered one, many are still trying to maximize "heads in beds." Given NYS's poor ranking on avoidable hospitalizations and cost, and its excess inpatient capacity, CON for hospital beds should be retained. This recommendation should be reexamined within the next 3 to 5 years.

E. <u>Recommendation #10:</u>
Use Certification of ACOs to Promote Appropriate Distribution of Facilities and Services and SHIP Goals

As the delivery system shifts toward integrated systems of care that receive the majority of their revenues through capitated or risk-based payments, the utility of CON becomes less clear. If providers are not paid on a fee-for-service basis, but rather are paid a fixed amount to keep people healthy, for example, the incentive to develop unnecessary capacity is significantly reduced.

Existing state regulations exempt health care providers operated by HMOs from CON requirements. Arguably, the same rationale that justifies an exemption for HMO-operated facilities could be applied to providers that receive principally risk-based reimbursement and participate in ACOs.

The Health Planning Committee considered recommending the elimination of CON requirements for providers that are participating in ACOs and receiving a majority of their revenue from risk-based payment arrangements. However, the Committee

concluded that it would be premature to make such a recommendation at this time. The current crop of Medicare-designated ACOs in New York are being paid on a fee-for-service basis with shared savings. It is unclear whether true risk-based payment methodologies will take hold (e.g., methodologies that involve both upside and downside risk or capitation) and have the anticipated effects.

The State is developing a certification process for ACOs, but has not implemented it at this time. The PHHPC recommends that the Department consult with the Council concerning the ACO certification process. This process could be a vehicle for ensuring that essential services are preserved and that population health, access and quality concerns are addressed. The certification process should also take into account the risk that payment models will promote inappropriate under-utilization of medically-necessary services. The applicability of CON to such providers should be reconsidered once the ACO certification process is finalized.

F. Recommendation #11: Update the CON Process for Hospice

The Council recommends that the Department examine its public need methodologies and identify those that require updating. In particular, the hospice need methodology should be updated. This methodology relies heavily on the incidence of cancer. It is well-established that hospice care is appropriate for a wide variety of terminal conditions in addition to cancer.

New York State has highest rate of Medicare inpatient days during the last 6 months of life (tied with NJ) and among lowest rates of hospice use among Medicare beneficiaries nationwide. (Dartmouth Atlas on Health Care, 2003-2007). Many factors undoubtedly contribute to the apparent under-utilization of hospice in New York –our CON process likely plays a minimal role. Nevertheless, these data suggest the need for interventions to expand access to hospice care. Updating our CON process is one place to start.

G. Recommendation #12: Update the CON Process for Pipeline Projects

DOH should take steps to ensure that public need is accurately evaluated when projects are in the pipeline. Specifically, providers should not be permitted to retain CONs for extended periods without bringing the approved project to completion and providing the approved services. This practice of "banking" a CON creates an illusion that public need is met and prevents other CON applicants from obtaining the approval necessary to provide needed services.

A firm expiration date of no more than three to five years should be established for CONs. Shorter time periods may be set on a project-specific basis. However, no CON should be on hold for more than 5 years. If construction is not commenced or an establishment is not finalized within 5 years, the CON should expire.

III. Update CON and Licensure to Reflect the Complexity of Physician Practices

Due to advances in medical care and market forces, we are seeing growth in the scope and influence of the physician practice sector – with large multi-specialty practices emerging that include hundreds of physicians and that provide most of the diagnostic and treatment services of a hospital, except for inpatient care and certain highly-specialized procedures. Physician practices are entering into arrangements with corporate entities, such as health insurers, hospitals, medical services organizations, and turn-key radiation oncology enterprises. These entities do not have an ownership interest or formal governance role in the practice, but exercise varying degrees of influence over the management and the delivery of care. Physician practices are also playing a leadership role in new care models - two-thirds of the accountable care organizations (ACOs) designated by the federal Centers for Medicare and Medicaid Services (CMS) in New York State are led by physician practices.

Despite the scope and complexity of their services and their close ties to corporate entities, physician practices typically consider themselves exempt from facility licensing requirements and CON. The line between a physician practice and a diagnostic and treatment center that requires a CON and licensure by the Department has grown murky. Because they are exempt from the operating and physical plant standards of a health care facility, they are often reimbursed at lower rates than licensed facilities.

Although they have the potential to dominate a health care market and significantly impact access, cost and quality, physician practices are subject to little oversight in comparison with licensed health care facilities. Similarly, medical school and hospital-affiliated faculty practice plans operate ambulatory care sites without a CON or licensure under the Public Health Law.[4] The relatively limited regulatory oversight of facilities that are organized as physician practices may expose the delivery system to unnecessary risks. In addition, certain types of equipment or services raise concerns that could be addressed through CON regardless of setting. For example, there is evidence that high-end diagnostic imaging is supply-sensitive, is over-utilized and poses risks associated excessive exposure to radiation. A recent study by the GAO found that providers' referrals for MRI and CT scans increased dramatically after they began to self-refer (i.e., after they purchased imaging equipment or joined a practice with equipment).[5] Yet, only the licensed setting is subject to CON.

A. <u>Recommendation # 13:</u>
Update the Criteria that Trigger the Facility Licensure Requirement and Equalize Treatment of Physician Practices and Facilities Under CON

The scope and pace of the Council's work did not permit an in-depth analysis of the benefits and burdens of the current rules. However, issues related to corporate ownership

[4] Faculty practice plans are governed by N.Y. Not for Profit Corporation Law §__.

[5] "Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions," GAO, Sept. 2012.

or control, and disparate treatment of physician practices and licensed facilities, repeatedly arose in its deliberations.

The Council urges the State to take steps to equalize the treatment of physician practices and licensed facilities under CON and licensure requirements. Some stakeholders suggested that licensed facilities should be exempt from CON for any service or equipment that could be offered by a physician practice, except surgery. Conversely, some Council members suggested that, in order to curb unnecessary spending and utilization, certain physician practice equipment and services should be brought into the CON process.

The Council requests of the Department a set of recommendations to equalize the treatment of physician practices and licensed facilities under CON and licensure. The Department's recommendations should be informed by input from stakeholders and:

- Consideration of the relative quality and cost of surgical, radiation therapy, and imaging services in physician practice and facility settings, including costs attributable to excess utilization due to self-referral patterns.
- Consideration of the impact of physician practice services such as surgery, radiation therapy and imaging on neighboring hospitals, access, disparities and public health.
- Consideration of the effectiveness of local initiatives like the Community Technology Assessment Advisory Board (CTAAB) implemented in the Finger Lakes Region.

The Council requests these recommendations within six months.

IV. Promoting Improvements in Quality and Efficiency through Governance

New York's process for approving new health care facility and home care agency operators, known as "establishment," strives to promote quality, integrity, and financial stability in health care by assessing the "character and competence" of individuals seeking to operate health care facilities and home care agencies, either as board members or as owners. The character and competence process and rules were developed when health care organizations were simpler – they were typically stand-alone facilities operated by not-for-profits or a small groups of individuals. With the increasing integration of health care facilities into systems, interstate expansion of health systems, and the growth of publicly-traded home care and dialysis providers in the State, the establishment process is at times administratively burdensome and not tailored to achieve its intended purpose.

Accordingly, the recommendations below attempt to achieve 3 goals:

- Rationalize the "taint" or disqualification rule to eliminate barriers to integration of systems and recruitment of experienced leadership, while maintaining safeguards to exclude non-compliant and low-quality providers;

- Align the process for reviewing character and competence with the growing complexity of health care organizations; and
- Strengthen the Department's authority to respond, when it becomes apparent that the governing body of a licensed provider is failing to provide quality care or heading towards financial collapse.

A. <u>Recommendation #14</u>
Rationalize "Taint" to Eliminate Barriers to Integration and Recruitment of Experienced Governing Body Members

Because it is difficult to assess character and competence based on an application, DOH relies, to a large extent, on the absence of negative factors (like professional discipline and exclusion from Medicare or Medicaid) to screen CON applicants. Applicants that have affiliations with health care facilities or agencies are also evaluated based on the compliance record of those facilities. Two or more recurring enforcements (final determinations of non-compliance) that threaten health or welfare within 10 years trigger disapproval of the applicant. This statutory bar is colloquially known as a "taint."

The Council recognizes that as health care organizations grow in complexity and geographic scope, as they seek to integrate to participate in new models of care and payment, the current approach to disqualification can have unintended consequences. Experienced and capable trustees and owners are needed to lead providers through the delivery system transformation currently under way. As systems grow, and trustees and owners become affiliated with additional entities or acquire more experience, there is an increased likelihood that they will be affiliated with one or more entities that have been the subject of recurring enforcements. Because the current rule mandates disqualification based on two or more recurring enforcements, it discourages the participation of experienced individuals in governance and the development of integrated systems.

In addition, within complex corporate families, screening individuals requires increasing investment of administrative resources by the Department, by applicants, and by agencies in other states that are asked to respond to requests for the compliance history of their affiliated providers. At the same time, reviewing information about individuals who may have no governance or operational responsibilities in relation to the entity seeking establishment, or about the compliance record of related entities that are several organizational layers removed from the regulated entity, may add little value to the review process and may not be the most effective use of State resources.

As part of Phase 1 of this project, the PHHPC recommended reducing the 10-year look-back to 7 years. The Council recommends building on that recommendation by modifying the taint rule to permit greater flexibility, increased attention to quality, and a stronger focus on organizations as opposed to individuals.

Instead of mandating disqualification of a proposed operator whenever an affiliated facility is subject to two identical enforcements that threaten health and welfare within 10 years, New York's establishment policy should disqualify proposed operators based on a

pattern of, or multiple, enforcements that evidence a failure in governance and/or systemic weakness. New York's policy should consider quality, as well as non-compliance, using measures and dashboards to be developed by the Office of Quality and Patient Safety. The pattern of non-compliance or poor quality may be demonstrated based on the performance of a single affiliated facility or more than one facility with which the individual is affiliated.

Rather than mandating disqualification when a proposed owner or trustee presents affiliations with a health care facility or agency that has a sub-standard compliance or quality record, there should be a presumption of disqualification which may be rebutted in limited circumstances. The presumption may be rebutted based on the individual's role in the organization and actions to address problems, the timing of his or her involvement, recent performance, and extent of his or her involvement in health-related organizations. The affiliations that should be considered should include not only ownership interests or board membership, but also services as the CEO or CFO of a facility or agency.

Compliance and quality reviews should not be limited to individuals. Organizational quality and compliance should be the primary focus when a facility or organization is seeking to acquire another operator or engage in a joint venture and in relation to parent organizations and corporate members of entities seeking establishment.

B. <u>Recommendation #15</u>:
Streamline Character and Competence Reviews of Established Not-for-Profit Corporations

Not-for-profit corporate structures have become increasingly complex as providers have forged new relationships and diversified their services and markets. One not-for-profit health systems has over 100 trustees on its board. When these large and complex systems seek to merge with or acquire another facility, the character and competence (C&C) review is burdensome and time-consuming. Moreover, the value added by the review of dozens of board members is not clear. As an alternative to DOH review of each board member of an established entity under these circumstances, the Council recommends that the Department:

- Require established not-for-profit operators to conduct a C&C review of new board members consistent with DOH regulations at the time of their appointment;
- Require that the operator update the C&C review in the event of any establishment action (e.g., merger, acquisition, joint venture);
- In lieu of DOH verification of disclosures by board members, require an attestation by the operator regarding the review and verification and the disclosure of any compliance or quality problems.

The Council recognizes that review consistent with DOH standards may be difficult for providers to operationalize, if a more flexible disqualification policy is adopted as described above. Providers will require guidance from DOH concerning the application

of this more flexible policy to particular individuals and organizations with less than perfect track records.

C. Recommendation #16: Streamline Character and Competence Reviews of Complex Proprietary Organizations (e.g., publicly-traded, private-equity-owned) and New, Complex Not-for-Profit Systems

Like not-for-profit corporations, proprietary health care organizations in New York State are becoming increasingly complex. Publicly-traded and private-equity-owned, multi-state entities have entered New York's dialysis market and have long been involved in the home care market. In addition, we are seeing the formation of large not-for-profit systems under new parent organizations, sometimes under the leadership of out-of-state systems, with multiple organizational layers and affiliates.

Reviewing individual board members, LLC members, officers, and controlling shareholders and the compliance record of each related entity up and down the corporate family tree is a labor-intensive process that delays the CON process and at times does not appear to add a great deal of value. Instead of reviewing individuals up to the top of the corporate tree, the Committee recommends that the DOH review focus on the individuals involved in the regulated entity and its direct parent (if the direct parent is a holding company, DOH should review a higher level entity).

Entity owners/grandparents and members should be assessed principally based on organizational compliance and competence. DOH should require an attestation from the ultimate parent and any controlling shareholders/members concerning the organizational compliance history and operational track record of the parent, controlling shareholders/members, and related entities; and the character and competence of any natural persons who are controlling owners, directors or officers. The applicant could, with the consent of DOH, opt for an independent, third-party review of its compliance history and track record and the character and competence of its principals, in lieu of the DOH review. DOH would make a recommendation to PHHPC as to character and competence based on the attestation, associated disclosures, and the third-party review or its own review.

D. Recommendation #17: Align "Passive Parent" Oversight with Powers Exerted by Parents and Promote Integrated Models of Care

For purposes of this report, a passive parent of a not-for-profit health care facility operator is a member under the Not-for-Profit Corporation Law (NFPCL) that does not exercise any of the active parent powers set forth below. Under the NFPCL, a member has authority to elect and remove some or all of the board members of the established operator; elect and remove officers; adopt, amend or repeal bylaws; amend the certificate of incorporation; and approve any plan to encumber property, dissolve, consolidate or merge the corporation, or dispose of its assets. A member of a not-for-profit corporation

is limited in the powers it may exert over a health care facility licensed under Article 28 of the Public Health Law, unless it is established as the operator of the facility.

Specifically, the following powers, known as the active parent powers, may not be exercised by a member, unless the member has received establishment approval:

- appointment or dismissal of hospital management level employees and medical staff, except the election or removal of corporate officers by the members of a not-for-profit corporation;
- approval of hospital operating and capital budgets;
- adoption or approval of hospital operating policies and procedures;
- approval of certificate of need applications filed by or on behalf of the hospital;
- approval of hospital debt necessary to finance the cost of compliance with operational or physical plant standards required by law;
- approval of hospital contracts for management or for clinical services; and
- approval of settlements of administrative proceedings or litigation to which the hospital is party, except approval by the members of a not-for-profit corporation of settlements of litigation that exceed insurance coverage or any applicable self-insurance fund.

Although these powers may not ordinarily be exercised absent establishment approval, the regulations provide a mission/philosophy exception that permits a passive parent to exercise powers for the purpose of requiring the subsidiary (known as the affiliate) to operate in conformity with the affiliate's mission and philosophy.

Passive parent models vary based on the unique circumstances of the organizations involved. In some cases, the same group of individuals serves as the board for the parent entity and each of its affiliates, while in other cases, the boards are overlapping. Some affiliates with passive parent relationships retain their own CEO; others share the CEO of the passive parent.

The Council recognizes that passive parent relationships may benefit the delivery system by offering weak health care facilities access to a stronger administrative infrastructure, by rotating specialists through facilities that lack them, and by lower prices from vendors through bulk purchasing. Passive parent relationships may assist small, community hospitals in leveraging enhanced rates from health plans. A passive parent relationship may also be a stepping stone to a more fully integrated relationship, as the affiliate cleans up its balance sheet and improves the efficiency and quality of its operations.

However, the Council is concerned about the lack of oversight of passive parent arrangements and the lack of accountability of passive parents for the quality of care and financial stability of their affiliates, despite the significant degree of control they may exert through the board members they appoint and through management or administrative services agreements. Because passive parents are not financially integrated with their affiliates, they lack a stake in the success of the affiliates. They may treat the affiliates as

a revenue source and foster dependence on the parent and instability by siphoning off management fees and lucrative clinical cases.

The Council also recognizes the possibility that a passive parent could force the wholesale replacement of an existing board. If the passive parent were a proprietary entity, the not-for-profit mission of the facility could be compromised.

The Council notes that some passive parents negotiate with health plans to secure enhanced reimbursement for their affiliates. In the absence of clinical integration, these arrangements do not necessarily contribute to the quality or efficiency of the care delivered by the affiliates, and the added value justifying the enhanced reimbursement is questionable.

The Council has concluded that some oversight of passive parent arrangements is warranted. However, the Council does not want to discourage beneficial passive parent relationships that may lead to more integrated systems and bring improvements in quality and efficiency. And, the Council recognizes that the powers of passive parent, although significant, are not as extensive as an active parent. Accordingly, the Council is not recommending a full-blown establishment requirement for passive parents. Instead, the Council recommends that the Department initiate the following abbreviated approval process:

- Prior to the commencement of a passive parent relationship, the established health care facility should be required to submit a notice to the Department identifying the entities involved and their board members, a copy of the proposed affiliation agreement, and the organizational documents.
- DOH would have 90 days to recommend a disapproval to PHHPC. If no action were taken, the transaction could go forward.
- Grounds for disapproval would be a poor record of compliance, integrity, or quality on the part of the passive parent or its affiliates or lack of sufficient financial resources within the system.

Approved passive parent relationships would be subject to a three-year time limit. Prior to expiration of the approval, the affiliate could seek an extension of the relationship, or the passive parent could seek establishment as an active parent. Requests for extensions would be reviewed based on the system's compliance record, financial stability, and quality of care.

Affiliates with existing passive parents would not be required to seek the Department's approval of current relationships. However, existing relationships would be subject to the time-limitation and review every three years. In addition, existing passive parents would be subject to the 90-day review for any new affiliation they seek to initiate.

In addition, in order to ensure that, purchasers and consumers are reaping added value in exchange for higher costs, when passive parents negotiate with health plans to secure

higher payments for their affiliates, the passive parents and affiliates should be clinically-integrated.

E. Recommendation #18:
Improve Transparency of Major Changes in Board Membership

DOH should create a more structured process for the annual filings required of facilities regarding their board membership. As part of that process, the Department should be notified of any change of 25 percent or more of the members of a facility board within a 12-month period.

F. Recommendation #19:
Strengthen DOH Authority to Respond to Failures in Governance

The proposed changes in character and competence reviews recognize that these reviews are merely an initial screen based on an application and the absence of disqualifying factors. A perfect character and competence review does not guarantee that the resulting health care facility or home care agency will provide high-quality care. Ongoing monitoring and the authority to intervene in the event of deficient governance are more effective tools in assuring the clinical quality, integrity and financial stability of health care providers.

Under current law, the Department has authority to revoke, limit or suspend operating certificates, and PHHPC has the authority to revoke an establishment. However, in many instances, revoking or otherwise limiting the operating certificate of a provider is an unacceptable strategy, as it would reduce access to needed health care services in a community. Typically, it would be preferable to bring in a temporary operator or new board members to turn around the facility.

Earlier this year, the Department advanced legislation to permit it to appoint temporary operators of hospitals and D&TCs and to replace board members, under extreme circumstances where health and safety of patients is of concern and financial instability threatens patient care. The PHHPC supports legislation that would permit such interventions under those limited circumstances.

In addition, given the Committee's proposed expansion of the use of applicant attestations to establish character and competence, and the proposed integration of quality considerations into establishment reviews and reviews of applications to expand services or capacity, the Committee recommends using limited-duration operating certificates with greater frequency:

- Where new operators are established;
- Where new models of care are created; and
- Where compliance or quality of care issues are identified.

V. Incorporate Quality and Population Health into CON Reviews; Streamline Financial Feasibility Reviews; and Relax the Revenue Sharing Prohibition

The Council has emphasized throughout this redesign process the importance of advancing the Triple Aim. While CON has historically been focused on cost and quality through control of supply of health care resources, the Council finds that health care quality and population health can also be advanced by CON. At the same time, the Council recognizes that CON impacts these dimensions only indirectly.

The Principles for Reform adopted by the Council in June stated that:

> CON is one of several regulatory tools that can be used to affect the configuration and operations of healthcare delivery systems. It should be applied only (i) where it is likely to be cost-effective in comparison with other tools available to achieve desired goals; (ii) where the goal sought is directly related to the development, reconfiguration, or decertification of health care facilities, programs or services.

A. <u>Recommendation #20:</u>
Consider performance on quality benchmarks and relationship to the SHIP, when reviewing applications to expand services or sites.

While we cannot expect CON or licensure to solve our health care quality and population health concerns, the Committee recommends that quality and population health considerations be incorporated into the CON and licensure processes consistent with the principles for reform adopted by the PHHPC in June. Specifically:

- When construction projects involve expansion of capacity or services, ensure that operator is meeting or exceeding quality benchmarks established by the State.
- Regardless of whether CON is required for a particular construction project, require prior approval of clinical construction projects to assure physical plant safety. This may be accomplished through an architectural review or certification by a licensed architect consistent with the PHHPC's Administrative Streamlining recommendations.
- Require CON and licensure applicants to demonstrate that they have implemented, or plan to implement, a certified electronic health record system and connect to the Statewide Health Information Network ("SHIN-NY") to assure health information exchange capacity as condition of CON approval and licensure. This requirement may be waived for small construction projects that are subject only to a limited review for compliance with physical plant safety standards.
- Require submission of SPARCs data, consistent with the ACA requirements related to race, ethnicity and disability, as a contingency or condition of CON approval or licensure of projects by existing providers.
- Expand the current public need schedules to solicit information concerning the ways in which projects will help address the priorities and focus areas in the State Health Improvement Plan (SHIP).

B. <u>Recommendation #21:</u>
The Department of Health should pursue a more calibrated approach to financial feasibility reviews.

The Committee recognizes the important role of financial feasibility and cost reviews. However, the Committee recommends a more calibrated approach to financial feasibility reviews that would focus State resources on financially-weak providers, while reducing administrative hurdles for stronger ones. Specifically:

- The Department should conduct ongoing monitoring of the financial status of hospitals and nursing homes, using standardized metrics, to assess their financial performance and respond as appropriate.
- CON applications submitted by financially stable hospitals should be subject to less scrutiny for financial feasibility.

In addition, financial reviews should include consideration of the impact of capitation and bundled payments in feasibility submissions. They should also provide greater flexibility in debt structures for high-performing hospitals.

C. <u>Recommendation #22</u>:
Relax the prohibition on revenue sharing among providers that are not established as co-operators.

The Council has also considered the continuing relevance and utility of the Department's prohibition against the sharing of revenue by established operators with non-established entities. This prohibition was created in order to prevent unlicensed entities from exercising undue influence over established operators. It also arose out of a concern that compensation arrangements based on a percentage of revenue might incentivize contractors to stimulate unnecessary utilization of health care services in order to maximize revenues.

The Council has been advised that this prohibition has prevented contractual arrangements among providers and between providers and vendors in which compensation is based on a percentage of revenues. To comply with the letter of the law, providers and contractors have devised compensation arrangements that entail fixed fees with frequent updates.

Contractual arrangements that involve revenue sharing can create effective incentives to support new collaborative models of care and participation in innovative payment arrangements with payers and purchasers. To promote cost-effective collaborations among providers, the \Council recommends that the Department relax its revenue-sharing prohibition with respect to compensation arrangements among providers. Review of the terms of revenue sharing arrangements and limits on the percentage of revenues that may be shared may be necessary, but establishment of participating providers as co-operators should not be required.