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EXECUTIVE SUMMARY

New York State, like the rest of the nation, faces daunting health and health care challenges, and is developing strategies to address them through Governor Cuomo's Medicaid Redesign Team (MRT) and the implementation of initiatives under the federal Affordable Care Act. An epidemic of chronic disease is crippling individuals and taking an economic toll. Health care spending nationally is rising at an unsustainable rate. Moreover, there is growing evidence that a substantial portion of the nation's health care expenditures –estimates range from 20 to 47 percent -- is wasted due to failures in care delivery or coordination, overtreatment, administrative complexity, pricing failures, and fraud and abuse.[1] New York's health care delivery system contributes to those wasted dollars. It ranks 50th in the nation in avoidable hospital use and only 22nd for prevention and treatment quality.[2] And, New Yorkers continue to experience significant disparities in health and health care based on such factors as race, ethnicity, disability, and socioeconomic status.[3]

The Affordable Care Act (ACA) and the MRT are providing innovative approaches to tackling these challenges and advancing the Triple Aim of better care, better health and lower costs. These approaches include access to affordable health insurance (under the ACA) and new models of care and payment that improve care coordination and incentivize quality and better outcomes, while reducing overall costs. New York is pursuing an amendment to its federal Medicaid waiver that will support these new models, and it is implementing a comprehensive State Health Improvement Plan to promote improvements in population health.

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[1] Berwick, D.M., Hackbarth, A.D. "Eliminating Waste in US Health Care. *JAMA* 307.14(2012): 1512-13. *See also, Better Care at Lower Cost: The Path to Continuously Learning Health Care in America.* Institute of Medicine. (Sept. 6, 2012): 3-9 (estimating that 30 percent of health care spending in the US-- roughly $750 billion in 2009-- was wasted).

[2] The Commonwealth Fund Commission on a High Performance Health System, State Scorecard (2009), available at http://www.commonwealthfund.org/Maps-and-Data/State-Data-Center/State-Scorecard/DataByState/State.aspx?state=NY

[3] S*ee* Medicaid Redesign Team Health Disparities Work Group Data and Information, available at www.health.ny.gov/statistics/community/minority/medicaid_redesign_team.htm .

These initiatives, along with broad market forces, are driving a dramatic transformation of the healthcare delivery system. Health care providers are breaking out of their service silos and creating strategic linkages along the care continuum and across geographic regions to support care coordination, and improve quality, outcomes and efficiencies. Likewise, payers are developing payment strategies, networks and benefit designs that promote higher quality care and better outcomes at a lower overall cost. Ambulatory care is assuming a dominant position in the health care delivery system, and physician practices are growing in size and scope.

Recognizing that New York's health care regulations need to adapt to these sweeping changes and that regional strategies will be key to advancing the Triple Aim, Governor Cuomo and Commissioner Shah charged the Public Health and Health Planning Council with redesigning the State's certificate of need (CON) program and developing a framework for regional health planning. Its goal has been twofold: (1) to streamline the CON process by eliminating administrative steps that no longer serve their intended purpose, impede achievement of policy goals, or are not cost-effective; and (2) to develop a regulatory and health planning framework that, together with payment incentives and other policy tools, drives health system improvement and population health.

New York's evolving health care environment poses new opportunities and new risks that call for new regulatory responses. The creation of integrated systems of care holds promise for improving quality and outcomes through better care coordination, use of evidence-based practices, robust data analysis, and systematic performance improvement. Payment arrangements that reward quality and outcomes have the potential to reduce delivery system fragmentation and preventable and unnecessary utilization, while improving population health. The scale of integrated systems promises to produce administrative efficiencies and enable providers to spread fixed costs and risk. Together, all of these factors have the potential to bend the cost curve and improve the quality of life for New Yorkers.

While the new models of care and payment show great promise, they also raise concerns. Large integrated systems and physician practices that accept risk-based or value-based payments have the potential to improve outcomes while reducing overall costs; but they may also exercise market power to drive out competition and drive up prices. Thus, essential and safety net providers may be destabilized by the growth of physician practices and integrated systems that attract lucrative patients, but decline to serve Medicaid beneficiaries and the uninsured. Payment arrangements that transfer risk to providers may contribute to instability and diminished access to necessary services. Risk-based payments may also discourage the provision of medically-necessary care.

CON is not an all-purpose, regulatory tool that can be deployed to maximize all of the opportunities created by health care reform or address all of the risks. CON impacts the supply and distribution of health care resources. It is best suited to curbing excess health care capacity that drives unnecessary utilization and spending. It can also promote access to services by channeling development to under-served areas and may help to protect the viability of essential providers. CON does not, however, provide funding for struggling

providers, nor does it monitor payment arrangements, affect the health status of populations or prevent the delivery system failures that may generate preventable utilization and excess spending. Other policies and regulatory approaches, such as licensure and surveillance, insurance oversight, grants, public health interventions, and regional planning, may provide more effective responses to these issues.

Where CON is deployed, its policies and processes must be adapted to promote beneficial innovations, while mitigating risks. The PHHPC identified several shortcomings of CON in relation to advancing the Triple Aim in the context of the changing health system. For example, CON does not cover services provided by physician practices that may destabilize essential providers or drive up health care spending. CON may delay the development of licensed primary care sites that will be needed to address the needs of newly-insured New Yorkers and support new models of care. And, CON's 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.

At the threshold of what promises to be a major transformation in health care delivery, the PHHPC recommends changes to New York's CON and licensing process to support successful integrated systems of care and new care and payment models. Its recommendations facilitate an expansion of the primary care capacity needed to serve the one million New Yorkers newly-insured under the Affordable Care Act – capacity that will also serve as the foundation for new care models. The recommendations also create a path to equalizing and clarifying the regulatory oversight of physician practices in comparison with licensed health care facilities in New York. In addition, the PHHPC recommends modifications to the process of establishing new health care facility and home care agency operators, in order to support the integration of health systems. Finally, the PHHPC's recommendations strengthen oversight of health care facility and health system governance, support expanded access to hospice, and incorporate quality and population health factors into CON reviews.

All the same, the health and health care challenges facing New York cannot be overcome through the efforts of one type of regulation or one sector alone. They are heavily influenced by local and regional factors that demand local and regional strategies. Advancing the Triple Aim requires multi-sector collaboration at the regional level – among all health stakeholders, including the State and local governments, consumers, business, public health officials, providers, payers, unions, transportation, education, social services, and more. Accordingly, the PHHPC recommends the creation of Regional Health Improvement Collaboratives (RHICs) to convene and actively engage stakeholders, analyze data, and develop a consensus around strategies to promote the Triple Aim.

The report is organized in seven parts:

- Part I describes the Council's CON Redesign process;
- Part II evaluates health system performance in New York;
- Part III describes health system trends;

- Part IV provides recommendations for regional planning;
- Part V provides recommendations for CON and licensure that relate to supply and distribution of services;
- Part VI sets forth recommendations for strengthening governance and streamlining reviews of the character and competence of new health care operators;
- Part VII sets forth recommendations related to streamlining the financial component of CON reviews, facilitating provider relationships that involve innovative payment arrangements, and incorporating quality and population health considerations in to CON reviews

The report includes the following recommendations:

1. 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 better care for individuals, better health for populations and lower per capita costs.

2. Create multi-stakeholder Regional Health Improvement Collaboratives (RHICs) to conduct regional planning activities.

3. Create 11 geographic planning regions.

4. Each RHIC should advance each dimension of the Triple Aim in its region**.**

5. 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.

6. Eliminate CON for primary care facilities, whether D&TCs or hospital extension clinics; retain licensure requirements.

7. Exempt projects funded with State Department of Health grants from public need review and provide for limited financial review.

8. Enter into a contract with a research institute to advise the Department and the PHHPC concerning emerging medical technologies and services that might be appropriate for CON.

9. Reconsider the utility of CON for hospital beds in the next three to five years.

10. Consider the use of ACO certification, in lieu of CON for certain facilities, to promote appropriate distribution of facilities and services and Prevention Agenda 2013 goals.

11. Update the CON process for hospice.

12. Update the CON process for approved pipeline projects**.**

13. Update the criteria that trigger the facility licensure requirement and equalize the treatment of physician practices and facilities with respect to CON.

14. Rationalize "taint" policies to eliminate barriers to integration and recruitment of experienced governing body members.

15. Streamline character and competence reviews of established not-for-profit corporations.

16. Streamline character and competence reviews of complex proprietary organizations (e.g., publicly-traded, private-equity-owned) and new, complex not-for-profit systems.

17. Align "passive parent" oversight with powers exerted by parents and promote integrated models of care.

18. Improve the transparency of major changes in board membership.

19. Strengthen the Department's authority to respond to failures in governance**.**

20. Consider performance on quality benchmarks and relationship to the SHIP, when reviewing applications to expand services or sites.

21. Pursue a more calibrated approach to financial feasibility reviews.

22. Relax the prohibition on revenue sharing among providers that are not established as co-operators.

This report is not intended to be the final word on regulatory reform in the context of an evolving health care delivery system. Rather, it is intended to lay the groundwork for an extended conversation about the strategic direction of New York's regulatory oversight of a health care delivery system in transition. The long-term effects of the Affordable Care Act and Governor Cuomo's Medicaid Redesign Team initiatives remain to be seen. As the delivery system changes and adapts in response to these reforms, the Department of Health and the PHHPC will undoubtedly revisit the alignment of regulations with new models of health care organization and payment.

I. THE COUNCIL'S CERTIFICATE OF NEED REDESIGN PROCESS

A. The PHHPC's Charge

Governor Cuomo and Commissioner Shah charged the PHHPC, in January 2012, with the redesign of the CON process. The Council's work was to encompass:

- A fundamental re-thinking of CON and health planning in the context of health care reform and trends in health care organization, delivery and payment.

- Development of a regulatory and health planning framework that, together with payment incentives and other policy tools, drives health system improvement and population health.

The Health Planning Committee of the PHHPC took the lead in convening stakeholders and in analyzing issues and options for CON redesign. The Committee's work proceeded in two phases: (1) administrative streamlining of the CON review process; and (2) fundamental re-thinking of CON in the context of current and forthcoming changes in the organization, financing and delivery of health care.

The Triple Aim framework for health system improvement provided the foundation for the Committee's deliberations. First introduced by the Institute for Healthcare Improvement, the Triple Aim demands simultaneous health system improvement efforts on three dimensions:

- Better care, including improvements in safety, effectiveness, patient-centeredness, timeliness, efficiency and equity;
- Better health for populations; and
- Lower per capita costs.[4]

As the State and federal governments ask health care providers and payers to adopt systematic approaches to advance the Triple Aim, government regulations and payment policies should be aligned to support those approaches. Accordingly, the Council's recommendations for the future of CON and regional health planning were developed with the Triple Aim in mind.

This work to redesign New York's Certificate of Need program complements earlier and ongoing efforts by the Department to reform and improve the CON process. Prompted by stakeholder concerns over processing times for CON applications and by the need to align the scope of the program with increasingly limited State resources, the Department over the past several years has implemented a number of changes in CON requirements and in the ways in which applications are submitted and reviewed. These are:

- Increases in the project cost thresholds for administrative and full CON review;

[4] *See* IHI Triple Aim Initiative, available at http://www.ihi.org/offerings/Initiatives/TripleAim/Pages/default.aspx.

- Exemption of certain types of major medical equipment from full review, in favor of administrative or limited review;
- Improvement in the efficiency and transparency of the CON process through implementation of NYSE-CON, an electronic system for the submission of CON applications;
- Consolidation of the former State Hospital Review and Planning Council (SHRPC) and the Public Health Council (PHC) into the Public Health and Health Planning Council (PHHPC) to eliminate the dual CON review functions of the two councils, and to combine the public health mission and expertise of the PHC with the SHRPC's mission and expertise in health care delivery systems in a mutually supportive fashion;
- Exemption from CON review of projects for the construction, renovation and replacement of nonclinical infrastructure and equipment;
- Development of a Memorandum of Understanding (MOU) between the Department and the Dormitory Authority (DASNY) to expedite reviews of architectural drawings for CON projects;
- Implementation, on a pilot basis, of a process for architectural self-certification of CON projects of less than $15 million.

B. Solicitation of Stakeholder Comments

To inform its work, the Committee twice solicited comments from stakeholders, in September, 2011 and June, 2012. The general themes that emerged from the stakeholder comments were:

- The importance of timeliness in the issuance of decisions on CON projects and the need for further streamlining of the CON review process;
- The need for equitable regulatory treatment of licensed health care facilities and physician practice-based services with respect to the initiation and expansion of major services and medical equipment;
- The importance of CON support for new models of care, such as co-located programs and freestanding emergency services;
- The need for strengthened regional and local health planning, of a type that would not become a regulatory barrier to development and innovation;
- The need for health planning and CON to promote population health and eliminate health disparities;
- The importance of transparency in the CON and planning processes, including the engagement of consumers and other community stakeholders.

Stakeholder comments are attached at Appendix __.

C. Phase 1 – Administrative Streamlining

The Committee held six meetings between January and June, 2012, to undertake Phase 1 of its work as well as one joint meeting with the PHHPC's Public Health Committee. It developed a statement of mission, vision and principles (attached as Appendix __) to guide both Phases. The Committee also called for background papers on the history of CON, recent reforms, and the current process. The Finger Lakes Health Systems Agency provided assistance in developing these papers.

In June, 2012, the full PHHPC adopted the Committee's mission and vision statement, and principles for reform, along with its recommendations for administrative streamlining of the CON program (attached as Appendix 2). The main features of these proposed changes entail the elimination of CON public need review for certain construction projects that do not involve additions to beds or service capacity; reduction in the number of ambulatory and outpatient services subject to certification in favor of an on-line registration process for information and tracking; simpler architectural review of construction projects prior to CON approval, with a greater focus on post-CON licensure (physical plant safety); and more streamlined review of character and competence for changes in ownership of health care facilities and in the establishment of new owners and operators.

The following principles for reform guided both phases of the redesign process.

- The Certificate of Need program should support:
    - Preservation and expansion of access to needed health care services;
    - Containment of costs and improved cost-effectiveness;
    - Health care quality and reliability; and
    - Improved population health and elimination of health disparities.
- The mechanisms that CON uses to promote the alignment of health care resources with community need must evolve in the face of dramatic changes in the health care environment. CON should complement related planning initiatives, payment reforms and emerging models of care that promote care coordination and reduce inappropriate utilization.
- CON decisions should be informed by local/regional planning based on data and community input. Health planning, including that performed by the PHHPC, should be comprehensive and should consider health care resources of both institutional providers and physician practices. The PHHPC and health planning organizations should play a proactive role in promoting health care development that is aligned with community needs. Regional planning should encompass not just the supply of health care, but also strategies regarding the organization and delivery of care, population health and health care utilization.

- 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.

- The CON program should focus on health care projects and services that have a significant impact on health care costs, access or quality, such as those that are supply-sensitive or volume-sensitive,[5] require major capital investment, generate high operating costs, compromise access to care, require highly-specialized expertise, or involve emerging medical technologies.

- Certification or licensure alone, without consideration of public need, is sufficient for projects that do not require major capital investment, are not supply- or volume-sensitive, do not generate high operating costs or compromise access to care, and do not involve emerging medical technologies.

- The CON program should facilitate coordinated and integrated delivery of all health care services, including behavioral health, developmental disability, and physical health services. Certification or licensure processes should be examined and updated to promote integration of behavioral and physical health services.

- Proposals for administrative streamlining should be considered in light of longer term issues, such as reinvigorating health planning, approval of new types of facilities, role of private capital, impact of payment reforms, and delivery system configurations.

D. Phase 2 – Fundamental Redesign

In June of 2012, the Council, through the Health Planning Committee, began examining CON in a more fundamental manner. To assist in this process, the Department retained the United Hospital Fund and its Director of Innovation Strategies, Gregory Burke, to identify and analyze trends in organization and payment and their implications for the CON process. The Committee convened eight public meetings between June and November, covering topics ranging from health system performance in New York to innovations in health care financing and organization, to regional health planning, among others (a list of the meetings and associated materials are attached as Appendix __; Mr. Burke's report is attached as Appendix __)..

The Committee's deliberations were informed by a review of New York's health system performance today and an analysis of new directions in health care organization and

[5] For purposes of this document, a health care capital project or service is supply-sensitive if the supply of the health care resource in question influences the utilization of that resource, and the level of utilization driven not by medical theory or evidence, but rather by capacity and payment incentives. (Dartmouth Atlas of Health Care, available at http://www.dartmouthatlas.org/keyissues/issue.aspx?con=2937). A health care service is volume-sensitive if a high volume of the service is associated with improved quality or outcomes.

payment. The Committee worked to ensure that its recommendations would drive health system improvement, by supporting beneficial innovation and mitigating associated risks.

II. HEALTH SYSTEM PERFORMANCE IN NEW YORK STATE

To inform its deliberations, the Committee examined the strengths and weaknesses of New York's health system. By many accounts, New York's health care delivery system is characterized by fragmented care, overuse of inpatient services, insufficient primary care, uneven quality, and disparities in health status and health care. In an effort to compare New York's health system performance to other states', the Committee looked to The Commonwealth Fund's state and local scorecards, as a comprehensive assessment of state health system performance.[6]

The Fund's state scorecard evaluates performance across five key dimensions based on more than 30 indicators for which data is collected nationwide. The dimensions are:

- Access - rates of insurance coverage for adults and children, and other indicators of access and affordability;
- Prevention and treatment – measures of effective care, coordinated care, and patient-centered care;
- Potentially avoidable use of hospitals and costs of care - identifiers of hospital care that might have been prevented or reduced with appropriate care and follow-up and efficient use of resources, as well as the annual costs of Medicare and private health insurance premiums.
- Equity - differences in performance associated with income level, type of insurance, or race or ethnicity.
- Healthy lives – measures of the degree to which a state's residents enjoy long and healthy lives, including factors such as smoking and obesity.[7]

According to the Commonwealth Fund's 2009 state scorecard, New York's health system scores well on access and equity, at the median on prevention and treatment, and poorly on avoidable hospitalizations and costs. Overall, New York ranked 21st in the nation, with the following rankings among five categories:

- Access: 18

[6] Other dashboards and report cards focus on particular elements of health system performance. For example, the AHRQ produces a dashboard focused on quality using some of the same data elements used by the Commonwealth Fund. Agency for Healthcare Research and Quality, New York Dashboard for Health Care Quality Compared to All States, 2011, available at http://statesnapshots.ahrq.gov/snaps11/dashboard.jsp?menuId=4&state=NY&level=0. On the 2011 AHRQ quality dashboard, New York State ranks.in the low average range. It scores well on preventive measures, such as vaccines and mammograms, but below average on the acute, chronic care, hospital, home health, heart disease and respiratory disease measures. The County Health Rankings, produced by the Population Health Institute of the University of Wisconsin, focus on population health measures by county, but do not include statewide rankings. (available at http://www.countyhealthrankings.org).

[7] D. McCarthy, S. K. H. How, C. Schoen, J. C. Cantor, D. Belloff, Aiming Higher: Results from a State Scorecard on Health System Performance, The Commonwealth Fund, October 2009.

- Prevention and treatment: 22
- Avoidable hospital use and costs: 50
- Equity: 11
- Healthy lives: 17 [8]

Although the Commonwealth Fund has not released an update of the 2009 State Scorecard, some state-level data appear on its 2012 local scorecard. These data do not suggest dramatic changes in the New York's rankings.[9]

Clearly, the category of avoidable hospital use and costs deserves attention. In that dimension, the Commonwealth Fund's scorecard ranks New York below the median on every measure, and in the bottom 10 for:

- Medicare admissions for ambulatory care sensitive conditions
- Percent of home health patients with a hospital admission
- Inpatient care intensity in the last two years of life among chronically-ill Medicare beneficiaries
- Total Medicare reimbursements per enrollee.[10]

The Commonwealth Fund's Local Report Card, shows that costs, quality, and access vary significantly by region within New York State. The Fund's Local Report Card ranks the nation's 306 hospital referral regions (HRRs) across four dimensions (access, prevention and treatment, avoidable hospital use and costs, and healthy lives) based on 43 indicators. Overall rankings for New York's HRRs are:

- First Quartile: Albany, White Plains, Buffalo, Rochester, and the eastern Adirondacks, which is included in the Burlington, Vermont region[11]
- Second Quartile. Manhattan,[12] Elmira, Syracuse, Binghamton, and Eastern Long Island
- Third Quartile: Bronx

Accordingly, the Committee concluded that, while there is room for improvement in every dimension, priorities for the state to drive health system performance must include reducing avoidable hospitalizations and costs, and improving prevention and the effectiveness of treatment. In addition, the Committee observed that statewide

[8] The Commonwealth Fund Commission on a High Performance Health System, State Scorecard (2009), available at http://www.commonwealthfund.org/Maps-and-Data/State-Data-Center/State-Scorecard/DataByState/State.aspx?state=NY.

[9] Authors' analysis of state-level data reported in the Commonwealth Fund's Scorecard on Local Health System Performance. D. C. Radley, S. K. H. How, A. K. Fryer, D. McCarthy, and C. Schoen, Rising to the Challenge: Results from a Scorecard on Local Health Performance, 2012, The Commonwealth Fund, March 2012.

[10] *Ibid.*

[11] David C. Radley, Ph.D., M.P.H., Sabrina K. H. How, M.P.A., Ashley-Kay Fryer, Douglas McCarthy, M.B.A., and Cathy Schoen, M.S., Rising to the Challenge: Results from a Scorecard on Local Health System Performance, 2012. Small portions certain Pennsylvania, New Jersey and Connecticut hospital referral regions also extend into New York State.

[12] The Manhattan hospital referral region includes Manhattan, Brooklyn and Staten Island.

approaches will not always suffice. Local and regional approaches will be necessary to address weaknesses in delivery system performance and population health.

III. A HEALTH CARE DELIVERY SYSTEM IN TRANSITION

The Health Planning Committee considered not only the current state of New York's health care delivery system but also its future. New York is charting a new course in health care aimed at improving quality and population health and bending an unsustainable cost curve 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 reached almost 18 percent of the gross domestic product (GDP) in 2011 and is projected to reach 20 percent by 2020.[13] There is growing evidence that a substantial portion of those expenditures – estimates range from 20 to 47 percent -- represents waste attributable to failures in care delivery or coordination, overtreatment, administrative complexity, pricing failures, and fraud and abuse.[14] 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 compared to other industrialized nations, the quality of the care we purchase and the outcomes we experience are too often less than optimal.[15] And, health care quality, outcomes and accessibility are too often worse for racial and ethnic minorities and low-income people.[16]

Governor Cuomo and Commissioner Shah are tackling these challenges through initiatives advanced by the ACA and the Governor's Medicaid Redesign Team (MRT) that address the imperatives of the Triple Aim. These initiatives include new models of care, such as accountable care organizations (ACOs), patient-centered medical homes (PCMHs), and health homes, among others. These models emphasize care coordination, chronic disease management, and reduction of preventable inpatient admissions. PCMHs receive enhanced payments in exchange for meeting performance standards related to access and continuity, chronic disease management, use of health information technology, care coordination and performance improvement. Health homes also receive enhanced payment (and potential for shared savings) for providing care coordination across a network of providers to Medicaid beneficiaries with with multiple chronic conditions, including behavioral health concerns, who are at high risk for avoidable hospitalizations. ACOs are organized networks of providers responsible for the health of a defined population of insured beneficiaries. Fifteen Medicare ACOs have been

[13] 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 .

[14] Berwick, D.M., Hackbarth, A.D. "Eliminating Waste in US Health Care. *JAMA* 307.14(2012): 1512-13. *See also, Better Care at Lower Cost: The Path to Continuously Learning Health Care in America.* Institute of Medicine. (Sept. 6, 2012): 3-9 (estimating that 30 percent of health care spending in the US-- roughly $750 billion in 2009-- was wasted).

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

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

designated in New York State, and providers are creating similar models for commercially-insured and self-insured populations.[17]

New payment models are replacing fee-for-service payments with value-based and risk-based payments that reward prevention and quality. While the fee-for-service model rewards individual providers for the volume of services they provide, the new payment models reward quality and outcomes. They require avoidance of preventable utilization and often demand coordination among different types of providers. For example, avoiding penalties for preventable readmissions requires careful post-discharge coordination among hospitals, nursing homes, home care agencies, and other community-based providers. Value-based payments are not limited to Medicare and Medicaid. Commercial insurers and self-insured purchasers are reportedly following suit, expanding the use of arrangements such as shared savings, episodic payments, partial capitation, and global capitation.[18]

In addition to advancing these new care and payment models, the State is expanding its Medicaid managed care program and pursuing a long-term strategy of fully-integrated care management for all Medicaid beneficiaries.[19] Benefits previously delivered on a fee-for-service basis, such as prescription drugs and personal care, have been added to the managed care benefit package. Also, populations previously excluded or exempt from managed care are now being enrolled as program features are developed to ensure the continuity of their services. This includes the mandatory enrollment of individuals receiving community-based long term care into managed long term care plans. In addition, the State is developing models of care to address the provision intensive behavioral health services to those currently enrolled in mainstream managed care plans.

New York's pending 1115 Medicaid waiver amendment will support the development of new models of care and payment. With Medicaid savings from prior years, New York proposes to fund thirteen new programs: primary care expansion, a health home development fund, new care models, Vital Access Provider and Safety Net Provider programs, public hospital innovation, supportive housing, long term care transformation and managed care integration, safety net hospital capital stabilization, hospital transition to integrated systems, health workforce, public health innovation, and regional health planning. This funding will provide the capital necessary to create new alignments among providers, to build and test innovative, cost-effective care models, to complete the transition to managed long-term care, and to integrated evidence-based public health interventions into the Medicaid program. It will also support regional health improvement collaboratives that convene stakeholders to develop data-driven regional strategies to advance the Triple Aim and optimize the impact of the ACA and the waiver funds.

Comment [k1]: Insert in Table.

[17] Trends and Changes in New York's Health Care Delivery and Payment Systems: Implications for CON and Health Planning," presentation by Gregory Burke, United Hospital Fund, July 25, 2012.
[18] *Ibid.*
[19] "A Plan to Transform the Empire State's Medicaid Program: Multi-Year Action Plan," 2012 at 9, available at www.health.ny.gov/health_care/medicaid/redesign/docs/mrtfinalreport.pdf.

The expansion of Medicaid managed care and the emergence of the new payment and care models are already fueling transformation of the health care delivery system by encouraging new relationships among providers and payers that support care coordination and disease management. They are also promoting ambulatory care as a means to improve outcomes and reduce expensive inpatient care. The success of this transformation will depend on several building blocks: effective governance of new systems of care, health information exchange and robust data analysis, capital investment, and a sustained and systematic focus on population health.

A) New Care Models and Payment Mechanisms Drive New Relationships

Spurred by new payment incentives, new care models, and the imperatives of a managed care expansion, providers and payers in New York are forging new relationships. 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. The silos between behavioral health and physical health are breaking down with these providers integrating and co-locating services. Behavioral health and physical health providers are organizing into health home networks and working with regional behavioral health organizations (BHOs). 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.[20]

Efforts to align payment incentives with desired outcomes, while containing costs, are stimulating not only linkages among providers, but also linkages among health care payers, purchasers and providers. Payers and purchasers are partnering with health systems to create exclusive and tiered networks supported by value-based payments.[21] In at least one case, a health insurer and a health system have entered into a joint venture to sponsor an IPA that will serve as the exclusive network for a portion of the insurer's products. Another insurer has created a physician practice to provide a particular chronic disease management model to its Medicare Advantage enrolees. While reminiscent of the staff-model HMOs of the 1980s and 1990s, these models rely on benefit design and provider payment incentives to influence utilization and spending, rather than gatekeepers and utilization review agents.

B) Evolving Roles of Inpatient and Ambulatory Care

Although inpatient care will remain essential to the delivery system, it will play a diminishing role in 21st century health systems. Inpatient utilization has been declining

[20] "Trends and Changes in New York's Health Care Delivery and Payment Systems: Implications for CON and Health Planning," presentation by Gregory Burke, United Hospital Fund, July 25, 2012. Gregory Burke, Trends and Changes in the New York State Health Care System: Implications for the Certificate of Need Process," United Hospital Fund, unpublished report (Nov. 2012); 19-20.
[21] *Ibid.*

gradually over the past several years due to medical advances that have reduced lengths of stay and permitted increasingly complex procedures to be conducted on an ambulatory basis.[22] If new care and payment models are successful in improving health and preventing avoidable admissions, this trend will accelerate.

In order to maintain their financial viability, hospitals must find ways to replace shrinking inpatient revenues and to partner with other providers to deliver services more efficiently. While academic medical centers and strong community hospitals are aligning with other providers to create regional systems of care, many rural and safety net hospitals are struggling to find a viable path in this changing environment.

By contrast to inpatient services, ambulatory services are growing in importance as the foundation for new care models and a vehicle for capitalizing on new payment arrangements.[23] New primary care capacity must be developed to support these models and serve the one million New Yorkers expected to become insured under the ACA. Accordingly, many hospitals are opening extension clinics, acquiring physician practices, and expanding their faculty practice plans. Independent physician practices are growing in size, scope and market power, with multi-specialty groups offering surgery, imaging and even radiation therapy services. One indicator of the rising strength of physician practices in New York State is the sizeable number of physician practice-led ACOs here – 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.[24]

Federally-qualified health centers (FQHCs) -- diagnostic and treatment centers (D&TCs) that provide comprehensive primary care regardless of ability to pay -- are likewise growing in size and geographic scope with an infusion of capital through federal grants authorized by the ACA. These health centers, along with hospital extension clinics, will continue to serve as a major source of primary care, particularly for rural and low-income populations.[25]

C) Building Blocks of New Models: Governance, Capital, and Health IT

New models of care and payment impose new operational, administrative, and financial demands on health care providers. To succeed, they require strong governance and management to manage payment risk and costs, to promote clinical integration and

[22] SPARCS, Annual Report Generator, Inpatient Discharges by Major Service Category, 2000-2010.
[23] See Scott A. Berkowitz, "Accountable Care at Academic Medical Centers – Lessons from Johns Hopkins," *NEJM*, no.. 7 (Feb. 2011): e12. Melinda Abrams, et al., "Realizing Health Reform's Potential: How the Affordable Care Act Will Strengthen Primary Care and Benefit Patients, Providers and Payers," Commonwealth Fund (Jan. 2011). Beth Kutscher, "Outpatient Care Takes the Inside Track," *Modern Healthcare.com, Aug. 4, 2012.*
[24] Gregory Burke, "Trends and Changes in the New York State Health Care System: Implications for the Certificate of New (CON) Process, unpublished report, United Hospital Fund (Nov. 2012): 26.
[25] Eli Y. Adashi, et al., Health Care Reform and Primary Care – The Growing Importance of the Community Health Center, *NEJM*, no.22 (June 2010): 2047-50.

ensure effective coordination along the continuum, and to engage in continuous performance improvement.[26]

Capital investment in primary care capacity and information technology is also essential. High-quality primary care is the key to achieving the savings necessary to succeed under new payment mechanisms. Collection, analysis and exchange of individual and population health information are critical elements of these models. Interoperable electronic health records (EHRs) enable communication and coordination among providers; clinical decision support systems promote adherence to evidence-based practices; and patient registries support population health initiatives, chronic disease management and quality improvement. Information technology is also needed to measure provider performance and manage utilization and costs.[27]

D) Population Health

Sustained improvements in population health represent both the goal and the rationale for new models of care and payment.[28] Along with improvements in health care delivery, success will depend on community-wide strategies to establish primary and secondary prevention programs, eliminate health care disparities, and address the social determinants of health.

To promote improvements in health status, initiatives advanced by the MRT and the ACA link population health and the health care delivery system. For example, the federal ACO regulations require ACOs to manage the health of a designated population of Medicare beneficiaries, to focus on prevention and intervene early to address the care needs of various population segments. Other care models that involve value-based or risk-based payments demand a similar focus in order to succeed. In addition, the ACA requires hospitals to conduct community health needs assessments and community benefit plans. The Department of Health has asked hospitals to work with local health departments and other stakeholders in developing their assessments and in addressing at least two priorities in the State's Prevention Agenda 2013, including one directly related to addressing racial, ethnic, socioeconomic, disability-related or other health disparities.

The Public Health Committee of the PHHPC is taking the lead in developing, with stakeholders, the Prevention Agenda 2013 (also known as the State Health Improvement Plan) -- a five-year strategic plan for population health improvement in New York. This comprehensive plan includes evidence-based practices for improving population health in each of five priority areas and provides guidance for local health departments, hospitals and other stakeholders in their efforts to assess and improve community health.

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[26] Lawton R. Burns and Mark V. Pauly. Accountable Care Organizations May Have Difficulty Avoiding The Failures Of Integrated Delivery Networks Of The 1990s. Health Affairs, 31, no.11 (2012):2407-2416. Shortell SM, Gillies R, Wu F, " United States Innovations in Healthcare Delivery," *Public Health Reviews*, no. 32 (2010):190-212.

[27] *See* "Features of Integrated Systems Support Patient Care Strategies and Access to Care, but Systems Face Challenges," U.S. G.A.O, November 2010.

[28] See Donald M. Berwick, Thomas W. Nolan and John Whittington. The Triple Aim: Care, Health and Cost. Health Affairs, 27, no. 3 (2008): 759, 764.

The plan identifies five statewide priorities for the next five years:

- Prevent Chronic Diseases
- Promote a Healthy and Safe Environment
- Promote Healthy Women, Infants and Children
- Promote Mental Health and Prevent Substance Abuse
- Prevent HIV, STIs, Vaccine-preventable Diseases and Healthcare-associated Infections

Prevention Agenda 2013 establishes focus areas and goals for each priority area and defines indicators to measure progress toward achieving these goals, including reductions in health disparities among racial, ethnic, and socioeconomic groups and among persons with disabilities. The plan also identifies interventions for action for each goal. (Prevention Agenda 2013 attached at Appendix __).

The Prevention Agenda 2013 will provide a framework not only for local health department activities, but also for the community health needs assessments and community benefits activities required of hospitals by the ACA. Regional health planning activities (described in detail in Part IV below) will also use the Prevention Agenda as the blueprint for their efforts to improve population health.

E. Opportunities and Challenges

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 delivery system fragmentation and decrease preventable and unnecessary utilization, while improving population health. The scale of integrated systems promises to produce administrative efficiencies and enable providers to spread fixed costs and risk. 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.[29]

[29] Martin Gaynor and Robert Town, "The Impact of Hospital Consolidation-Update," Robert Wood Johnson Foundation, June 2012.

They may reduce options for consumers who want 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 needed revenue for safety net providers, while declining to serve Medicaid beneficiaries and the uninsured. In addition, essential providers that serve rural or low-income communities may be left behind in the race to create integrated systems. To the extent that success under new payment mechanisms relies on the provision of services to a large, well-insured population, these providers may not be attractive partners in the race to develop regional systems. They may lack sufficient capital, administrative depth, or patient volume and may be forced to close their doors.

The recommendations in this report seek to provide a sound approach to CON and licensure that supports beneficial innovation while mitigating the risks posed 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 the risks described above. However, it can be used as a tool to promote access to services and protect the viability of essential providers. Other tools, such as antitrust policies or the emerging certificate of public advantage process, insurance laws, nascent accountable care organization (ACO) certification regulations, grants, and the physician discipline process may provide more effective responses to many of the above risks.

Regional planning can help to monitor the pace and outcomes of change, including those outcomes that are unintended. This type of planning, with feedback loops both to local communities and to Albany, should have a salutary effect on delivery system behavior and provide important guidance for evolving public policy. It will help to ensure that the transformation of the delivery system proceeds in the best interests of all New Yorkers.

IV. ADVANCING THE TRIPLE AIM THROUGH REGIONAL PLANNING

Given regional variation in health system performance, daunting challenges, and dramatic change in the delivery system, regional health planning holds promise as a vehicle for advancing the Triple Aim. The health and health care challenges confronting New York are multi-sectoral and cannot be solved by providers, payers, or consumers alone. They vary by region and locality and demand regional and local solutions. These challenges call for a data-driven, structured effort that brings together diverse stakeholders to assess population health and health system performance in a region and develop consensus-

based strategies to address weaknesses. Accordingly, the Council recommends the following framework for regional health planning in New York:

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 better care for individuals, better health for populations and lower per capita costs.

The Council endorses the following principles for regional health planning:

- Regional health planning must be collaborative, and neither regulatory nor bureaucratic;
- Regional health planning must be conducted by entities that:
    - Focus on both health and healthcare, including behavioral health, and coordinate with the local planning process for mental hygiene services;
    - Provide for representation, formal engagement and meaningful participation of all affected stakeholders.
    - Collect, analyze, and display data in an objective manner.

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.

- The State's responsibilities in relation to regional health planning must include :
    - Oversight of the strategic direction and high-level goals of regional planning;
    - Establishing benchmarks for performance and evaluating outcomes;
    - Encouraging participation in regional planning through policy levers, such as grant awards; and
    - Developing a common data set to support regional planning activities and to permit comparisons among regions.
- Regional health planning should serve to enhance the financial stability of the health care delivery system.

B. <u>Recommendation #2</u>:

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 leaders, 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 consistent with the map at figure _.

- 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 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, it will be important for regions to engage in sub-regional and inter-regional activities, and to consider interstate issues, in order to optimize the impact of the RHICs.

D. Recommendation #4:

Each RHIC should advance 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:

- Better health for populations.
    - RHICs should measure performance of their region and sub-populations within the region against Prevention Agenda 2013 metrics and report on them transparently and publicly;
    - RHICs should engage in activities to advance at least two Prevention Agenda 2013 priorities selected by community stakeholders based on community needs, commit to improvements in these priority areas in a defined time period, and use evidence-based strategies to achieve measurable objectives. To the extent possible, RHICs should

coordinate with and support local health department and hospital planning activities related to the Prevention Agenda 2013.

- Better care. Some examples of activities that might be pursued in this area include:
    - Measurement of health system performance and publication of quality data based on specified metrics;
    - Organizing, leading, and/or supporting regional quality collaboratives;
    - Technical assistance in support of development of patient-centered medical homes (PCMHs);
    - Identifying evidence-based patient and community engagement activities and supporting implementation.
- Lower per capita cost of care. Some examples of appropriate activities include convening, analytics, and technical support for:
    - Analysis of regional experience in health care utilization against benchmarks and identifying specific areas in which the region has higher-than-expected utilization rates;
    - Organizing regional initiatives to reduce preventable utilizations of services, such as implementation of evidence-based practices concerning the use of diagnostic imaging, or PQI admissions;
    - Health and health care needs assessments;
    - Organizing and supporting multi-payer, value-based payment and benefit design initiatives;
    - Analysis and publication of quality, cost, and spending data;
    - Assisting in the creation and operation of 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, disability-based, or geographic.

RHICs may also choose to address other health- and health care-related issues. For example, they may analyze and develop strategies 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 initiatives referenced in the 1115 waiver application. In fact, the State's 1115 waiver amendment repeatedly indicates that preference will be given to applicants that have the support of regional planning entities. RHICs 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.

This description of potential RHIC activities is not intended to be exhaustive. Stakeholders in a particular region may determine that their RHIC should address a local or regional need or engage in an activity that is not identified in this report.

The Council carefully considered whether review of CON applications might be a suitable activity for a RHIC. It recommends that, unlike the health systems agencies (HSAs) of a former era, CON review should not be a core, or expected, function of the RHICs. They are instead intended to undertake proactive health planning for their respective regions and to stimulate new initiatives to meet identified needs, rather than to serve as part of the state's regulatory process in approving or disapproving specific proposals of one health care provider or another. Under no circumstances should any RHIC serve to delay or hold hostage any CON application coming before the Department or the Council. At the same time, the Council recognizes that a RHIC, may have a helpful perspective on matters under consideration by the PHHPC, including a forthcoming CON application. RHICs should be free to submit commentary for the benefit of the Department and the Council, to inform their respective statutory responsibilities.

The Council is also aware that two HSAs remain in New York--the Finger Lakes HSA (FLHSA) and the Central New York HSA -- that have a statutory role in reviewing selected CON applications. In the event that either or both become designated RHICs, the Council understands that they would continue their residual role with respect to CONs.

E. <u>Recommendation #5</u>:

The PHHPC should consult with the RHICs concerning 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.

V. ADVANCING THE TRIPLE AIM THROUGH CERTIFICATE OF NEED AND LICENSURE

A. Purpose and Utility of CON

CON is one of several regulatory tools that can be used to drive health system performance and advance the Triple Aim. Thirty-seven states (including the District of Columbia) have CON programs. They vary in scope -- six states cover only long-term care services, while most, like New York cover a broader array of facilities, equipment and services. Several states with CON programs cover services and equipment regardless of setting – whether they are found in physician practices or licensed facilities. A detailed description of New York's CON program is set forth at Appendix __.

CON programs are based on the assumption that health care markets are too inefficient to produce an optimal quantity and distribution of health care services. In health care

markets, unlike typical markets, the suppliers of services have a strong influence over demand, by virtue of ordering services that their patients consume. Patients, unlike consumers of most goods and services, generally lack the expertise, or have the opportunity to become prudent consumers of health care services. Few have the expertise to determine, for example, the medical necessity of a CT scan, or to weigh whether another type of imaging, or none at all, would be more appropriate. And, almost no one is able to shop for quality while experiencing chest pains. In any case, health care services are less sensitive to price than other services. Consumers with health coverage pay for only a fraction of their health care costs, and many consumers view (often rightfully) health care as essential – they are willing to spend more for health care and are unwilling to seek out the provider with bargain basement prices.

CON strives to mitigate these inefficiencies by imposing certain restraints where markets fail. It seeks to limit the supply and guide the distribution of heath care resources, in order to reduce health care costs, improve quality and promote access to necessary services. It exerts downward pressure on costs and spending by curbing the development of excess capacity (especially for supply-sensitive services) that can drive up unnecessary utilization and promote wasteful health care spending.[30] It attempts to consolidate the volume of highly-specialized services and professional expertise among a limited number of facilities in order to promote quality and optimize outcomes.[31] CON also works to channel the development of services where they are needed and to rein in unnecessary capital expenditures.

In addition, CON has been used to protect safety net providers and community hospitals from destabilizing competition that could jeopardize essential services and access. CON has also been used as an all-purpose lever to condition market entry or expansion on actions that support policy goals (such as Medicaid access or charity care). While controversial, this use of CON has been credited with protecting access for low-income individuals.[32]

[30] For purposes of this report, a health care capital project or service is supply-sensitive if the supply of the health care resource in question influences the utilization of that resource, and the level of utilization is driven not by medical theory or evidence, but rather by capacity and payment incentives. For a discussion of "supply-sensitive" care, see Dartmouth Atlas of Health Care, available at http://www.dartmouthatlas.org/keyissues/issue.aspx?con=2937

[31] A health care service is volume-sensitive if a high volume of the service is associated with improved quality or outcomes. Numerous studies have identified a relationship between volume of a specialized service or procedure and outcomes. *See, e.g.* Ethan A. Halm, Clara Lee, and Mark R. Chassin, "Is Volume Related to Outcome in Health Care? A Systematic Review and Methodologic Critique of the Literature," *Annals of Internal Medicine*, no. 137 (2002): 511. Mary S. Vaughan-Sarrazin and others, "Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States With and Without Certificate of Need Regulation," *Journal of the American Medical Association* 288, no. 15 (2002): 1859. *Ibid.*, 1862.

[32] Yee, Tracy, et. al, "Health Care Certificate-of-Need Laws: Policy or Politics?" NIHCR, *Research Brief No. 4*, May 2011 available at http://www.nihcr.org/CON_Laws; Ellen S. Campbell and Gary M. Fournier, "Certificate of Need Deregulation and Indigent Hospital Care," *Journal of Health Politics, Policy and Law, no. 4* (Winter 1993).

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.

A. CON's Impact on Cost, Quality and Access

In order to evaluate CON's utility in addressing the risks associated with a health care delivery system in transition, the Health Planning Committee reviewed the literature assessing the effectiveness of CON as a tool to promote appropriate supply, rein in health care spending and improve quality. It concluded that the evidence is equivocal.

Studies conducted by the Dartmouth Atlas on Health Care demonstrate an association between the supply of certain services and health care utilization and spending:

> The single most powerful explanation for the variation in how patients are treated is the fact that much of the care they receive is "supply-sensitive"; that is, the frequency with which certain kinds of care are delivered depends in large measure on the supply of medical resources available . . . . Nationally, supply-sensitive care accounts for well over 50% of Medicare spending. . . . Hospitalizations for most medical admissions, ICU stays, physician visits, specialist referrals,

diagnostic tests, home health care, and long-term care facilities belong to the "supply-sensitive" category of care. [33]

A recent study conducted by the National Institute of Health Care Reform of health care spending by the automakers in 19 communities nationwide found that the lowest cost communities in the nation were Syracuse and Buffalo. According to the study, differences in the quantity of health care services consumed represented 18 percent of the variation in spending among the communities.[34]

In addition, numerous studies have shown an association between the volume of specialized services performed by a facility or a physician and improved outcomes. CON promotes consolidation of volume and expertise by limiting the number of facilities that are permitted to perform certain procedures. Based on this body of literature, New York has imposed CON controls on cardiac and transplant services. More recent studies are demonstrating a strong volume-quality association for other procedures; esophageal cancer, pancreatic cancer, abdominal aortic aneurysms, pediatric cardiac problems, and AIDS treatments show significantly different mortality rates between high- and low-volume health care providers.[35]

The evidence is inconclusive, however, regarding the effectiveness of CON as a mechanism for reducing supply and associated health care spending or for consolidating volume and improving quality. Given the significant variation among CON programs and health care markets, it has been difficult for researchers to control for the rigor of CON implementation and various market factors that impact costs and quality. Studies evaluating the impact of CON on health care costs and spending are inconsistent.[36] As

[33] Wennberg, John E., et al. "Tracking the Care of Patients with Severe Chronic Illness-The Dartmouth Atlas of Health Care 2008." (2008): 1-174.
[34] ChapinWhite, "Health Status and Hospital Prices Key to Regional Variation in Private Health Care Spending, NIHCR, Feb. 2012.
[35] Ethan A. Halm, Clara Lee, and Mark R. Chassin, "Is Volume Related to Outcome in Health Care? A Systematic Review and Methodologic Critique of the Literature," *Annals of Internal Medicine*, no. 137 (2002): 511.
[36] *E.g.*, Certificate of Need Endorsement by Daimler Chrysler, July 2002; *See also,* Ford Motor Co., CON Study (CY 2000); Statement of General Motors Co. on CON Program in Michigan (2002). E.g Yee, Tracy, et. al, "Health Care Certificate-of-Need Laws: Policy or Politics?" NIHCR, *Research Brief No. 4*, May 2011 available at http://www.nihcr.org/CON_Laws; Ferrier, Gary D., Hervé Leleu, and Vivian G. Valdmanis. "The impact of CON regulation on hospital efficiency." *Health care management science* 13.1 (2010): 84-100.; Hellinger, Fred J. "The effect of certificate-of-need laws on hospital beds and healthcare expenditures: An empirical analysis." *Am J Manag Care* 15.10 (2009): 737-744. Fric-Shamji, Elana C., and Mohammed F. Shamji, "Impact of US State Government Regulation on Patient Access to Elective Surgical Care," *Clinical & Investigative Medicine*, Vol. 31, No. 5 (October 2008); Conover, Christopher J., and Frank A. Sloan. "Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?" *Journal of Health Politics, Policy and Law* 23.3 (1998): 455-481; Conover, Christopher J., and Frank A. Sloan. "Evaluation of Certificate of Need in Michigan." *Center for Health Policy, Law and Management, Duke University, 2003 [cited 04/09 2004]. Available from http://www.michigan.gov/documents/DecIssued-Year_2003_83491_7.pdf* (2003): Part IV at 39, 45-46, 84, 96. Arnold, J. and Daniel Mendelson. "Evaluation of the Pennsylvania Certificate of Need Program." Lewin-ICF, (1992); Begley, Charles E., Milton Schoeman, and Herbert Traxler. "Factors that May Explain Interstate Differences in Certificate-of-Need Decisions." *Health Care Financing Review* 3.4 (1982): 87-94.

for the impact of CON on the quality of volume-sensitive services, research provides stronger evidence the value of CON.[37]

There are few studies of the impact of CON on access, although it is frequently cited as a mechanism for improving and preserving access, particularly for low-income patients.[38] There is some evidence that CON protects access in urban and rural areas by shielding community and safety net hospitals from competition and preventing exodus to suburbs.[39] Observational studies have noted that CON is often used to impose requirements on facilities related to the provision of services to Medicaid beneficiaries and the uninsured.[40] CON also provides an opportunity to prevent decertification of services and beds where they are needed.

When other states have repealed CON laws, the effects on capacity and access have varied based on stringency of CON program, existing saturation in the market, relative spending, the type of facility or service, and demographic trends. Some states reportedly experienced surges in beds, ambulatory surgery centers, cardiac services, and/or dialysis.[41] Others experienced short-term growth followed by retrenchment or no change in growth rates.[42] The experience of Ohio when it repealed CON for hospitals is noteworthy – 15 hospitals closed, 11 in urban areas, some of which migrated to the suburbs. At the same time, there was significant growth in ambulatory surgery and diagnostic imaging centers.[43]

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[37] *See* Ethan A. Halm, Clara Lee, and Mark R. Chassin, "Is Volume Related to Outcome in Health Care? A Systematic Review and Methodologic Critique of the Literature," *Annals of Internal Medicine*, no. 137 (2002): 511. Mary S. Vaughan-Sarrazin and others, "Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States With and Without Certificate of Need Regulation," *Journal of the American Medical Association* 288, no. 15 (2002): 1859. *Ibid*., 1862. Vaughan-Sarrazin et al. also reported that the "mean patient volume in states with continuous certificate of need regulations was 84% higher than in states without regulations. *But see* Verdi J. DiSesa and others, "Contemporary Impact of State Certificate-of-Need Regulations for Cardiac Surgery: An Analysis Using the Society of Thoracic Surgeons' National Cardiac Surgery Database," *Circulation* 114, no. 20 (2006): 2126. The conclusions of this DiSesa are called into question by its effort to control for "random state effects" which may mask the state regulatory impacts it attempts to evaluate. *Ibid. at 2123-24.* S. A. Lorch, P. Maheshwari, and O. Even-Shoshan, "The Impact of Certificate of Need Programs on Neonatal Intensive Care Units," *Journal of Perinatology* 32 (2012): 39, 41, 42.

[38] Yee, Tracy, et. al, "Health Care Certificate-of-Need Laws: Policy or Politics?" NIHCR, *Research Brief No. 4*, May 2011 available at http://www.nihcr.org/CON_Laws.

[39] Yee, Tracy, et. al, "Health Care Certificate-of-Need Laws: Policy or Politics?" NIHCR, *Research Brief No. 4*, May 2011 available at http://www.nihcr.org/CON_Laws; Fric-Shamji, Elana C., and Mohammed F. Shamji, "Impact of US State Government Regulation on Patient Access to Elective Surgical Care," *Clinical & Investigative Medicine*, Vol. 31, No. 5 (October 2008); Ellen S. Campbell and Gary M. Fournier, "Certificate of Need Deregulation and Indigent Hospital Care," *Journal of Health Politics, Policy and Law, no. 4* (Winter 1993).

[40] *Ibid.*

[41] Conover, Christopher J., and Frank A. Sloan. "Evaluation of Certificate of Need in Michigan." *Center for Health Policy, Law and Management, Duke University, 2003 [cited 04/09 2004]. Available from http://www.michigan.gov/documents/DecIssued-Year_2003_83491_7.pdf* (2003): Part IV at 39, 45-46, 84, 96.

[42] *Ibid.*

[43] *Ibid.*

While difficult to measure in quantitative terms, it is believed that in New York, the sentinel effect of CON, together with actual CON disapprovals, reduces unnecessary capital spending, exerts pressure on providers to locate licensed services and facilities in communities where they are needed, and promotes the consolidation of highly specialized services. [44] In addition, the threat of disapproval (particularly of ambulatory surgery centers and other ambulatory care facilities) has induced beneficial collaborations among physician practices, hospitals and FQHCs. In the Rochester area, CON decisions to approve only a portion of the inpatient beds requested by three hospital systems triggered a regional effort to reduce preventable inpatient utilization and strengthen hospitals in outlying areas.

B. CON and New Models of Care and Payment

CON's role in controlling costs through curbs on supply is predicated in large part on the existence of a payment system that rewards the delivery of greater quantities of care and more complex, capital-intensive care. In the context of payment mechanisms that incentivize health and discourage preventable utilization, the utility of CON as a mechanism to reduce health care spending is questionable. However, value-based and risk-based payments are just beginning to take hold. Even the Medicare ACOs are receiving fee-for-service payments, albeit together with shared savings. Hospitals, in particular, are struggling to manage through this transitional period. Many are still trying to maximize their inpatient census while minimizing readmission penalties. Hospital-sponsored ACOs are still vying for high-end services like cardiac surgery. Thus, in the near term, New York's health care markets remain flawed in ways that justify some controls on supply.

In the longer term, several factors are expected to improve efficiencies in health care markets and arguably lessen the need for CON. The transition away from fee-for-service to value-based and risk-based payments should discourage unnecessary capital investment and supply-driven utilization. New health plan benefit designs are expected to make consumers more value conscious in their health care choices. These changes, together with the availability of cost and quality data through the launch of an all-payer database in New York State and expanded publication of such data have the potential to promote quality and price competition.

While the potential of this transformation is enormous, the Council recognizes that the actual impact of new models on the ground is uncertain. First, the impact of new payment mechanisms may vary by health care sector. Moreover, even if broad penetration of effective, risk-based payments and improved market efficiencies were to be achieved, there may be a long-run role for CON in promoting an appropriate distribution of health care services, if not in curbing supply. It is conceivable that risk-based payment mechanisms may incentivize the development and preservation of health care services in only in geographic areas where risk can be spread across large populations that do not have complex and costly needs. Risk-based payments may

[44] Although relatively few CON applications are officially denied, many that would otherwise be denied are set aside at the request of the applicant when a decision to disapprove appears imminent.

discourage the delivery of services in high-cost or low-density communities. This concern may be mitigated through adjustments in payments or alternative regulatory mechanisms, such as ACO certification, health plan network requirements, or possibly facility licensure and decertification requirements. However, in the absence of effective alternative requirements, CON may continue to be an appropriate tool.

The recommendations below seek to apply the principles for reform adopted by the PHHPC in June 2012 to support beneficial innovation, while mitigating risks. They promote the Triple Aim by reducing restraints on primary care development, facilitating the creation of integrated systems, and strengthening DOH oversight of governance. They also strive to ensure that CON operates in a cost-effective manner, by eliminating unnecessary or low-value administrative steps, and investing resources where they can have the greatest impact.

D. 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 features that typically trigger the need for CON review -- it is not supply-sensitive or volume-sensitive or capital-intensive. The value of imposing a CON review on primary care facilities in light of the need for increased primary care capacity appears limited. Most states appear to have reached this conclusion, as few apply CON to primary care facilities.

Accordingly, PHHPC recommends exempting primary care facilities from CON. 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, advanced 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 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.
- The Council is aware 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.

E. <u>Recommendation #7</u>:

Projects funded with 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, to the extent that regional planning considerations have been incorporated in the RFA. 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 components approved through an RFA process and components that were not part of the RFA should not be eligible for this exemption. If a project involves additional elements, a public need and financial evaluation will be necessary to review a project in its entirety.

F. <u>Recommendation #8</u>:

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

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, in comparison with other modalities.

The Council recognizes that it is difficult for the State to remain current regarding 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 services and transplant surgery, might be appropriate for CON review due to a strong volume-quality association. The Council recommends that the Department contract with an academic or research institution to conduct periodic environmental scans and identify emerging, capital-intensive technologies and volume-sensitive services that might be appropriate for CON or, in particular, for the Department's new medical technology demonstration. The Department should consult with the PHHPC concerning the recommendations of the research institute and the adoption of policies in response to those recommendations.

G. <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 has 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. These data suggest that hospitals are voluntarily taking beds out of service in response to diminished demand.

The Council has concluded that, in the foreseeable future, payment incentives may eliminate the supply-sensitivity of hospital beds. However, the penetration and impact of new payment mechanisms have yet to be 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 New York'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 three to five years.

H. <u>Recommendation #10</u>:

Consider use of ACO certification, in lieu of CON for certain facilities, to promote appropriate distribution of facilities and services and Prevention Agenda 2013 goals.

As the delivery system shifts toward integrated systems of care that receive substantial revenues through capitated or risk-based payments, the utility of CON becomes less clear. If providers are to be paid a fixed amount to keep people healthy, for example, the incentive to develop unnecessary capacity will be 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 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 an additional component of shared savings. It is unclear whether or when 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, which has not yet been implemented. The PHHPC recommends that the Department consult with the Council concerning the ACO certification process. This certification process could be a vehicle for ensuring that essential services are preserved and that population health, access and quality concerns are addressed. Certification should also take into account the risk of inappropriate under-utilization of medically-necessary services. The applicability of CON to such providers should be reconsidered once the ACO certification process is finalized.

I. <u>Recommendation #11</u>:

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. The current methodology relies heavily on the incidence of cancer, but it is well-established that hospice care is appropriate for a wide variety of terminal conditions.

New York State is tied with New Jersey for the highest rate of Medicare inpatient days during the last six months of life and has among lowest rates of hospice use among

Medicare beneficiaries nationwide.[45] Many factors undoubtedly contribute to the relative 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.

J. Recommendation #12:

Update the CON process for approved pipeline projects.

DOH should take steps to ensure that public need is accurately evaluated when approved 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 two years for establishment projects and five years for construction projects 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 five years. If construction is not commenced within five years or an establishment is not finalized within two years, the CON should expire. Once a CON expires, the provider would have to re-apply for, and receive, a CON in order to go forward.

H. Recommendation # 13:

Update the criteria that trigger the facility licensure requirement and equalize treatment of physician practices and facilities with respect to CON requirements.

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 extensive diagnostic and treatment services – including most of the 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. While these entities do not hold an ownership interest or formal governance role in the practice, they 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

[45] "Inpatient Days per Decedent, By Interval Before Death and Level of Care Intensity," "Hospice Days per Decedent During the Last Six Months of Life," The Dartmouth Atlas of Health Care, 2003-2007, available at www.dartmouthatlas.org; *See also* David Goodman, Amos Esty, Elliot S. Fisher, Chiang-Hua Chang, "Trends and Variation in End-of-Life Care for Medicare Beneficiaries with Severe Chonic Illness,"Dartmouth Atlas of Health Care (Apr. 2012).

accountable care organizations (ACOs) designated by the federal Centers for Medicare and Medicaid Services (CMS) in New York State are led by physician practices.[46]

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, those physician practices 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.[47] 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. [48] Yet, only the licensed setting is subject to 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 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.

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[46] Burke, *supra* note 21.

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

[48] Nat'l Council on Radiation Protetion and Measurements, NCRP Report No. 160, Mar. 2009. DJ Brenner DJ and EJ Hall, "Computed Tomography : An Increasing Source of Radiation Exposure," *NEJM*, no. 22 (Nov. 2007): 2277-2284. Berrington de Gonzalez A., et al., "Projected Cancer Risks from Computed Tomographic Scans Performed in the United States in 2007," *Archives of Internal Medicine*, no. 22 (Dec. 2009): 2071-77. This trend has been identified even in integrated systems. R Smith-Bindman, et al., "Use of Diagnostic Imaging Studies and Associated Radiation Exposure for Patients Enrolled in Large Integrated Health Care Systems, 1996-2010," *JAMA*, no. 22 (Jun. 2012): 2400-2409. 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). "Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions," GAO, Sept. 2012.

The Council requests that the Department analyze options and develop a set of recommendations to equalize the treatment of physician practices and licensed facilities under CON and licensure – either by applying CON and licensure to similar services, or exempting similar services from CON and licensure, regardless of setting. The Department's recommendations should be informed by input from stakeholders and:

- Consideration of the relative quality and cost of surgical care, 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.

VI. 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 was 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 is 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 ten 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, and 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 ten-year look-back to seven 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.

When a proposed owner or trustee presents affiliations with a health care facility or agency that has a pattern of, or multiple, enforcements, or a sub-standard 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 system, for example, 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 entity already established to operate a health care facility or agency in New York State, 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. <u>Recommendation #16</u>:

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. <u>Recommendation #17</u>:

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 have assisted 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, the ability of these arrangements to contribute to the quality or efficiency of the care delivered, and the added value justifying the enhanced reimbursement, are 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 a 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. It should be asked to demonstrate how the proposed arrangement will benefit the health care facility seeking to affiliate, as well as the passive parent and its system.
- 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; or lack of evidence that the passive parent arrangement would benefit the proposed affiliate, as well as the parent and/or existing affiliates.

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, quality of care, and evidence that the passive parent arrangement is mutually beneficial for the parent or its affiliates. Implementation of a plan for clinical integration should be considered in determining whether the arrangement is mutually beneficial.

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.

The Council considered recommending a requirement that parents and affiliates be clinically integrated in order to negotiate collectively with health plans to secure enhanced reimbursement. Clinical integration, as described by the Federal Trade Commission and Department of Justice, for purposes of evaluating compliance with antitrust laws, involves "an active and ongoing program to evaluate and modify practice patterns by the venture's providers and to create a high degree of interdependence and cooperation among the providers to control costs and ensure quality."[49] Clinical integration typically requires the implementation of clinical protocols and system-wide performance standards, integrated information technology to permit the sharing of clinical and cost information, the analysis of utilization and claims data to improve quality and reduce costs, financial incentives to encourage satisfaction of performance standards and adherence to protocols, and significant investment in training and performance improvement.[50]

The Council supports clinical integration as a vehicle for advancing the Triple Aim. It believes that requiring clinical integration as a condition of collective negotiation would promote integrated systems that provide higher quality, evidence-based, and efficient care. It would also ensure that affiliates benefit from passive parent arrangements and that purchasers and consumers reap added value in exchange for higher costs incurred, when passive parents negotiate with health plans to secure higher payments for their affiliates.

However, stakeholders raised concerns that requiring clinical integration as a condition of collective negotiation would intrude on the authority of antitrust enforcement agencies and force providers to move too quickly to integrate, thereby deterring them from initiating the very relationships that serve as the foundation of clinical integration programs. As a result, the Council is recommending that a plan for clinical integration be considered as part of the assessment of the mutual benefit of the passive parent arrangement.

E. <u>Recommendation #18</u>:

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.

This recommendation would improve the Department's ability to monitor changes in control of health facilities. It would also ensure that the Department has updated

[49] Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 F.R.67026, 67027 (Oct. 28, 2011).
[50] ***See*** Thomas B. Leary, Robert F. Leibenluft, "Guidance for Clinical Integration: Updated Working Paper," American Hospital Association, Sept. 2010, available at www.aha.org .

information concerning the composition of facilities' governing bodies, in the event that compliance, quality of care, or financial issues demand intervention by the Department.

F. <u>Recommendation #19</u>:

Strengthen DOH authority to respond to failures in governance.

The proposed changes in character and competence reviews (see Recommendations 15 and 16) 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.

VII. 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 2012 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 2012. Specifically:

- When construction projects involve expansion of capacity or services, ensure that the 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 (EHR)system and connect to the Statewide Health Information Network ("SHIN-NY") to assure health information exchange capacity as condition of CON approval and licensure. The EHR and SHIN-NY requirements may be waived for small construction projects that are subject only to a limited review for compliance with physical plant safety standards. The Council is sensitive to the fact that certain services are highly sensitive and raise heightened confidentiality concerns. For providers of these services uploading data to the SHIN-NY may problematic. The Council recommends that the Department develop a way to comply with these requirements that addresses these concerns. 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 Prevention Agenda 2013.

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.

CONCLUSION

This report, together with the administrative streamlining recommendations adopted in Phase 1, lays the groundwork for a new paradigm for regional planning, CON and licensure in New York State that will support the Triple Aim. Through regional health improvement collaboratives, community stakeholders will develop consensus-based strategies to improve health and health care and reduce costs. The report promotes primary care development by eliminating CON and requiring only licensure for primary care facilities. The report also recognizes the changing nature and roles of physician practices and provides a path for equalizing the regulatory oversight applied to services that are provided in both practice- and facility-based settings. The recommendations remove barriers to integration of systems through revisions to the "establishment" process, while strengthening the Department's ability to oversee passive parents and intervene when governing bodies fail to direct their institutions properly. Finally, the recommendations provide a mechanism for incorporating quality and population health considerations into CON reviews.

The PHHPC expects to revisit CON and licensure policy as the delivery system evolves. The expansion of integrated systems that receive most of their revenues through risk-based payments may call for additional changes in CON and licensure or an entirely new form of regulation in lieu of CON. The transformation of the delivery system may also require changes in law or regulation that are beyond the purview of the PHHPC. For example, the growing acceptance by providers of risk-based payments may demand changes in how the State oversees the transfer of risk to providers, especially given the virtual absence of oversight of risk transfers between self-insured plans and providers. Regional planning and sound regulatory oversight that supports beneficial innovation, while mitigating risks, will strengthen New York's efforts to achieve better care, better health and lower costs.