



Ambulatory Services Recommendations

Public Health and Health Planning Committee

December 12, 2013

Guiding Tenets

- Recommendations developed with consideration for:
 - Patient Safety and Quality
 - Transparency to Consumers
 - Stabilization of the Medical Home
 - Support of Safety Net
 - Health Information Technology Integration

Presentation Format

- Define the service
- Present recommendations
- Discuss proposed mechanism to achieve necessary level of oversight



Retail Clinic Recommendations

Limited Services Clinics: Focused, Episodic Care

- Provide a limited set of services that require only a focused history and physical examination intended for episodic care related to an illness or for immunizations.
- The Limited Services Clinics are not intended to be patient-centered medical homes or a source of continuing care.

Establish Naming Convention

- “Limited Services Clinics”. Require use of the term Limited Services Clinic in the name at the retail site. For example, “MinuteClinic, a Limited Services Clinic”.
- Conveys the narrow scope of services provided.
- Educates the general public that the full range of services offered by other clinics is NOT provided.
- Mirrors name chosen by Massachusetts which will assist in customer recognition.

Define Limited Services Clinics

- Involves episodic care that requires only a focused history and physical examination related to an illness or for certain 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.
- Excludes surgical services, dental services, physical rehabilitation services, mental health services, substance abuse services, or birth center services.

Define Scope of Services

- Prescribed set of pre-identified diagnostic and treatment services that includes certain immunizations.
 - Does not include venipuncture or the prescribing of controlled substances.
- Prohibit services to patients twenty-four months of age or younger.
 - Infants may have special health care needs. Visits afford pediatricians the opportunity to catch up on immunizations, discuss other potential problems and facilitate patient/provider relationship.
- Prohibit childhood immunizations (excluding influenza vaccine).
 - The requirement is intended to ensure that children 18 years of age and younger have contact with their regular primary care physician at least once per year.

Disclosures to Consumers

- Make clear to the consumer which services are and are not offered by the Limited Services Clinic:
 - Require signage to be prominently posted that states the services provided.
 - Where 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.

Accreditation

- Secure third party 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.

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.
- Require policies and procedures that specify staffing pattern.

Stabilization of Medical Home

- Provide a roster of primary care providers accepting new patients. 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. To ensure continuity of care, the following steps are required:
 - 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.
- Roster 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.

Stabilization of Medical Home

- Develop policies and procedures to identify and limit the number of repeat encounters with patients.

Health Information Technology

- Overall continuity of care will be facilitated by requiring ambulatory services providers to connect to the larger health care delivery system through the following:
 - 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 ongoing management of a plan of care for every patient.
 - Require ePrescribing.

Statutory and Regulatory Amendments

- Amend Section 2801-a of the public health law to add “Limited Services Clinics” (LSC) 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.
- Add statutory language to exempt LSCs from Certificate of Need review.



Urgent Care Recommendations

Define Urgent Care Service

Providers: Acute, Episodic, Non-Life Threatening

- Episodic illness or minor traumas that are not life-threatening or permanently disabling.
- Urgent care is not intended to be a patient-centered medical home or a source of continuing care.
- Urgent care is not intended for emergency intervention for major trauma, life threatening or potentially disabling conditions and is not intended for monitoring and treatment over prolonged periods.

Define Urgent Care Scope of Services

- 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.

Establish Naming Convention

- Restrict use of the term “Urgent Care” and its equivalents to those providers offering urgent care services as defined and approved by the Department.
- Urgent care providers cannot use the word “emergency” or its equivalent in their names.

Disclosures to Consumers

- Make clear to the consumer which services are and are not offered by the urgent care provider:
 - 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.

Patient Safety and Quality

- Require policies and procedures for referring patients whose needs exceed services provided and to ensure continuity of care.
- Require policies and procedures that specify staffing pattern.

Stabilization of Medical Home

- Provide a roster of primary care providers accepting new patients. 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. To ensure continuity of care, the following steps are required:
 - 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.
- Roster 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.

Stabilization of Medical Home

- Develop policies and procedures to identify and limit the number of repeat encounters with patients.

Health Information Technology

- Overall continuity of care will be facilitated by requiring ambulatory services providers to connect to the larger health care delivery system through the following:
 - 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 ongoing management of a plan of care for every patients.
 - Require ePrescribing.

Statutory Action

- Through statute, define urgent care service providers and scope of services.
- Only providers meeting the definition (see slide 3 “Define Urgent Care Scope of Services”) can use the name "Urgent Care".
- To be approved to use the name, providers will need to meet specified criteria demonstrated through certification (Art 28) or accreditation (non-Art 28) by accrediting organizations approved by the Department.

Non-Article 28 Urgent Care Requirements: Accreditation

- 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: Operating Certificates

- 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 OR a private physician practice affiliated with an Article 28 may provide Urgent Care Services if they obtain accreditation by an accrediting organization approved by the Department.
- 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.

Additional Accreditation Requirements

- If a non-Article 28 provider loses its accreditation, both the accrediting body and the provider would be required to report such change to the Department of Health in a timely fashion.
- A non-Article 28 provider that wishes 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).



Urgent Care Discussion



Free Standing Emergency Department Recommendations

Establish Naming Convention and Definition

- “Hospital-Sponsored Off-Campus ED”
 - Name 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 CMS
 - Latitude given for the facility name held out to the public
 - Should use the name of the hospital that owns the facility and “Satellite Emergency Department”

Define Standards and Scope of Services

- A Hospital-Sponsored Off-Campus ED will be subject to the same standards and requirements as a hospital-based ED with regard to:
 - Minimum training of providers
 - Staffing
 - Array of services provided
 - It is noted that off-campus EDs do not have the capacity to handle the full scope of traumas and life-threatening conditions as a hospital-based ED (e.g. surgery and conditions requiring inpatient admission)
- Must demonstrate compliance with CMS Hospital Conditions of Participation

Define Hours of Operation

- Hours of operation will generally be 24/7
- Part-time operation will be allowed, subject to CON approval
 - Must operate at least 12 hours a day
 - Consideration will be made for distance to the nearest hospital-based ED

Stabilization of Medical Home

- Provide a roster of primary care providers accepting new patients. 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. To ensure continuity of care, the following steps are required:
 - 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.
- Roster 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.

Disclosures to Consumers

- Require clear nomenclature, signage and a communication plan for off-campus EDs
- Communication plan should include:
 - Collaborative planning with regional emergency medical services
 - Public information campaign for informing the public about capacity and hours of operation

Patient Safety and Quality Requirements

- Receive ground ambulance patients.
- EMS protocols for transfer of patients requiring higher levels of care.

Health Information Technology

- Overall continuity of care will be facilitated by requiring ambulatory services providers to connect to the larger health care delivery system through the following:
 - 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 ongoing management of a plan of care for every patients.
 - Require ePrescribing.

Accreditation

- Secure accreditation from a national accrediting body. 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 would be surveyed by the Department of Health.

Regulatory Amendments

- Amend Title 10, Section 720.1 pertaining to General Hospital Accreditation requirements.
- For those hospitals with off-campus Emergency Departments, accreditation reviews must include the off site facility.

Regulatory Amendments

- 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.
 - Full CON review including approval by the PHHPC will be required.
 - Emergency Approval by the Commissioner may be allowed in instances of a hospital closing where adequate alternative resources cannot be arranged in a timely fashion to address the void in services (per Section 401.2).

Regulatory Amendments

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

Regulatory Amendments

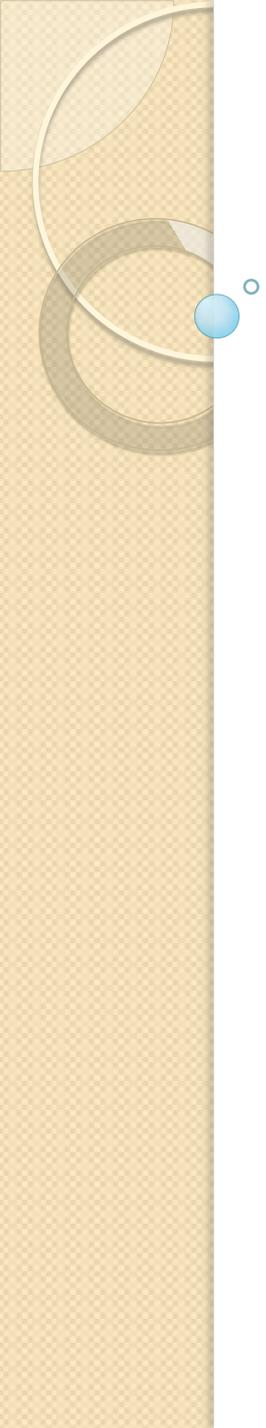
- Update and revise Title 10 Section 405.19 that addresses standards for emergency services to include requirements that are specific to Hospital-Sponsored Off-Campus EDs:
 - Scope of services
 - Minimum hours of operation
 - Criteria for part-time operation
 - Capacity to receive ground ambulance patients
 - Transfer and referral protocols

Considerations for Approval of Part-time Operation

- Criteria to be specified in Title 10, Section 405.19
- Amend Title 10, Section 709 to include specific need criteria. Consideration will be made for the local and unique circumstances necessitating part-time operation.
- Require Full CON Review for a new off-campus ED that will operate part-time.
- Require Full CON Review for an existing full-time ED proposing a reduction in hours of operation.
- Emergency Approval by the Commissioner may be allowed in instances of a hospital closing where adequate alternative resources cannot be arranged in a timely fashion to address the void in services (per Section 401.2).



Free Standing Emergency Department Discussion



Non-Hospital Surgery Recommendations

Ambulatory Surgery

- Currently Ambulatory Surgery is highly regulated by both CMS and NYS.
- Recommendation:
 - Make no changes to current regulatory oversight of ambulatory surgery

Current Oversight: Office-based Surgery

- PHL 230-d, enacted in 2007, requires that surgical or invasive procedures involving more than minimal sedation or local anesthesia or liposuction of 500mls or greater performed by designated licensees (includes physicians, physician assistants and specialist assistants) in a non-Article 28 setting to become accredited and file adverse event reports with the Patient Safety Center.
 - Currently there are approximately 1000 accredited OBS practices.
- As of February 2014 this law will apply to podiatrists privileged to perform ankle surgery.

Office-based Surgery Advisory Committee

- Existing statute (PHL 230-d) developed with guidance of the Committee on Quality Assurance in OBS appointed by the Public Health Council.
 - OBS Advisory Committee continues to provide feedback and guidance to the Department on matters related to OBS. Recommendations endorsed by the Committee will be highlighted as part of the presentation.

Guiding Tenets of OBS Reform

- Primacy of patient safety and quality
- Importance of adherence to standards of practice and delivery of appropriate care in OBS settings - consistent with the Triple Aim.
- Necessity of data to assure quality and safety, advance the science and contribute to healthcare planning and consumer decision making.

Registration

- Require registration of all new and existing OBS/OBA practices with the Department
- Require submission of procedure and quality data as determined by the Department to the Department.

Definitions

- Clarify that neuraxial and major upper and lower extremity regional nerve blocks are included in OBS definition of “greater than minimal sedation or local anesthesia.”
- Define office-based anesthesia (OBA) as general anesthesia, neuraxial anesthesia, major upper and lower extremity regional nerve blocks, moderate and deep sedation.
- Limit OBS/OBA procedural time to six hours and limit post-procedure time to meet discharge criteria to six hours.

Accreditation and Adverse Event Reporting

- 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.

Accrediting Agencies

- Require accrediting agencies to share the outcomes of survey and complaint/referral investigations and other requested with the Department.
- 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.

Statutory Amendments

- Existing statute, PHL 230-d, will need to be amended.



Non-Hospital Surgery Discussion



Upgraded D&TC Recommendations

Regulatory Amendments

- Revise Title 10, Section 752-2 of the regulations to remove UD&TCs.
 - There is no need for this model given the development of new models of care, including urgent care and hospital-based off-campus emergency departments.



Upgraded D&TC Discussion