

## **NYS Public Health and Health Planning Council: Oversight of Ambulatory Care Services**

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The health care system in the United States is undergoing seismic shifts in insurance coverage, payment mechanisms, and modes of delivery - all at once. In 2014 alone, an estimated 15 million uninsured Americans will receive health coverage between the Medicaid expansion and the health insurance marketplaces engendered by the Affordable Care Act (ACA). Both government and private payors are driving a transformation from volume-based reimbursement to value-based purchasing through bundled payments, global budget contracts, accountable care organizations, and other new payment models. And perhaps most importantly, the actual structures of the health care delivery system are changing. While hospitals remain important centers of gravity in the health system, services are increasingly being delivered via ambulatory care. The shift to ambulatory care is giving rise to new delivery structures, such as retail clinics and urgent care centers, as well as a reinvention of existing ambulatory care capacity, as seen with the patient-centered medical home model and the movement toward team-based care. To protect the interests of the public, oversight of ambulatory care services must keep pace with these rapid changes.

### **Background**

In January 2012, Commissioner of Health Nirav R. Shah, M.D., M.P.H., charged the Public Health and Health Planning Council (PHHPC) with the development of a health planning framework that drives health system improvement. The December 2012 report of the PHHPC - entitled Redesigning Certificate of Need and Health Planning - examined trends in health care organization and sought to align Certificate of Need (CON) and health planning processes with these changes. The PHHPC recommended that deliberations on health planning be conducted through regional, multi-stakeholder collaboratives. By recommending retaining licensure requirements but eliminating need assessments for primary care facilities, it anticipated the expansion of capacity needed for the one million New Yorkers who will gain coverage under the ACA. Additional recommendations dealt

with regulatory oversight of physician practices; modifications to the process of establishing new health care facility and home care agency operators; strengthening health system governance review; supporting expanded access to hospice; and incorporating quality and population health factors into CON review. The December 2012 PHHPC report laid the groundwork for strategic alignment of regulatory oversight with new models of health care organization and payment.

In this report, the PHHPC builds the framework for public oversight of ambulatory care services. Three introductory principles are germane. First, the vision of high-performing ambulatory care remains rooted in the Triple Aim (better health, higher-quality care, lower costs) - with a particular emphasis on continuity of care for patients. Second, there is a need to better define the taxonomy of ambulatory care services. From the perspective of the state government, clarification requires improved reporting from new health care entities (e.g., retail clinics); connections with regional and state health information technology hubs; and coordination among state agencies including the Department of Health, the Department of Mental Hygiene, the Department of Financial Services, and the new Health Plan Marketplace. A uniform nomenclature would also facilitate the consumer's understanding of rights and responsibilities. Third, the regulatory mechanisms employed - from mandatory reporting to licensure to regional planning to Certificate of Need - should remain flexible and match the degree of consensus regarding the appropriate regulatory path. For areas with considerable uncertainty about the consequences of any new regulation, incremental steps - often beginning with reporting requirements - can help shed light on a prudent way forward.

### **A Vision for Ambulatory Care**

The landscape of health care delivery is undergoing rapid metamorphosis. In the future, more care will be delivered in the outpatient setting; it will be managed by teams of providers, often working across distributed networks; and much of it will be remotely delivered through telehealth. Existing institutions are restructuring around this reality, as evinced both by the evolution of certain hospitals into full health care delivery systems, by

the expansion of a number of Federally Qualified Health Centers into powerful regional providers of care, and by the emergence of large multispecialty physician groups—with some of each taking on financial risk. Risk-based contracts have shown promise in slowing the increase in medical expenditures for public payors (e.g., Medicare) as well as private payors. Many of the arrangements are grounded in the concept of “accountable care,” in which a group of providers accepts responsibility for all health care services required by a given population - and is held accountable for cost and quality outcomes. Of the 148 Medicare Accountable Care Organizations (ACOs) currently operating nationwide, 15 are located in New York. Two-thirds of the 15 are sponsored by physician groups rather than hospitals. Meanwhile, other categories of “disruptive innovators” - such as retail clinics, startup primary care networks, and ambulatory surgery centers - are testing out models of care with the potential to upend current payment and delivery paradigms. In this environment, the primacy of acute care as the financial driver of the health care system is challenged and the role of ambulatory care is heightened.

### A foundation of high-performing primary care

High-quality ambulatory care depends on the bedrock of excellent primary care. New York must both improve and extend primary care to accommodate the million New Yorkers who will gain coverage via the Affordable Care Act. Because new models of ambulatory care may blur the boundaries of primary care, it is useful to invoke the Institute of Medicine’s definition of primary care: “The provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.” While superlative models of primary care will be context-dependent across diverse communities, a few main elements are becoming apparent:

- Patient-centered medical home model with team-based care delivery;
- Population health management with sophisticated risk stratification;
- High-risk patient management;

- Rapid but judicious access to specialty expertise; and
- Integrated behavioral health.

Taken together, these components of high-performing primary care provide a foundation for delivering on the Triple Aim and enshrining continuity of care as a central goal of the larger ambulatory care enterprise.

### Innovations in specialty ambulatory care services

New models of ambulatory care delivering specialty services have complicated relationships between hospitals and physicians over the past two decades. Enhanced physician practices (so-called physician “mega-groups”), non-hospital surgery (including ambulatory surgery centers and office-based surgery), advanced diagnostic imaging centers, and radiation therapy all fall into this category. The number of these facilities has steadily increased - in New York and around the country - as physicians, taking advantage of new forms of technology and available capital, pursue new ventures separate from hospital centers. Proponents argue that such novel arrangements create “centers of excellence” for specialty care and, in the case of enhanced physician practices, promote community-based population health. Detractors argue that, despite providing complex and costly services, the enhanced arrangements operate with insufficient oversight of safety and quality - and that they cherry-pick more affluent patients.

The amalgamation of “specialty ambulatory care services” multiplies the complexity of each category of service. Enhanced physician practices are in some ways the most natural accountable care organizations - but they can also destabilize existing safety net providers by drawing away commercially-insured patients. Non-hospital surgery spans care sites with drastically different cost structures and regulatory responsibilities. Scant evidence exists to guide patients to appropriate sites of care - and thus the same procedure may be performed in office-based surgery, ambulatory surgery centers, and hospitals.

## Way Forward

Despite the broad penetrance of convenient care options and specialty ambulatory services across the United States, there are few precedents to call upon with respect to comprehensive ambulatory care oversight. New York therefore has an opportunity to be a trailblazer in developing sound oversight while encouraging innovation in the field. The work of the Medicaid Redesign Team on Health Homes - and the primary care expansion and new care models in the state's proposed 1115 Medicaid waiver - demonstrate New York's commitment to ambulatory care. This report builds on those antecedents and the PHHPC's redesign of Certificate of Need to craft a path forward.

The report's recommendations regarding oversight of ambulatory care flow from five specific premises:

- Regulation should strive to create conditions for fair competition in the ambulatory care market, particularly between institutional providers and independent professional practices. However, in cases of market failure, particularly in underserved areas, other regulatory considerations may predominate in order to develop highly integrated "utility-style" models of care.
- The public's awareness of novel ambulatory care services is a paramount consideration. Standard nomenclature for services and public signage should serve to reduce consumer confusion.
- Patient safety and quality standards for new models of care should equal or exceed existing clinical standards.
- Continuity of care, particularly with patients' primary care practices, should be preserved and promoted.
- A robust data infrastructure, implemented via interoperable health information technology systems, should support providers' reporting requirements as well as patients' continuity of care. Over time, the availability of this data should enable further refinement of the state's own regulatory system.

## Limited Services Clinics (Retail Clinics)

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### Recommendations

#### 1. Naming Convention

- Retail clinics will be known as “Limited Services Clinics.”
- The term “Limited Services Clinics” is to be used in the name and in signage at the retail site and in any other materials that describe a clinic and/or services.

#### 2. Define Scope of Services

- Provide a limited set of basic health services intended to serve as episodic care related to minor ailments illness as well as immunizations.
- Offer unscheduled, walk-in appointments. Typically includes extended business hours.
- Services are of a nature that may be provided within the projected duration of patient encounters, using available facilities and equipment. These services should require only a focused history and physical examination and may include simple wellness and screening services for chronic conditions such as diabetes and hypertension.
- Excludes surgical services, dental services, physical rehabilitation services, mental health services, substance abuse services, or birth center services.
- Prohibit dispensing controlled substances or conducting any laboratory testing except for CLIA-waived tests.
- Prohibit administering services to patients who are 24 months of age or younger.
- Prohibit administering childhood immunizations to patients under 18 years of age, except for vaccination against influenza.

#### 3. Accreditation

- Secure and maintain accreditation by a national accreditation organization approved by the Department.

- If a provider loses its accreditation, the provider and the accrediting body would be required to report such change to the Department of Health in a timely fashion.

#### **4. Consumer Disclosure**

- Signage must be prominently posted that states the services provided.
- Where applicable, signage is required to indicate that prescriptions and over the counter supplies, etc., can be purchased from any business and do not need to be purchased on-site.

#### **5. Patient Safety and Quality**

- Require a medical director at the corporate level of the retail organization who is licensed and currently registered to practice medicine in New York State.
- Require policies and procedures for referring patients whose needs exceed services provided and to ensure continuity of care.
- Prohibit offering or providing any incentive, inducement and payments to clinical staff for referring or recommending to patients' items or services provided at the site or by the host provider.

#### **6. Stabilization of the Medical Home**

- Provide a roster of primary care providers accepting new patients to patients indicating that they do not have a primary care provider. The list must identify preferred providers who have achieved recognition as a Patient-Centered Medical Home (PCMH) or other designation, and a description of what the designation means. The list must include Federally Qualified Health Centers and other providers who serve Medicaid and low-income patients, people with disabilities, and identify cultural and linguistic capabilities when available.
  - Provide the list to each patient who indicates they do not have a primary care provider.

- Recommend to the patient that they schedule an initial and/or annual appointment with a primary care provider.
- If indicated, recommend a follow-up visit with a primary care provider.
- Develop policies and procedures to identify and limit the number of repeat encounters with patients.

## **7. Health Information Technology**

- Require utilization of a certified electronic health record (EHR) for sharing of patient information to all authorized clinicians and participation in interoperable systems, as deemed appropriate by the Department.
- Provide a copy of medical records to the patient consistent with current Public Health Law.
- Require documentation, execution, and management of a discharge plan of care for every patient.
- Require ePrescribing.

## **Statutory Action**

To implement these recommendations, the following statutory changes are required:

- Amend Section 2801-a of the Public Health Law to add “Limited Services Clinics” under the category of Article 28 diagnostic or treatment centers.
  - Statutory authority will allow corporations to provide professional services that are currently prohibited.
  - The statute does not preclude private physician offices from providing professional services in a retail setting.
- Require an architectural review to assure health and safety requirements are met.

## Urgent Care

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### Recommendations

#### 1. Define Urgent Care Provider and Urgent Care Scope of Services

- Urgent Care is for the treatment of acute episodic illness or minor traumas. Urgent care is not for emergency intervention for major trauma, life threatening or potentially disabling conditions or for monitoring and treatment over prolonged periods. Urgent care is not intended to be a patient-centered medical home or a source of continuing care.
- Offer unscheduled, walk-in appointments. Typically includes extended business hours.
- Minimum characteristics/services that a provider must have in order to be considered an urgent care provider include:
  - Accepts unscheduled, walk-in visits typically with extended hours on weekdays and weekends
  - X-Ray and EKG
  - Phlebotomy and Lab Services (CLIA waived tests)
  - Administration of oral (PO), sublingual (SL), subcutaneous (SC), intramuscular (IM), intravenous (IV), respiratory, medication and IV fluids
  - Uncomplicated laceration repair
  - Crash Cart Supplies and Medications; ACLS and PALS protocol capable, as evidenced by staff holding current certification
- All training, equipment, medication and protocols must be appropriate for the population served, including the pediatric population.

## 2. Naming Convention and Consumer Disclosure

- Restrict use of the term “Urgent Care” to those providers offering urgent care services as defined and approved by the Department.
- The term “Urgent Care” is to be used in the name and in signage at the provider site and in materials. Commercial terms (e.g. “Convenient Care”, “FastMed”, etc.) could still be used in a provider’s name, but would need to add “Urgent Care”. For example, “FastMed Urgent Care”.
  - The word “emergency” or its variations, such as “Emergi-care” or “Emergent-care” cannot be used by urgent care providers or other providers unless licensed by the State as an emergency department.
  - Providers offering specialized services (e.g. orthopedic services) typically do not offer the defined scope of urgent care services as the model of urgent care described in this report and cannot use the term “Urgent Care”. They are more appropriately characterized as specialty care with walk-in appointments.
  - Providers offering the defined scope of urgent care services required, but limiting their practice to a specific population of patients, such as a pediatric or geriatric population, may be allowed to use the term “Urgent Care” but need to specify the specific population serviced in their name such as “Pediatric Urgent Care” or “Geriatric Urgent Care”.
- Signage must be prominently posted that states the services provided.
- Where applicable, signage is required to indicate that prescriptions and over the counter supplies, etc., can be purchased from any business and do not need to be purchased on-site.

### 3. Approval to be Called “Urgent Care” Provider

- To be approved to use the name, providers will need to meet specified criteria demonstrated through certification and/or accreditation by accrediting organizations approved by the Department.
  - Non-Article 28 Urgent Care Requirements:
    - Private physician offices, including those affiliated with an Article 28, wanting to provide Urgent Care Services need to obtain accreditation by an accrediting organization approved by the Department. No CON review required.
  - Article 28 Urgent Care Requirements:
    - Most Article 28 providers already secure accreditation from a national accrediting body and the accrediting review must include an on-site review of the urgent care provider. If an Article 28 provider is not accredited by a third party, the urgent care provider will be surveyed by the Department of Health.
    - Existing Article 28 hospital or D&TC providers wanting to provide Urgent Care Services must go through a limited review to have urgent care identified on their operating certificate.
    - A private physician practice affiliated with an Article 28 may provide Urgent Care Services as a private physician office if they obtain accreditation by an accrediting organization approved by the Department OR they can become an Article 28 through a full CON review.
    - Establishment of new Article 28 hospital or D&TC providers wanting to provide Urgent Care Services must go through full CON review and have urgent care identified on their operating certificate.

See Appendix for discussion of types of CON reviews.

#### **4. Disclosures to Consumers**

- Require signage to be prominently posted that states the services provided.
- If applicable, require signage to indicate that prescriptions and over the counter supplies, etc., can be purchased from any business and do not need to be purchased on-site and prohibit any incentive, inducement and payments to clinical staff for referring or recommending to patients' items or services provided at the site or by the host provider.

#### **5. Patient Safety, Quality and Accreditation**

- Require policies and procedures for referring patients whose needs exceed services provided and to ensure continuity of care.
- To be called an "Urgent Care" provider, providers are required to obtain accreditation from an accrediting organization as determine by the Department, as discussed above.
  - If a provider loses its accreditation, both the accrediting body and the provider are required to report such change to the Department of Health in a timely fashion.
  - A provider that wants to provide an Urgent Care Service that requires more than minimal sedation or local anesthesia must seek Office Based Surgery accreditation (pending evaluation of urgent care accreditation requirements for equivalence with OBS accreditation). This is consistent with current private practice OBS requirements.

#### **6. Stabilization of the Medical Home**

- Provide a roster of primary care providers accepting new patients to patients indicating that they do not have a primary care provider. The list must identify preferred providers who have achieved recognition as a Patient-Centered Medical Home (PCMH) or other designation, and a description of what the designation means. The list must include Federally Qualified Health Centers and other providers who serve Medicaid and low-

income patients, people with disabilities, and identify cultural and linguistic capabilities when available.

- Provide the list to each patient who indicates they do not have a primary care provider.
- Recommend to the patient that they schedule an initial and/or annual appointment with a primary care provider.
- If indicated, recommend a follow-up visit with a primary care provider.
- Develop policies and procedures to identify and limit the number of repeat encounters with patients.

## **7. Health Information Technology**

- Require utilization of a certified electronic health record (EHR) for sharing of patient information to all authorized clinicians and participation in interoperable systems, as deemed appropriate by the Department.
- Provide a copy of medical records to the patient consistent with current Public Health Law.
- Require documentation, execution, and management of a discharge plan of care for every patient.
- Require ePrescribing.

## **Statutory Action**

Through Statute, require that the use of the term “Urgent Care” be restricted to those providers offering the minimum scope of urgent care services as defined and approved by the Department and who meet other requirements, as described above.

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## Freestanding Emergency Departments

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### Recommendations

#### 1. Establish Naming Convention and Definition

- The name “Hospital-Sponsored Off-Campus Emergency Department” will be used in regulation to describe an emergency department that is hospital-owned and geographically removed from a hospital campus, in alignment with language used and model supported by the Centers for Medicare & Medicaid Services (CMS).
- The facility name that is held out to the public is not required to be called a “Hospital-Sponsored Off-Campus Emergency Department”. It is recommended that Hospital-Sponsored Off-Campus Emergency Departments (EDs) use the name of the hospital that owns the facility followed by “Satellite Emergency Department” in order to assist with consumer awareness.

#### Regulatory Amendment:

Amend Title 10, Section 700.2 to define Hospital-Sponsored Off-Campus Emergency Department. Restrict off-campus ED ownership to hospitals and prohibit non-hospital owned EDs, in accordance with model preferred by CMS.

#### 2. Define Standards and Scope of Services

- Subject to the same standards and requirements as a hospital-based emergency department with regard to the minimum training of providers, staffing, and the array of services provided at the facility;
- Must demonstrate compliance with all CMS Hospital Conditions of Participation (CoP)<sup>1</sup>;
- Will be subject to federal EMTALA requirements to stabilize and treat all patients presenting for treatment without regard for their ability to pay;

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<sup>1</sup> Center for Medicare and Medicaid Services. (2008). Requirements for Provider-based Off-campus Emergency Departments and Hospitals that Specialize in the Provision of Emergency Services. <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter08-08.pdf>

- Must have capacity for receiving ground ambulance patients; and
- Must establish transfer protocols with local EMS providers and hospital-based emergency departments to ensure timely transfer of patients requiring a higher level of care.

**Regulatory Amendment:**

Amend Title 10, Section 405.19 to include requirements that are specific to Hospital-Sponsored Off-Campus Emergency Departments. Update and revise to include requirements for scope of services, minimum training of providers, staffing, capacity to receive ground ambulance patients, and transfer and referral protocols.

**3. Define Hours of Operation**

- Hours of operation for a Hospital-Sponsored Off-Campus ED will generally be 24 hours per day, seven days per week.
- Part-time operation, at a minimum of twelve hours per day, may be allowed with consideration for the local and unique circumstances necessitating part-time operation.
- Requests for a new full-time off-campus ED, will require full CON review.
- Requests for part-time operation of a new off-campus ED or to reduce existing full-time ED hours of operation to part-time, will require full CON review.

See Appendix for discussion of types of CON reviews.

**Regulatory Amendment:**

Amend Title 10, Section 405.19 to include requirements regarding hours of operation that are specific to Hospital-Sponsored Off-Campus Emergency Departments. Update and revise to include minimum hours of operation, and criteria for which part-time operation may be considered.

#### **4. Develop a need methodology for Hospital-Sponsored Off-Campus Emergency**

##### **Departments.**

- Need criteria for Hospital-Sponsored Off-Campus EDs may include consideration of patient volume at existing hospital-based emergency departments as well as distance and travel time to the nearest hospital-based emergency department.
- Establishment of an off-campus ED will require full CON review.
- Emergency approval by the Commissioner of Health for establishment of an off-campus ED may be allowed in instances where a hospital is closing and where adequate resources cannot be arranged in a timely fashion to address the void in services (per Section 401.2).

##### **Regulatory Amendment:**

Amend Title 10, Section 709 to include specific need criteria for Hospital-Sponsored Off-Campus Emergency Departments.

#### **5. Accreditation**

- Secure accreditation from a national accrediting body for a hospital with an off-campus ED. The accrediting review must include an on-site review of the off-campus ED.
  - If a hospital loses its accreditation, the hospital and accrediting body would be required to report such change to the Department of Health in a timely fashion. If a hospital is not accredited by a third party, the off-campus ED will be surveyed by the Department of Health.

##### **Regulatory Amendment:**

Amend Title 10, Section 720.1 pertaining to General Hospital Accreditation requirements to indicate that for those hospitals with off-campus emergency departments, accreditation reviews must include the off-site facility.

## 6. Disclosures to Consumers

- Use clear nomenclature and signage to accurately convey to the consumer their hours of operation and capacity to deliver emergency care.
- Develop a communication plan that includes collaborative planning with regional emergency medical services as well as a public information campaign for informing consumers about the facility's hours of operation and capacity.

## 7. Stabilization of the Medical Home

- Provide a roster of primary care providers accepting new patients to patients indicating that they do not have a primary care provider. The list must identify preferred providers who have achieved recognition as a Patient-Centered Medical Home (PCMH) or other designation, and a description of what the designation means. The list must include Federally Qualified Health Centers and other providers who serve Medicaid and low-income patients, people with disabilities, and identify cultural and linguistic capabilities when available.
  - Provide the list to each patient who indicates they do not have a primary care provider.
  - Recommend to the patient that they schedule an initial and/or annual appointment with a primary care provider.
  - If indicated, recommend a follow-up visit with a primary care provider.
- Develop policies and procedures to identify and limit the number of repeat encounters with patients.

**8. Health Information Technology**

- Require utilization of a certified electronic health record (EHR) for sharing of patient information to all authorized clinicians and participation in interoperable systems, as deemed appropriate by the Department.
- Provide a copy of medical records to the patient consistent with current Public Health Law.
- Require documentation, execution, and management of a discharge plan of care for every patient.
- Require ePrescribing.

**Statutory Action**

No statutory action required. Regulatory amendments needed are identified in the text above.

## **Non-Hospital Surgery**

### **Ambulatory Surgery Centers and Office-Based Surgery**

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#### **Recommendations**

##### **Ambulatory Surgery**

No changes are recommended with respect to the current regulatory oversight of ambulatory surgery.

##### **Office-Based Surgery**

#### **1. Registration**

- Require registration of all new and existing office-based surgery/office-based anesthesia (OBS/OBA) practices with the Department.
- Require submission of procedure and quality data as determined by the Department.

#### **2. Definitions**

- Clarify that neuraxial and major upper and lower extremity regional nerve blocks are included in the OBS definition.
- Define OBA as general anesthesia, neuraxial anesthesia, major upper and lower extremity regional nerve blocks, moderate and deep sedation.
- Limit OBS/OBA expected procedural time to six hours and limit post-procedure time to meet safe and appropriate discharge to six hours.

### **3. Accreditation and Adverse Event Reporting Requirements**

- Require all physician practices performing procedures (including non-invasive procedures) utilizing more than minimal sedation to become accredited and file adverse event reports.
- Require all podiatry practices performing procedures (involving the foot as well as the ankle) utilizing more than minimal sedation to become accredited and file adverse event reports.
- Add “observation of longer than 24 hours within 3 days of OBS” and “unanticipated emergency department visit within 72 hours” to list of reportable adverse events.
- Extend reporting time to 3 days/72 hours.

### **4. Accrediting Agencies Requirements**

- Require accrediting agencies to share the outcomes of survey and complaint/referral investigations and other requested data with DOH upon request.
- Require accrediting agencies to survey OBS/OBA practices and carry out complaint/incident investigations upon DOH request.
- Require accrediting agencies to utilize American Board of Medical Specialties (ABMS) certification, hospital privileges or other equivalent determination of competency in assessing credentialing of practitioners to perform procedures and/or provide sedation/anesthesia.

### **Statutory Action**

Amend existing statute, Section 230-d of Public Health Law.

## **Upgraded Diagnostic and Treatment Centers**

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### **Recommendation**

Eliminate Section 2956 of Public Health Law which relates to the designation of upgraded diagnostic and treatment centers.

## Appendix: Types of CON Reviews

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A Certificate of Need (CON) application is required in order to establish a new operator or undertake construction, add certain services, or purchase major medical equipment. CON reviews have been divided into three broad categories, based on factors such as cost, services proposed, and safety issues:

- Full Review;
- Administrative Review; and
- Limited Review.

Full review applications require a recommendation or decision of the Public Health and Health Planning Council. Administrative reviews require approval of the Commissioner only, without a recommendation by the PHHPC. Limited reviews are also processed without referral to the PHHPC. They are typically reviews of the programmatic and physical plant aspects of less extensive construction projects or services additions or eliminations – similar to the types of reviews that would be done in a non-CON state to certify a facility or service. Projects involving nonclinical infrastructure are not subject to CON review, regardless of cost. Such projects require only a notification to the Department.

Under Article 28, projects involving the establishment of a new operator (including mergers and the establishment of an active parent) always require full review. In general, most projects with a capital cost of greater than \$15 million are subject to full review. Addition of beds, changes of level of care, and certain named high technology services always require full review. A referral to the Council is required for projects eligible for administrative review that receive a recommendation of disapproval by Department or staff of the relevant HSA. Review by the Council also provides an opportunity for public comment on CON projects.

Proposals eligible for administrative review typically have costs of up to \$15 million and do not require a recommendation from the PHHPC. Examples of administrative reviews include conversion of acute care beds within the same level of care or addition of primary care sites by an established provider; certain amendments to approved projects are also eligible.

Administrative review has been expanded over the years, so for instance health IT projects over \$15 million are eligible for administrative review; in certain specific circumstances, projects with costs as high as \$50 million may be reviewed administratively.

Unless otherwise subject to full or administrative review, proposals with a total project cost up to \$6 million are eligible for a limited review. Examples include minor construction, acquisition of lower-cost medical equipment, addition of certain services, decertification of beds and services, and relocation of clinics within the same service areas. Health IT projects with costs between \$6 million and \$15 million are also subject to limited review. Some limited reviews require only an architectural review to assure that health and safety requirements are met.

Full review and administrative review projects may also be reviewed by the regional Health Systems Agency, where they still exist; HSAs do not participate in limited reviews. There are two remaining HSAs in New York – the Finger Lakes Health System Agency and the Central New York Health Systems Agency. Under state law, the Council and the Department cannot take action on a CON application contrary to the recommendation of the HSA without affording the HSA the opportunity to request a public hearing on that action.

Generally, CON projects result in either an approval or disapproval decision. Under state law, if a project is not approved, it is prohibited – construction cannot occur, equipment cannot be purchased, services cannot be implemented – and is not eligible for Medicare or Medicaid reimbursement. Projects can also be approved with “contingencies” or “conditions” attached. Contingencies require specific action on the part of the applicant to resolve, typically within 60 days, before CON approval is completed/perfected. Conditions, on the other hand, impose on-going requirements that must be complied with during the life of the project. Recently, the Council has been approving operating certificates with limited duration, often for ambulatory surgery centers, to assure fulfillment of conditions.

Both to reflect medical/construction cost inflation and to streamline the CON program, the dollar thresholds that trigger a need for a CON review have been revised over time. Cost is only one factor which determines if a project requires a particular level of review, but it is a primary factor.

The types of CON reviews are described in the following regulatory sections of PHL. The Various need methodologies are in Part 709.

Full Review - 710.1(c)(2);

Administrative Review - 710.1(c)(3); and

Limited Review - 710.1(c)(5).