



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

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.

Provenance

In January 2012, Governor Andrew Cuomo and Commissioner of Health Nirav Shah 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 to retain licensure requirements but eliminate 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 out 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 (e.g., UnitedHealth Group). 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.

The Triple Aim

Amidst this turmoil, the principles undergirding the Affordable Care Act and the Medicaid Redesign Team's initiatives - the Triple Aim - remain a useful polestar. The core tenets of the Triple Aim are both a yardstick for what has been accomplished and a set of aspirations for the future:

- **Population health:** Ambulatory care should help shift the locus of health care from facilities to communities, with a concomitant refocusing on long, healthy lives for all (operationalized as health-adjusted life expectancy) as the metric of interest. This approach adopts a comprehensive notion of health determinants that are spread across domains of behavioral risk, social and economic circumstances, environmental exposures, and medical care. The balance and effects of many of these determinants, e.g., availability of healthy foods, parks and other safe places to play and exercise, exposure to environmental irritants, and safe housing, are specific to geographic locale. Several key provisions of the ACA highlight population health, such as Internal Revenue Service requirements for tax-exempt hospitals to demonstrate meaningful efforts to improve the health of the communities they serve. In New York, the State Prevention Agenda (also known as the State Health Improvement Plan) includes evidence-based practices for improving population health in each of five priority areas and provides guidance for local stakeholders in their efforts to assess and improve community health and reduce health disparities. New York State generally ranks in the second quartile on measures of healthy living collated by the Commonwealth Fund and the United Health Foundation. Improving performance in population health will require the full participation of ambulatory care providers in the State Prevention Agenda.
- **Health care quality:** New York has made strides in improving the quality of health care. For example, in the Medicaid program, National Committee for Quality Assurance (NCQA) commended the state's performance in increasing rates of childhood immunization, controlling blood pressure as part of diabetes management, screening for colorectal cancer, and assisting with smoking cessation. New York's pending 1115 Medicaid waiver could help advance further progress. Yet the world of health care quality improvement has yet to fully embrace ambulatory care into its purview. The majority of outpatient quality measures focus on preventive care, chronic disease care, and patient experience—important domains, but exclusive of equally important measures such as diagnostic accuracy, appropriateness of testing, and rates of medication errors. Therefore, efforts to improve ambulatory care must optimize quality metrics as well as refine the methods of measurement.
- **Costs of care:** New York has traditionally performed poorly on evaluations of health care efficiency, scoring 50th among all states on avoidable hospital use and costs in the 2009

Commonwealth Fund state scorecard. Again, Medicaid has been a bright spot, with reforms proposed by the Medicaid Redesign Team generating almost \$5 billion in savings thus far. Still more can be done, particularly with the Medicare and commercially-insured populations. A recent Institute of Medicine study of geographic variation in U.S. health care spending identified two major cost drivers, both of which carry implications for organization of ambulatory care. In the Medicare population, most of the variation in spending per beneficiary was in post-acute care (services provided by skilled nursing facilities, rehabilitation and long-term care hospitals, home health agencies, and hospices). In the commercially-insured population, post-acute care is only a minor contributor to variation in spending. Instead, price variation is the predominant factor, accounting for about 70% of the total expenditure variation. In both cases, post-acute care variation and price variation, careful regulation to help shape the ambulatory care market has the potential to generate greater efficiency in the broader health care system. As another cross-cutting strategy, redirecting inappropriate visits from Emergency Departments to other ambulatory care service serves to reduce costs in three dimensions—lower service charges, fewer imaging and other tests, and less likely admission to the inpatient unit. Per capita spending, with a particular focus on high-cost individuals, must remain a fundamental metric of interest in the Triple Aim.

- One additional principle is as significant as the Triple Aim when considering ambulatory services: continuity of care. Continuity of care is a “Triple Aim home run” - it helps bring about better health, improved health care quality, and lower costs. While some patients, particularly younger patients with acute illnesses, may prefer improved access to improved continuity, many more place high value on continuity of care, particularly those who are older or have multiple chronic conditions -i.e., those patients who are most vulnerable to serious illness and whose care incurs the highest costs. For these people especially, it is a continuing relationship with a caring professional that provides the needed context for shared decision-making and responsibility to maintain and improve one’s health. A growing corpus of evidence demonstrates the systemic effects of continuity of care: for example, a study of over 3 million Medicare beneficiaries showed an inverse effect between primary care continuity and preventable hospitalizations. To the extent new models of ambulatory care disrupt continuity of care, they may have negative ramifications for cost, quality, and health. The first step in tracking this phenomenon may be for primary care practices to begin measuring their patients’ continuity of care.

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 sine qua non elements are becoming apparent:

- Patient-centered medical home model with team-based care delivery. The Joint Principles of the Patient-Centered Medical Home, adopted in 2007 by the American Academy of Pediatrics, the American College of Physicians, the American Academy of Family Physicians, the American Osteopathic Association, and subsequently endorsed by dozens of specialty societies, describe the importance of each patient having "an ongoing relationship with a personal physician trained to provide first contact, continuous and comprehensive care...[T]he personal physician leads a team of individuals at the practice level who collectively take responsibility for the ongoing care of patients." The American College of Physicians (ACP) recently endeavored to further define team-based care in a position paper, stating "A clinical care team for a given patient consists of the health professionals—physicians, advanced practice registered nurses, other registered nurses, physician assistants, clinical pharmacists, and other health care professionals—with the training and skills needed to provide high-quality, coordinated care specific to the patient's clinical needs and circumstances." Importantly, the ACP position paper advocates for a cooperative inter-professional approach as a necessary coping strategy for looming physician shortages.
- Population health management with sophisticated risk stratification. Taking responsibility for population health in primary care requires managing the health outcomes of a group of individuals, often organized into patient panels. This perspective centers on deploying evidence-based interventions and disease management categories so as to triage and allocate health care resources in a cost-effective manner. The U.S. Department of Veterans Affairs, for example, has operationalized the concept by risk-stratifying populations of patients and customizing interventions to specific risks. Based on longitudinal EHR data spanning up to two decades, a Care Assessment Need (CAN) score, a statistical model, predicts a patient's risk of hospitalization or death at 90 days or 1 year with high reliability

and validity. The CAN score therefore stratifies patients who are at greatest risk for adverse outcomes; enhanced care management services can then be directed to those veterans.

- High-risk patient management. As popularized by Atul Gawande’s New Yorker article, “The Hot Spotters,” addressing the needs of the sickest and most vulnerable patients can be another Triple Aim home run. Nationally, just 10 percent of the population is estimated to account for about 64 percent of health care expenditures, often because of overutilization of the hospital, emergency room, and other acute care resources. By addressing care coordination, targeting intensive interventions, and ensuring greater access, this segment of the population benefits from improved health while reducing costs. Many primary care practices are now testing high-risk patient management, whether in an “ambulatory intensive care unit” or under another designation. Preliminary evidence from programs for high-risk elderly patients shows modest reductions in hospital and emergency department utilization—although it is unclear how generalizable these findings are to a broader (non-elderly) high-risk population.
- Rapid but judicious access to specialty expertise. The market for specialty services appears dissimilar from different vantage points. For private providers who take care of affluent, generally commercially-insured patients, the problem may be supply-driven overuse of expensive specialty resources. Meanwhile, patients and providers in safety-net systems often face a tremendous mismatch between supply and demand for specialty services—leading to significant wait times and delays in care. Innovations in accessing specialty expertise may help with both sides of the issue, by improving the value of specialty care while distributing its reach. For instance, in San Francisco, a program known as eReferral—piloted in a safety-net system—uses simple technology to allow for expeditious, iterative communication between primary care providers and specialists, sometimes obviating the need for in-person consultation. In the same vein, a national program known as Project ECHO has shown that with the right staffing and technology infrastructure, primary care providers can co-manage patients with complex, chronic disease like Hepatitis C.
- Integrated behavioral health. Individuals with serious physical health problems often have concomitant mental health issues, and nearly half of those with any mental disorder meet the criteria for two or more disorders. New York has been a leader in beginning to incorporate behavioral health services into primary care, particularly through Medicaid Health Homes. More broadly, however, most primary care doctors are ill-equipped or lack the time to fully address the psychosocial issues underlying many patients’ visits. In some cases, there is no ready access to dedicated behavioral health professionals—and rarely are physical health and behavioral health providers co-located to enable “warm handoffs”

between the two. A number of models for integrated or collaborative behavioral health and primary care are emerging. In one example, the Southcentral Foundation's Nuka System of Care in Alaska, behavioral health is normalized as a routine component of medical care, with integrated charts, care teams, and clinic design facilitating a spectrum of collaboration, from informal consultation to joint visits to more formal referrals.

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. Advanced diagnostic imaging is almost certainly overused, although the underlying reasons are more complicated than financial inducements; defensive medicine, patient preference, and time constraints all likely play a role. Meanwhile, radiation therapy might be appropriately utilized as a whole - but the predilection toward costlier modalities of radiation therapy without evidence of improved outcomes may warrant scrutiny.

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. Massachusetts recently chartered a state-level Health Planning Council charged with identifying health care service needs, laying out priorities for addressing those needs, and making recommendations for the appropriate supply and distribution of services. In its first phase, the Council is addressing six areas: behavioral and mental health services; primary care resources; post-acute care; ambulatory surgery; percutaneous coronary intervention; and trauma. Few other states have embarked upon a wide-ranging assessment of regulation of ambulatory care services. 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's work 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.

Health Planning Committee Charge

The *Report of the Public Health and Health Planning Council on Redesigning Certificate of Need and Health Planning*, released in December 2012, noted that 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 gradually over the past several years due to medical advances in technique, equipment and anesthesia care that have reduced lengths of stay and recovery time, permitting increasingly complex procedures to be conducted on an outpatient basis.¹

The increased demand for ambulatory care services resulted in a recommendation by the Public Health and Health Planning Council (PHHPC) to review and provide recommendations to update the criteria that trigger facility licensure and certificate of need (CON) requirements and normalize the treatment of physician practices and facilities. In addition, over the past few years, there has been a marked increase in the number of and types of ambulatory care services providers, including retail clinics, urgent care, and freestanding emergency departments. To assure access and achieve the Triple Aim of improving the quality of care, improving health and reducing health care costs for New Yorkers, the Health Planning Committee of the PHHPC has been considering how best to plan for, monitor and guide such services.

Core Principles

The Committee adopted core principles to guide its work. The following set of principles were approved by the PHHPC Health Planning Committee to direct its work and that of the Department of Health staff to the Committee. The principles support the development of recommendations, including statutory or legislative changes, and help ensure that the recommendations developed properly align with the intended public policy objectives.

Process Principles:

Core Principle #1 – Meet the multiple needs of the public by pursuing the Triple Aim of better care, better health, and lower cost.

Core Principle #2 – Develop recommendations that consider the needs and concerns of stakeholders.

Core Principle #3 – Ensure transparency in developing the recommendations.

¹ SPARCS, Annual Report Generator, Inpatient Discharges by Major Service Category, 2000-2012. Please see also Casalino, Lawrence P., Hoangmai Pham, and Gloria Bazzoli, "Growth of Single-Specialty Medical Groups," *Health Affairs* 23.2 (2004): 82-90, available at <http://content.healthaffairs.org/content/23/2/82.full> and American Hospital Association, "Trendwatch: The Migration of Care to Non-Hospital Settings," July 2006, available at www.aha.org/research/reports/tw/twjuly2006migration.pdf

Core Principle #4 – Rely on or prioritize evidence-based design principles.

Core Principle #5 – Limit statutory/regulatory changes to essential items and reduce unnecessary, obsolete or burdensome regulations imposed on the health care industry.

Outcome Principles:

Core Principle #1 – Support coordinated, patient centered care across the health care system.

Core Principle #2 – Assure access to high quality, equitable and affordable health care services for all NYS residents.

Core Principle #3 – Ensure quality of care and patient safety in all settings.

Core Principle #4 – Improve data sharing to better understand ambulatory care services providers, and more fully inform policy decisions and patient choices.

Solicitation of Stakeholder Comments

Prior to the first Health Planning committee meetings, the Department of Health solicited comments from stakeholders in February 2013, in order to inform the Committee and begin the process of stakeholder involvement. The stakeholder letter included questions posed to focus the discussion, including the organization's perspective on the risks and benefits presented by the growth of enhanced physician practices and the appropriate level of state oversight of their activities.

The general themes that emerged from the stakeholder comments were:

- Extending the CON process to all types of physician practice will limit innovation and decrease quality of care;
- Requiring physician practices to meet Article 28 standards and CON regulations must be accompanied by enhanced rates;
- Revise the CON regulations so that hospitals and diagnostic and treatment are not required to submit applications for services that may be provided in a non-Article 28 practice;
- The impact of all providers in a defined service area should be assessed to determine need and financial feasibility;
- The growth of urgent care centers could lead to a decrease in primary care visits but will not increase access for Medicaid patients;

Health Planning Committee Meetings

The Committee held five full day meetings in New York City (May 21; June 26; September 13; October 4) and Rochester (July 17) as well as their regularly scheduled Planning Committee meetings. Two additional Committee meetings will be held in Albany (November 20) and NYC (December 4) to vote on the recommendations, prior to a vote by the full Council in Albany (December 12). All Health Planning Committee meeting notices, agendas and materials were posted on the Department's PHHPC website. Presentations by the following stakeholders were solicited to inform the Committee deliberations:

- Physician Groups
- Large Physician Groups
- Hospital Groups
- Clinic Groups
- Commercial Payers
- New York Health Benefit Exchange
- Department of Financial Services
- Office of Health Insurance Programs
- Freestanding Emergency Rooms
- Urgent Care Associations

Public comment was encouraged throughout the process.

New York State Department of Health Staff Support

A series of reports, prepared by New York State Department of Health staff, were developed for consideration by the Health Planning Committee to assist them in their analysis of a variety of ambulatory care service arrangements including sets of options and recommendations.

Reports related to all sectors of the ambulatory care services spectrum were prepared and include advanced medical imaging, radiation therapy, nonhospital based surgery, retail clinics, urgent care, upgraded diagnostic and treatment centers and freestanding emergency departments. Two to three documents were provided for each of these sectors - a "background" paper that describes related issues, a "policy" paper that lays out options, pros/cons, and other state/federal models, and, in certain instances, potential recommendations, and were based on a literature review and evaluation of other states' approaches. These papers did not incorporate stakeholder feedback.

RECOMMENDATIONS BY SECTOR

DRAFT



Limited Services Clinics (Retail Clinics)

Background

Retail-based health clinics, typically located in pharmacies, supermarkets and big-box retailers, offer basic health services for minor ailments ranging from skin infections to sore throats and earaches, and may include simple wellness and screening services (for chronic condition such as diabetes and hypertension).

Retail clinics are marketed as offering consumers a convenient, easily accessible option for obtaining basic health care. They typically offer extended business hours - often 7 days a week, including evening hours, and may reduce inappropriate or unnecessary emergency room use. Retail clinics may also serve to expand access to certain basic services in the face of inadequate primary care capacity. Retail clinics offer lower costs to patients and insurers than other providers (physician offices, urgent care, emergency rooms). They are staffed primarily by licensed, non-physician health care practitioners, mostly nurse practitioners (NPs) and physician assistants (PAs).

There are currently 17 retail clinics in New York State that have established as physician offices and, as such, are not regulated by DOH. Among concerns with retail clinics is the need to define the proper scope of services they can provide, their potential to supplant the primary care physician and medical home, and the inherent incentive to over-prescribe medications due to their co-location in pharmacies.

It should be noted that statutory/regulatory options related to retail clinics have already undergone considerable discussion and review. An internal DOH Executive Workgroup was formed in the fall of 2012 and issued a set of recommendations for further consideration. A proposal to permit operation of retail clinics was included in the 2013-14 Executive Budget but was not enacted. Consequently, no statutory or regulatory changes have been effected for retail clinics. However, the draft recommendations developed for retail clinics are based on policy principles that can be applied to other ambulatory services providers.

Principal Issues

Scope of Services

The model of care provided by a retail clinic is not suited for all patients. Retail clinics offer a limited scope of services and only a very focused examination. Given the episodic nature of visits to retail clinics, they are not appropriate settings to care for infants or patients with chronic or multiple conditions.

Undermining Patient Centered Medical Homes

The patient centered medical home is emerging as a model for advancing primary care by providing “continuous and coordinated care throughout a patient’s lifetime to maximize health outcomes (American College of Physicians, 2010). Unlike medical practices based on the medical home model that emphasizes comprehensive, coordinated care, retail clinics provide episodic care for acute conditions and scaled-down preventive services. Some are concerned that retail clinics are poor substitutes for a regular source of comprehensive primary care, fail to adequately communicate with primary care providers about services delivered and ultimately undermine the doctor/patient or medical home relationship.

In addition, retail clinics may undermine the financial viability of primary care practices by diverting less complicated visits, thereby reducing volume and (in some cases) relatively well compensated cases for full-service providers. Others contend that retail clinics may have a positive effect by not consuming physicians’ time with simpler visits, leaving them more time to schedule and receive payment for more complicated patient visits.

Conflict of Interest

Because retail clinics are generally located within a larger business enterprise that includes a pharmacy, practitioners in the retail clinic may be motivated to over-prescribe or selectively prescribe both prescription and over-the-counter medications and supplies that are sold at the host store. Because of their for-profit status, there are also concerns that the business objectives of the sponsoring company may not align with public health goals.

Current Federal and NYS Regulations

None.

Other State Models:

Massachusetts is the only state to regulate retail clinics and refers to them as “limited services clinic” regulations. In 2006, the state realized that its existing clinic regulations did not address the retail

clinic model. The regulations developed address fragmentation of medical care and prohibit providing services to children less than 24 months of age and administering childhood immunizations.

Kentucky is proposing licensing regulations for retail clinics that allow them to perform only those services that the state defines as “minor health care” and retail clinics will be prohibited from treating patients younger than 18 months.

Recommendations:

Limited Services Clinics (Retail Clinics)

1. Statutory and Regulatory Amendments

Licensure requirements for Limited Services Clinics will distinguish these clinics from private physician offices and other health care facilities in order to allow nuanced regulation of these clinics.

- Add a new subdivision 17 to Section 2801-a of the public health law that would add “Limited Services Clinics” (LSC) under the category of Article 28 diagnostic or treatment centers.
- Add statutory language to exempt LSCs from Certificate of Need review.

2. Establish Naming Convention

Recommended name:

“Limited Services Clinics”. The name is chosen to convey the scope of services provided and avoid misleading the general public. The name mirrors that chosen by Massachusetts in order to assist with customer awareness.

3. Define Limited Services Clinics and Scope of Services

Recommended language:

Prescribed set of pre-identified diagnostic and treatment services that require only a focused history and physical examination that does not require venipuncture or the dispensing of controlled substances; may make use of only CLIA-waived tests; may be provided within the projected duration of patient encounters, using available facilities and equipment; and are for episodic care related to an illness or for immunizations. Limited Services Clinics specifically exclude surgical services, dental services, physical rehabilitation services, mental health services, substance abuse services, or birth center services.

- LSCs can 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 LSCs are not intended to be sources of continuing care.

- Prohibit administration of services to patients twenty-four months of age or younger. Infants may have special health care needs and serious illness that may not be readily identifiable. This requirement is intended to afford full-service primary care providers the opportunity to catch up on immunizations, discuss other potential problems and facilitate the patient/provider relationship.
- Prohibit administration of 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.
- The scope of services should require a minimal set of services such as adult immunizations.
- Require extended hours and weekend availability such as 7 days a week with a minimum of 12 hours on weekdays and 8 hours on weekends.

4. Disclosures to Consumer

Make clear to the consumer which services are offered – and which are not - by the LSC:

- 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 an 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. Accreditation, Patient Safety and Quality

- Require third party accreditation by a national accreditation organization approved by the Department. If a provider loses its accreditation, it would be required to report such change to the Department of Health in a timely fashion.
- Require evidence based clinical practice guidelines for diagnosing and treating patients.
- Require policies and procedures for referring patients whose needs exceed services provided.
- Require policies and procedures that specify staffing pattern.

6. Stabilization of Medical Home

LSCs are not intended to be patient-centered medical homes (PCMHs). Their providers supplement but must not displace – or replace – full-service primary care providers. PCMHs will be undermined in the absence of policies and procedures designed to ensure that patients utilize them appropriately as their principal source of primary care.

- Maintain an up-to-date roster of primary care providers accepting new patients within a reasonable geographic area. Provide each patient who does not have a primary care provider with the list. Roster must include community health centers and other providers who serve Medicaid and low-income patients.
- Develop policies and procedures to identify and limit the number of repeat encounters with patients.

7. Safety Net

In order to increase access to primary care, the following is required:

- LSCs are required to accept Medicaid patients as a condition of licensure.

8. 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), connected to the Statewide Health Information Network for New York (SHIN-NY) for sharing of patient information to all authorized clinicians. By so doing, results of patient imaging studies would be available to the patient's primary care provider, and any specialists involved in their care.
- Provide a copy of medical records to the patient consistent with current Public Health Law.
- Require structured interoperable health IT systems, policies, procedures and practice to support creation, documentation, execution, and ongoing management of a plan of care for every patients.
- Require ePrescribing.



Urgent Care

Background

Urgent care providers serve an important and expanding role in today's health care system. Because they generally offer walk-in, extended hour service, they provide an efficient, cost-effective way to serve acute care needs during hours when primary care practices are closed or serving at capacity, and when a patient's condition is not severe enough to warrant an emergency room visit. They benefit the public by serving as an alternative to emergency departments (EDs), thus avoiding high ED costs and potentially long wait times while also relieving stress on limited emergency resources and primary care capacity.

The Urgent Care Association of America estimates that there are 9,000 urgent care providers nationwide, with approximately 350 in New York State. One potential result of the growth of this model is that it may encourage patient over-reliance on urgent care at the expense of developing a continuing relationship with a primary care provider. There are also concerns that patients may present inappropriately to an urgent care provider when their condition is beyond the scope of urgent care and requires emergency services. Of note, urgent care in New York State is currently provided in a dual environment, with some providers established as Article 28 providers and others are organized as private medical practices. There is wide variation in the services offered by providers calling themselves "Urgent Care," creating consumer confusion.

Issues

Scope of Services

By definition, urgent care providers operate on an outpatient, unscheduled walk-in basis. Typical services include a medical history, physical examination and treatment services. Certain urgent care providers offer intravenous hydration, suturing of lacerations, or advanced services such as MRI and CT scans, EKG, and in-house lab services for immediate point-of-care testing. The table below depicts the range of services that may be offered, differing from basic to advanced level care, with varying hours of availability.

Urgent care providers are not prepared to care for critical, major trauma, life threatening or potentially disabling conditions. While some operate twenty-four hours a day, seven days a week, others are open during normal business hours (9AM to 5PM weekdays) plus early and late weekday and weekend hours. Because urgent care providers are not licensed as hospital emergency departments, they are not subject to the Emergency Medical Treatment and Labor Act (EMTALA), requiring acceptance of patients without regard for the ability to pay.

Urgent Care Models

	Basic		Moderate		Advanced Level	
Services	<ul style="list-style-type: none"> Limited waive testing 	<ul style="list-style-type: none"> Expanded waive testing No x-ray 	<ul style="list-style-type: none"> Expanded waive testing EKG Basic plain film x-ray 	<ul style="list-style-type: none"> Expanded waive testing Draw station with same day results Basic plain film x-ray 	<ul style="list-style-type: none"> Waive testing with point of care blood tests EKG Basic plain film x-ray CT scanning Ultrasound 	<ul style="list-style-type: none"> Expanded waive testing with point of care blood tests On-site STAT lab (CBC, comprehensive metabolic, liver function tests, etc.) EKG Radiology/ Imaging center (plain films, ultrasound, CT scan).
Hours	8-12 hours	8-12 hours, with some weekend and afterhours component	8-12 hours, with some weekend and afterhours component	12 hours or greater, with some weekend and afterhours component	12 hours or greater, with expanded weekend and afterhours component	16-24 hours, open 7 days per week with afterhours component

Boyle and Kirkpatrick, *The Healthcare Executive's Guide to Urgent Care Centers and Freestanding EDs*, 2012.

Note: Under the CMS Clinical Laboratory Improvement Amendments (CLIA) definitions, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result," as determined by the Food and Drug Administration. Only those tests that are CLIA-waived can be performed by a laboratory with a Certificate of Waiver.

Consumer Confusion

Given the vast range in services offered by providers referring to themselves as "urgent care", it can be difficult for consumers to have accurate expectations as to what an urgent care provider offers, which may lead to confusion about when to go to an urgent care provider versus their primary care provider versus an emergency department. According to a 2010 nationwide study conducted by RAND Corporation, as many as 27% of emergency department visits could take place in either a retail clinic or urgent care setting. The fact that some providers describe themselves as providing "emergent" or "emergency" care increases the potential for confusion. Consumers may also be

confused because some urgent care providers may be hospital extension clinics or otherwise affiliated with a hospital, thereby suggesting full-scale emergency capabilities.

Care Quality and Patient Safety Monitoring

Over the last thirty years, the urgent care industry has been establishing urgent care as a unique specialty of care, distinct from primary care or emergency care. The American Board of Physician Specialties offers urgent care board certification. However, the American Board of Medical Specialties does not currently recognize urgent care as a specialty or sub-specialty.

There are several urgent care certification and accrediting bodies, and the Urgent Care Association of America encourages urgent care provider certification and accreditation to establish urgent care service and quality standards and promote public understanding. The Association offers certification to urgent care providers that meet such criteria as being open seven days a week and offering walk-in care and X-Ray and IV capability. The Joint Commission, the Accreditation Association for Ambulatory Health Care and the National Association for Ambulatory Care also offer accreditation for urgent care providers.

It is not known how many urgent care providers in New York State are currently certified or accredited, and substantial differences may exist between providers in services offered, staff training, equipment, and quality standards.

Undermining Patient Centered Medical Home

There are concerns that patient over-reliance on urgent care providers may undermine the primary care relationship and the ability of the medical home to achieve care coordination. The convenience and low cost of urgent care providers may encourage some patients to use these providers instead of establishing a relationship with a primary care physician at all, or in circumstances in which a primary care visit would be more appropriate (i.e., repeat visits for a chronic condition). There is a potential risk that an urgent care provider may fail to make a correct diagnosis or embark on inappropriate treatment due to lack of access to the patient's full medical record.

Oversight

As previously mentioned, some urgent care providers operate as hospital extension clinics or as freestanding licensed Diagnostic & Treatment Centers, both subject to operational oversight by the Department of Health under Article 28 of Public Health Law. Other urgent care providers operate as private physician practices that are not subject to routine surveillance of any kind. Private physician practices are primarily regulated by the corporate practice of medicine rules governing structure, and by licensure and professionalism rules applicable to all individual physicians through State Education Law. In New York State, only a licensed physician or organization specifically authorized to do so may

practice medicine. The prohibition against the “corporate practice of medicine” is rooted in the principle that the practice of medicine is the province of trained, licensed professionals, and that clinical decisions should be made by professionals exercising their independent professional judgment, without undue influence from unlicensed third parties who are not subject to the same professional responsibility requirements, laws and rules. The prohibition against the corporate practice of medicine is not articulated in any one statute or regulation, but is a doctrine that emerges from the interaction of numerous laws and regulations, as well as judicial decisions, including Education Law §§ 6512,6513; Business Corporation Law, Articles 4, 15 and 15-A; Limited Liability Company Law, Articles 12 and 13; and Partnership Law.

Recommendations

Urgent Care

1. Require Licensure

Licensure Options include:

- 1a. Article 28 facilities that want to provide urgent care (as defined below) would have urgent care services identified on their operating certificate.
- 1b. Limited licensure. Create a separate category of licensure that is limited in oversight scope. Statutory change will be needed.

2. Require Accreditation – applies to Article 28 and Limited Licensure Urgent Care

Providers

- Require third party accreditation by a national accreditation organization approved by the Commissioner. If a provider loses its accreditation, it would be required to report such change to the Department of Health in a timely fashion.
- Any urgent care provider that wishes to provide services that require 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 treatments that may call for more than minimal sedation may include relocating a dislocated joint or performing imaging on patients who need assistance to stay still.

3. Naming Convention – applies to Article 28 and Limited Licensure Urgent Care Providers

- Restrict use of the term “Urgent Care” to those providers offering urgent care services as defined below. Urgent care providers cannot use the word “emergency” or its equivalent in their names.
- If specializing in pediatric urgent care, providers must so indicate in the practice name.

4. Define Urgent Care Provider and Scope of Services – applies to Article 28 and Limited Licensure Urgent Care Providers

Recommended language:

Episodic illness or minor traumas that are not life-threatening or permanently disabling. Urgent care is not intended for emergency intervention for major trauma, life threatening or potentially disabling conditions and does not substitute for primary care services or the ongoing care of chronic illness or physical rehabilitation.

Minimum characteristics/services that a provider must have in order to be considered an urgent care provider include:

- Extended Hours: At minimum 12 hours on weekdays, 8 hours on weekends
- Accepts unscheduled, walk-in visits
- Crash Cart Supplies and Medications; ACLS and PALS protocol capable, as evidenced by staff holding current certification
- 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
- Minor laceration repair

All training, equipment, medication and protocols must be appropriate for the population served, including the pediatric population.

Urgent care services do not include care of patients triaged to have life threatening or permanently disabling conditions, or require monitoring and treatment over prolonged periods. Also, urgent care services do not include surgery, dental services or birth center services.

5. Disclosures to Consumer

Make it clear to the consumer what services are and are not offered by the 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 an 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.
- If applicable, impose marketing and advertising restrictions.

6. Patient Safety and Quality

- Require evidence based clinical practice guidelines for diagnosing and treating patients.
- Require policies and procedures for referring patients whose needs exceed services provided.
- Require policies and procedures that specify staffing pattern.

7. Stabilization of Medical Home

Urgent care providers are not intended to be patient-centered medical homes (PCMHs). PCMHs will be undermined in the absence of policies and procedures designed to ensure that patients utilize them as their principal source of primary care.

- Maintain up-to-date roster of primary care portioned accepting new patients in provider's geographic area. Provide each patient who does not have a primary care provider with the list. Roster must include community health centers and other provides that serve Medicaid and low-income customers.
- Develop policies and procedures designed to address repeat encounters with individual patients who do not have a primary care provider.

8. Safety Net

In order to increase access to primary care, the following are required:

- Urgent care providers are required to accept Medicaid patients as a condition of licensure.

9. 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 certified electronic health record (EHR), connected to the Statewide Health Information Network for New York (SHIN-NY) for sharing of patient information to all authorized clinicians. By so doing, results of patient imaging studies would be available to the patient's primary care provider, and any specialists involved in their care.
- Provide copy of medical records to the patient consistent with current Public Health Law.
- Require structured interoperable health IT systems, policies, procedures and practice to support creation, documentation, execution, and ongoing management of a plan of care for every patients.
- Require ePrescribing.

DRAFT



Freestanding Emergency Departments

Background

Facilities that provide emergency services but are geographically separate from a hospital campus, or freestanding emergency departments (FEDs), have been expanding rapidly nationwide over the last ten years. Originally designed to fill voids in rural regions where emergency health care was scarce, FEDs have expanded to suburban and urban regions, primarily in areas experiencing rapid population growth. In New York State there are several providers of emergency services currently operating outside of a traditional hospital setting, and a number of applications with proposed free standing emergency department models under review by the Department.

While FEDs can increase patient access to emergency services and provide welcome public service, consideration must be given to concerns surrounding, quality of care and patient safety, utilization, and cost.

Issues

Quality and Patient Safety

There is little data available on the quality of services provided by FEDs. Most states that have instituted regulations require that FEDs be held to the same standards and requirements as hospital based EDs with regard to the array of services provided, minimum training of providers, staffing, and hours of operation. The primary mechanism for quality assessment has been review by an accrediting body, which most FEDs have undertaken on a voluntary basis.

It is generally recognized that FEDs do not have the capacity to handle the full scope of trauma and life threatening conditions as hospital-based emergency departments. Timely triage and transport to hospital-based services is therefore necessary for patients who require inpatient admission, surgery, or major trauma care. Ambulance services and the public need to understand the scope and limitations of FED services to minimize treatment delays.

Although the majority of FEDs operate on a 24/7 basis, part-time operation is permitted in some states. Coordination with regional emergency medical services, clear signage, and communication to

the public regarding hours of operation are necessary to ensure that patients are aware of and transported to alternative locations for emergency care when the FED is closed.

Utilization and Cost

A major concern of states, insurance companies, and other health care providers is over-utilization of FED services. Considerable overlap exists in the scope of services that can be provided at FEDs and in other ambulatory care settings including urgent care centers, primary care practices, and retail clinics. Similar to the experience in hospital-based emergency departments, patients with non-emergent health needs may choose to inappropriately seek care at an FED due to the convenience of its location or hours of operation.

FEDs that meet the CMS definition of a dedicated ED and that comply with the Emergency Medical Treatment and Active Labor Act (EMTALA) are reimbursed at a higher rate by Medicare, a rate that is two to three times higher than an urgent care visit. A “Type A” emergency department, one that operates 24/7, is reimbursed at a higher rate than a “Type B” emergency department operating on a part-time basis. Like hospital-based EDs, free standing emergency departments are paid a facility fee which contributes to the increased cost. With FED reimbursement rates running significantly higher than other ambulatory providers, it can become quite costly for the system and the patient when FED services are used unnecessarily.

In order to manage utilization, it is important to educate the public about the services FEDs provide that are not available at other ambulatory care providers and the higher cost that may be incurred for FED care. In addition, FEDs should be required to refer patients to primary care providers for follow-up care as well as educate patients whose medical needs can be handled by lower threshold providers.

Current Oversight of Freestanding Emergency Departments

Freestanding emergency department models differ from state to state with substantial variation in services provided, and associated regulatory oversight. The Centers for Medicare and Medicaid Services (CMS) first recognized FEDs in 2004, and issued guidance in 2008 on applicable regulatory standards for facilities providing emergency services in settings that are geographically removed from a hospital.

CMS Requirements for FEDs

CMS designates two classifications for EDs that are not part of a main hospital campus:

- Hospital Provider-Based EDs (also known as “Provider-Based Off-Campus EDs”) - Most common model, occurs when a Medicare-participating hospital that offers emergency

services establishes an ED located away from the main campus with that ED operating as a provider-based department of the hospital. This model does not require inpatient beds or 24/7 hours of operation.

- Hospitals Specializing in Emergency Services – Less common model where the burden of proof is on the provider to demonstrate that it meets the statutory definition of a hospital, i.e. that it is primarily engaged in the provision of services to inpatient, has inpatient capacity, and 24/7 availability.

The Provider-Based Off-Campus ED model has generally been looked upon favorably by CMS, as the off-campus ED is considered a division of a hospital and held to the same conditions of participation and standards as an emergency department on the main hospital campus.

New York State Oversight of FEDs

New York State's limited experience with the oversight of FEDs has been guided by Title 10 Section 405.19, the regulation governing hospital-based emergency departments. FEDs in New York State have been required to operate 24/7 and adhere to the same staffing requirements as EDs located in traditional hospital settings. Historically, CON approval has required that the FED be part of a hospital and include at least two inpatient beds. Recently, however, New York has agreed to relax the inpatient bed requirements and has also considered allowing part-time operation.

Applications for construction or conversion of an existing facility to an FED have been handled on a case by case basis by the Department. Need criteria have considered FEDs with hospital beds to be a division of the hospital, and FEDs without beds as an ambulatory care clinic. Currently several CON applications proposing FED models are under Departmental review. In addition, two requests were made in 2013 to downgrade existing hospital emergency department services to part-time operation. As interest in this model of care continues to grow, it becomes imperative for DOH to establish mechanisms for regulatory oversight that are consistent and that protect patient safety and quality of care.

Recommendations

Freestanding Emergency Departments

- 1. Amend regulations (Title 10 Section 700.2) to allow establishment of hospital owned FEDs (referred to as "Provider-Based Off-Campus ED" by CMS) and prohibit establishment of FEDs that are non-hospital owned (referred to as "Hospitals Specializing in Emergency Services"). Certificate of Need will be a requirement and subject to the Full Review by the Public Health and Health Planning Council.**

The requirement to be hospital owned FEDs will limit the unwanted proliferation of FEDs seen in other states that allow non-hospital owned facilities. Rapid growth of FEDs not owned by hospitals has been associated with excessive costs, unfair competition and duplication of personnel and equipment. Restricting FEDs to hospital ownership also assists in ensuring the quality of care and ready access to hospital based care for higher acuity patients.

In accordance with CMS policy, provider-based off-campus EDs should be permitted in New York State, and should demonstrate compliance with CMS' Hospital Conditions of Participation (CoPs) including:

- Medical staff practicing at the off-campus ED must be part of the hospital's single organized medical staff.
- The responsibilities of the hospital's Governing Body apply to the services and activities of the off-campus ED.
- Nursing personnel at the off-campus ED must be part of the hospital's single organized nursing service.
- Emergency laboratory services must be available to the off-campus ED during all of its operating hours.
- The off-campus ED must be integrated into the hospital's quality assessment/ performance improvement (QAPI) program.
- The medical records of patients seen at the off-campus ED must be part of the hospital's single medical record system.
- Infection control practices at the off-campus ED must meet the requirements of the Infection Control CoP.

2. Require Provider-Based Off-Campus EDs to adhere to Title 10 Section 405.19 for Emergency Services. Update and revise, as indicated, to include requirements specific to FEDs.

Recommended additions to Title 10 Section 405.19 include:

- Establish Naming Convention and Scope of Services. Establish a definition using the CMS classification for "Provider-Based Off-Campus Emergency Department" and set a standard for the minimum scope of services to be provided. Modify existing requirements for 24/7 hours of operation to allow off-campus EDs to operate on a limited hours schedule.

Approving an off-campus ED to operate less than 24/7 should take into consideration the distance to the nearest hospital with an emergency department. If the distance is greater than an agreed upon standard, 24/7 operation should be required.

- Disclosures to Consumer. Require clear nomenclature, signage and a communication plan for off-campus EDs operating on a limited hours schedule.

The communication plan should include collaborative planning with regional emergency medical services and a public information campaign for informing the public about the hours of operation.

- Quality and Patient Safety. Require off-campus ED capability to receive ground ambulance patients and establishment of EMS protocols for transfer of patients requiring higher levels of care.

The off-campus ED is responsible for educating EMS about their capacity including the level of acuity they are qualified to treat and that is appropriate for their resources. Protocols should include transfer agreements with hospitals with capacity to treat emergency patients and in close proximity to the off-campus ED.

- Stabilization of the Medical Home. Require off-campus EDs to have a protocol for linking patients with primary care providers.

Off-campus EDs are required to establish linkages with primary care providers for the purpose of referral and follow-up. After treatment is administered, referral should be made to the appropriate level provider for follow-up. The off-campus ED should assist those patients without a primary care provider with finding one that is accessible by maintaining an up-to-date roster of primary care practitioners accepting new patients in provider's geographic area. The roster must include community health centers and other providers that serve Medicaid and low-income customers.

3. Develop a need methodology for establishment of Provider-Based Off-Campus Emergency Departments. Title 10, Section 709 will be amended to include specific need criteria.

It is anticipated that a number of hospitals may be interested in establishing off-campus emergency departments or converting full-time emergency departments to part-time hours of operation. To ensure an appropriate number and distribution of such facilities, need criteria must be developed to guard against excess capacity.

- Need criteria may include consideration of distance and travel time to the nearest hospital-based emergency department.

4. Require Accreditation

- For hospitals that have Provider-Based Off-Campus EDs, require accreditation from a national accrediting body such as JCAHO. The accrediting review must include an on-site review of the off-campus ED. If a provider loses its accredited or “deemed status” by an accrediting body, it would be required to report such change to the Department of Health in a timely fashion.

5. Health Information Technology

Overall continuity of care will be facilitated by requiring providers to explicitly connect to the larger health care delivery system through the following:

- Require utilization of a certified electronic health record (EHR), connected to the Statewide Health Information Network for New York (SHIN-NY) for sharing of patient information to all authorized clinicians. By so doing, results of patient imaging studies would be available to the patient’s primary care provider, and any specialists involved in their care.
- Provide copy of medical records to the patient consistent with current Public Health Law.
- Require structured interoperable health IT systems, policies, procedures and practice to support creation, documentation, execution, and ongoing management of a plan of care for every patients.
- Require ePrescribing.



Upgraded Diagnostic and Treatment Center

Background

Upgraded Diagnostic and Treatment Centers were created in regulation in 1995 as a response to the closure of rural hospitals so that communities would have access to limited emergency services in a diagnostic and treatment center environment. There are currently no upgraded diagnostic and treatment centers in New York, nor are there similar models in other states except for the most remote and frontier.

History

In the mid to late 1980's a specific focus on rural health care services began to be developed across the nation as a response to the closure of rural hospitals. One major initiative at the federal level was the creation of the Office of Rural Health Policy (ORHP) that would focus solely on rural health policy and programs within the Department of Health and Human Services. In 1991 the ORHP created the State Office of Rural Health program with the goal that there would be an office focused on rural health issues in every state. The New York State Office of Rural Health was also created in 1991 and receives approximately \$170,000 in federal funding to coordinate statewide rural health policy.

In the face of rural hospital closures nationally, the New York State Office of Rural Health worked with the state Rural Health Council to develop alternative types of providers to serve rural communities. Along with Critical Access Hospitals, Upgraded Diagnostic and Treatment Centers (UD&TCs) were created as an option that would allow for the continuation of certain health care services, particularly emergency services, in event of hospital closure. UD&TCs are a New York State specific model.

While the regulations for UD&TCs were put into place in 1995, there are currently no facilities licensed as such nor have there been any establishment applications submitted. It is widely thought that there have been no UD&TC applications because there is not an adequate, defined reimbursement methodology. There was one facility that pursued designation, but using a blended clinic and emergency department rate for financial modeling, found that it was not feasible due to the capital and staffing costs incurred in providing "limited emergency services."

What is an Upgraded Diagnostic and Treatment Center?

UD&TCs, as codified in regulation in Title 10, Section 752-2, are defined as a general hospital that has relinquished its inpatient acute care bed capacity or an Article 28 diagnostic and treatment center that provides primary care services in a rural area. UD&TCs, whether previously a hospital or not, are intended to provide “limited emergency services.”

Specifically, a UD&TC must:

- possess a valid operating certificate and be in compliance with all other applicable state and federal requirements;
- participate in a rural health network defined as an affiliation of health care providers serving a rural area, pursuant to a contract or joint cooperative agreement, . . .
- have a formal affiliation with a general hospital;
- be located in a rural area, defined as any county with less than two hundred thousand persons or any town which has a population of less than two hundred persons per square mile, or if approved by the Commissioner, any town which has a population of less than two hundred fifty persons per square mile.

Optional Limited Emergency Services

In addition to primary care services, UD&TCs may elect to provide limited emergency services on a 24-hour a day basis, seven days a week, within a network-wide emergency medical services (EMS) system as defined by a network operational plan or cooperative agreement. The UD&TC must ensure the availability of a 24-hour a day, continuous on-line communications link with its affiliated hospital(s) and other appropriate providers of emergency services, medical backup, consultation, inter-facility transport and medical control. Emergency services must be coordinated with other services of the UD&TC to facilitate continuity of care and discharge planning when post emergency needs do not require transfer to another facility.

UD&TCs that do not provide 24-hour a day on-site limited emergency services must ensure that patients in need of emergency care and arriving at the facility during non-operating hours are provided with information necessary to obtain emergency care.

The medical staff must be qualified to provide emergency services in accordance with patient needs and the service capabilities of the facility and must include at least one licensed physician and one or more currently licensed or registered health care practitioners including but not limited to registered physician's assistants and nurse practitioners.

It is important to note UD&TCs are neither freestanding emergency departments nor urgent care centers, because UD&TCs are to provide services within a coordinated system of care that includes a hospitals and other community based providers.

Perceived Benefits of Upgraded Diagnostic and Treatment Centers

UD&TCs were developed to provide an alternative for communities that need health care services, including limited emergency care, but are not able to support a hospital. UD&TCs must provide services within a network so that continuity of care is ensured. UD&TCs would be able to alleviate pressure on local emergency squads, many of which are largely volunteer.

Experience in Other States

The Frontier Extended Stay Clinic (FESC) is a model analogous to UD&TCs. The Medicare Modernization Act of 2003 gave authority to the Centers for Medicare and Medicaid Services (CMS) to conduct a demonstration program to reimburse extended stay care received by Medicare beneficiaries at clinics located in remote and frontier communities. Additionally, the ORHP created a grant program in 2004 to work with 4 FESCs in Alaska and 1 in Washington.

A FESC is a clinic that is:

- located in a community where the closest short term acute care or critical access hospital is at least 75 miles away or is inaccessible by public road; and
- designed to address the needs of seriously or critically ill or injured patients who, due to adverse weather conditions or other reasons, cannot be transferred quickly or patients who need monitoring and observation for a limited period of time.

FESCs are allowed to keep patients for extended stays for more than 4 hours only if weather or other reasons prevent transport. FESCs provide urgently needed care but are not permitted to:

- perform surgery except for those cases that may be performed in a physician's office;
- provide general or epidural anesthesia or deep sedation, or
- perform planned delivery of newborn babies.

The CMS Demonstration Authority ends in 2013 with the possibility that the FESC model may then be extended to all states. It is estimated that fewer than 10 clinics in the lower 48 states meet the location requirements.

Evaluation findings have shown that the FESC model is financially feasible in Alaska due to lower transport costs for transfers and because clinics were able to be reimbursed for observation patients for whom they were already providing services.

Recommendation

Upgraded Diagnostic and Treatment Centers

When Upgraded Diagnostic and Treatment Centers were established in regulation, they were intended to provide limited emergency services to rural communities. Given new models of care, including urgent care and freestanding emergency departments, there is no further need for this model.

- 1. Revise Article 28 regulations to remove Upgraded Diagnostic and Treatment Centers.**

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Advanced Diagnostic Imaging

Background

Advanced diagnostic imaging can benefit patients when used appropriately - it detects diseases and conditions early and it allows health care practitioners to direct patients to the health care services they need. But, when used inappropriately, advanced diagnostic imaging provides practitioners and patients with minimal clinical benefits, wastes scarce health care resources and can even jeopardize patient safety.

As a profitable service with growing demand and low barriers to entry, advanced diagnostic imaging, that includes diagnostic magnetic resonance imaging (MRI), computed tomography (CT), and nuclear medicine imaging such as positron emission tomography (PET), has attracted many new providers. There has been a dramatic proliferation in the volume of diagnostic medical imaging services prescribed by practitioners, including non-radiologists, raising concerns about patient safety, costs and implications for the health care industry.

Issues

Inappropriate Use and Overuse

The rapid pace of advances in the field of advanced medical imaging and a lack of knowledge on how best to leverage these technologies to appropriately serve the needs of each patient have created challenges to ensuring the most efficient diagnostic pathways and optimal outcomes for patients. Many providers, organizations and individual physicians argue that much of the utilization of advanced diagnostic imaging classified as “waste” by payers provides practitioners with information used to make early diagnoses of disease, limit complications, reduce long term costs and improve patient outcomes. Others argue that increased utilization of these services is a result of defensive medicine.

A report by John Iglehart in *The New England Journal of Medicine* (2009) indicated that, between 2000 and 2007, use of imaging studies grew faster than that of any other medical service in the Medicare population. A 2008 report, “Ensuring Quality through Appropriate Use of Diagnostic Imaging,” by America's Health Insurance Plans claimed that 20% to 50% of all “high-tech” imaging provide no useful information and may be unnecessary.

A 2012 study published in *The Journal of the American Medical Association* by lead author Dr. Smith-Bindman, a radiologist and epidemiologist, looked at data on one million to two million patients a year from 1996 to 2010 in six health maintenance organizations across the United States, only some of whom had imaging. The number of CT scans tripled over the study period, to 149 per 1,000 patients in 2010, while the number of MRI's quadrupled, to 65 per 1,000 patients in 2010. Since the health maintenance plans were part of integrated health care delivery systems that are clinically and fiscally accountable for the outcomes and health status of the population served, financial incentives did not seem to drive the increase. Rather, the changes seemed to derive from improvements in scanning technologies that made them more widely applicable, along with the fact that patients more often requested the scans. Also, the authors said, some doctors practiced "defensive medicine," ordering tests to guard against malpractice lawsuits.

The *Choosing Wisely* campaign, an initiative of the ABIM Foundation, developed in concert with many national organizations representing medical specialists, is encouraging physicians, patients and other health care stakeholders to perform certain tests and treatments less often, with imaging prominent among them.

Quality and Patient Safety

The overuse of imaging services poses a risk to patient safety. CT and PET scans use ionizing radiation that may expose people to potentially cancer-causing radiation. Because ionizing radiation exposure is cumulative over a person's lifetime, excessive and unnecessary use of advanced imaging is cause for concern.

CT scans deliver high quality imaging and are becoming the dominant imaging modality. CTs, however, also represents the largest contributor to an increase in population radiation exposure based on reports from the National Council on Radiation Protection and Measurements. The usage of CT scans has more than tripled in the past decade and currently there are about 80 million CT scans performed in the United States each year.

MRI's do not use ionizing radiation but are not without risks. MRI risks are mainly due to the use of contrast agents, risks also associated with CT and other imaging methods involving administration of contrast.

The Smith-Bindman study states that while advanced medical imaging has benefits, allowing problems to be diagnosed earlier and more accurately, its value needs to be weighed against potential harms, which include a small cancer risk from the radiation.

Costs

Multiple independent studies have concluded that as many as one-third of all advanced imaging services are either clinically inappropriate or they do not contribute to a physician's diagnosis or the ultimate health outcomes for the patient (National Imaging Associates). Often, traditional technology can be utilized, rather than an advanced imaging procedure, as a more efficient and economical diagnostic tool for physicians and other practitioners.

GAO estimates that in 2010, providers who self-referred likely made 400,000 more referrals for advanced imaging services than they would have if they were not self-referring. These additional referrals cost Medicare about \$109 million. The \$109 million is just the effect from Medicare patients.

If it is assumed that one-third of advanced imaging tests performed across the nation are unnecessary, the data strongly suggests that efficient radiology benefits management could cut America's radiology expenditures by \$20 billion to \$30 billion annually (National Imaging Associates).

Current Federal and NYS Regulations

The federal Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, required freestanding advanced diagnostic imaging facilities performing CT, MRI, and nuclear medicine) that seek Medicare reimbursement to be accredited by January 1, 2012. In addition to impacting overutilization and costs, MIPPA also sought to ensure the quality of advanced diagnostic imaging procedures.

There are other regulations regarding radiation at both the federal and state levels. The United States Food and Drug Administration regulations cover the manufacture of radiation producing equipment; however, they do not regulate the use of this equipment. The use is generally under professional practice (i.e. medicine, dentistry, etc.) which are regulated by the states. The federal Atomic Energy Act of 1954 authorizes the Nuclear Regulatory Commission (NRC) to regulate the use of radioactive materials. New York State (NYS), under this law, is an "agreement state" and as such the state agrees to adopt and enforce standards that are comparable or exceed the federal rules. Radiation producing equipment (all x-ray machines, fluoroscopy, computed tomography services (CT) and linear accelerators are registered with either the New York State Department of Health (NYS DOH) or the New York City Department of Health and Mental Hygiene (NYC DOHMH). All radioactive materials used in medicine are licensed as well by those same entities. Licensure is more restrictive than registration; however, both require the facility operator to maintain minimum quality and safety standards. The NYS DOH and NYC DOHMH inspect all these facilities periodically (every 1-4 years for medical use facilities) depending on their size and scope. The Departments' regulations only authorize the review of quality and safety issues. There is no assessment or review of "need" or of

appropriateness or other issues that do not relate to the quality of imaging, treatment or radiation safety.

Within the State, the Bureau of Environmental Radiation Protection (BERP) oversees the requirements of 10 NYCRR Part 16, the state regulations that are at least as stringent as the federal standards in 10 CFR 20-35. The Department of Health (BERP) has proposed an amendment to Part 16 that will require facilities operating computed tomography (CT) equipment to be accredited by the American College of Radiology (ACR) or The Joint Commission or the Intersocietal Accreditation Commission (IAC, formerly ICACTL), within 12 months of the passage of that amendment. Approximately 75% of the facilities operating CT in NYS already meet this requirement, as it is identical to the Medicare Improvements for Patients and Providers Act (MIPPA) requirement (discussed later in this report). Currently this draft rule is being reviewed by the Governor's Office. The draft rule would only apply to CT and not magnetic resonance imaging (MRI) or other aspects of advanced imaging.

Recommendations

Advanced Medical Imaging

- **Revise Title 10 regulations to define advanced diagnostic imaging using the Federal definition as defined in the Medicare Improvements for Patients and Providers Act (MIPPA) language.**

MIPPA definition of advanced medical imaging:

Section 135 (B) ADVANCED DIAGNOSTIC IMAGING SERVICES DEFINED- In this subsection, the term 'advanced diagnostic imaging services' includes--

- (i) diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and
 - (ii) such other diagnostic imaging services, including services described in section 1848(b)(4)(B) (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.
- **Require accreditation by a nationally approved organization**
 - Require third party accreditation by a national accreditation organization approved by the Department. If a provider loses its accreditation, it would be required to report such change to the Department of Health in a timely fashion.

- Accreditation criteria include the following elements:
 - Qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services.
 - Qualifications and responsibilities of medical directors and supervising physicians, such as training in advanced diagnostic imaging services in a residency program, expertise obtained through experience or continuing medical education courses.
 - Procedures to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished.
 - Procedures to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by the supplier.
- DOH has proposed Part 16 amendments that will require accreditation of all CT operators. Under this requirement, accreditation requirements will be extended to MRI and PET Scans and other imaging services, as determined.
- **Require use of evidence-based practice guidelines to determine appropriateness of medical imaging options.**
 - The American College of Radiology (ACR) “Appropriateness Criteria” will be used as it is the primary reference. The ACR imaging guidelines are developed in consultation with dozens of other medical colleges to attain consensus on when an imaging technology is appropriate to confirm a diagnoses. Most medical specialties refer to the ACR with respect to imaging.
- **Require through regulation documentation in every patient’s electronic medical record of the CT scan or other medical imaging study as determined by the Department and radiation dosage used.**
 - Documentation in electronic medical records will help doctors and patients keep track of studies conducted and radiation exposure and provide further incentive to avoid unnecessary imaging. Require that reports and images (including radiation dosages) be made available on the SHIN-NY. Reporting data on dose level can prevent future radiation accidents and enhance scientific and biomedical research.

- **Require registration and data submission for all providers including existing providers that have advanced medical imaging equipment or new providers purchasing such equipment (e.g. practice size; services; payer mix).**
 - Data will provide the state with information on the supply of equipment available in the State and benefit any future proposals on this topic to proceed with more accurate information.
- **Approximately three years after registration/data submissions is begun and the data is analyzed, evaluate if Certificate of Need for providers that plan to add advanced diagnostic imaging equipment is indicated.**

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Radiation Therapy

Background

Radiation Therapy (RT) uses high-energy radiation to shrink tumors and kill cancer cells. X-rays, gamma rays and charged particles are types of radiation used for cancer treatment. RT systems have become more complex and have been refined to better target the cancer and minimize surrounding tissue damage through “image guided radiation therapy” (IGRT) and “intensity modulated radiation therapy” (IMRT). The advanced systems rely on computer networks and electronic data storage.

About half of all cancer patients receive some type of RT during the course of their treatment. Many times this involves short, daily treatments for consecutive weeks or months. Consequently, offering access to services which is convenient for patients so they can continue in their daily activities has been a primary concern and correlates with the move towards integrated community based cancer care. This model allows patients to have access to all their care in an integrated, local setting. This works well for cancer care as there are many components to a treatment plan, e.g. the use of advanced imaging to guide radiation therapy and chemotherapy.

Issues

Utilization

There have been concerns raised about the overuse of RT. There are allegations that without any certificate of need review RT centers can proliferate and increase utilization. This is mainly a concern when advanced therapy (IMRT) is used when conformal radiotherapy (older RT) might be just as helpful. Dr. Ronald Chen and others published a study in *The Journal of the American Medical Association* (JAMA, May 20th, 2013) concluding that IMRT and conformal radiotherapy for prostate cancer were equivalent, despite the much higher cost for IMRT. In contrast to advanced medical imaging, the Committee did not identify general overuse of RT since in order to receive RT one has to be diagnosed with cancer. However, the Committee did share the concern that certain types of RT, as noted above, are over utilized.

Costs

RT is very costly, and according to a 2010 analysis of Medicare data done by Thomas Jefferson University in Philadelphia, the number of patients receiving services grew 33% and the costs of therapy grew 156% from 1998-2008. Most of the increase in charges is attributed to the use of IMRT- which they report has grown 930% since its inception in 2002. A 2006 National Cancer Institute (NCI) report based on 2005 SEER data demonstrates that the majority of cancer costs are attributed to chemotherapy and not diagnostic advanced imaging or radiation therapy. Reports from Millman (2011) and Avalere Health (2012), demonstrate that physician based integrated cancer care is less costly than hospital based care.

Quality and Safety

Equipment maintenance and dosage calculations are obvious quality and patient safety areas of concern but there are also broad quality implications for complex radiation therapy systems. RT requires highly trained, competent staff working in a well-organized and monitored system of care that is driven by a quality improvement program. Accreditation and society practice guidelines have driven improvements in this area.

Accreditation

There are many accrediting options for RT. The American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) and The Joint Commission (JC) have programs as do other professional radiology groups. Regulations, such as Part 16, are used to set minimum standards that must be met for simple, straightforward items. Accreditation can then be used to address more complex situations that may involve clinical judgment, are rapidly changing or involve business aspects that drive utilization. The DOH Bureau of Environmental Radiation Protection (BERP) recently amended Part 16 to require accreditation for RT. The ACR, ACRO and other professional organizations also offer optional practice guidelines for RT.

Current Federal and State Regulation

The federal Atomic Energy Act of 1954 authorizes the Nuclear Regulatory Commission (NRC) to regulate the use of radioactive materials. NYS, under this law, is an “agreement state” and as such the state agrees to adopt and enforce standards that are comparable or exceed the federal rules. Within NYS, the Bureau of Environmental Radiation Protection (BERP) oversees the requirements of 10 NYCRR Part 16, the state regulations that are at least as stringent as the federal standards in 10 CFR 20-35. (See Advanced Imaging, above) BERP, as noted above, recently amended Part 16 to update the quality assurance provisions and require that RT providers be accredited by the American College of Radiology (ACR) or the American College of Radiation Oncology (ACRO) or another equivalent

organization within 18 months of the effective date of the regulations. There are also Part 405.15 regulations if the RT provider is an Article 28 facility.

RT is exempt from the federal Medicare Improvement for Patients and Providers (MIPPA) Act of 2008 (see Advanced Diagnostic Imaging section). There has been pending legislation to include them but nothing has been enacted.

Most large states have standards for radiation safety in radiation therapy similar to NYS's Part 16. Many have similar quality assurance requirements as well, although NY has been a leader in the area of radiation safety. All providers using radioactive materials must comply with federal NRC requirements; however the vast majority of RT is done using linear accelerators (LINACs) and these generally fall under state regulatory authority.

The process for CON and licensure varies across states. NYS includes "character and competence" review as part of the CON process. Other states include "character and competence" review as part of licensure. This difference makes comparing CON/licensure requirements among states problematic.

- New Jersey- Since 2004 LINACS removed from CON, licensure continued through policy (not a regulation). Licensing includes a character and competence review and physical plant requirements. There are no accreditation requirements.
- Connecticut- Non-hospital based LINACS require a CON. Licensure is not required for physician practices that have LINACS, but CON is. CON is primarily a need review, with some financial and access reviews and no architectural review. Architecture review is included in licensure.
- Massachusetts- Beginning in 2009 physician based operators could no longer apply for exemptions to "Determination of Need" (DON). Existing practices were grandfathered in over a 6 month period. They report they have had no new applications for RT since this policy was implemented because the state says there is no need.

Recommendations

Radiation Therapy

1. Require use of evidence-based practice guidelines to promote appropriate therapy options.

- The American College of Radiology (ACR) and American College of Radiation Oncology (ACRO) have optional practice guidelines for RT. Use of these guidelines will assist in addressing the concerns raised about the appropriate use of certain types of RT, such as IMRT for prostate cancer and proton beam therapy.

2. Eliminate CON for Article 28 Radiation Therapy Providers (Therefore, CON is not a requirement for any provider)

- There is considerable oversight of all radiation therapy providers because they are subject to DOH Bureau of Radiation Protection (BERP) Part 16 requirements (and Part 405 regulations if they are an Article 28 facility) and Nuclear Regulatory Commission (NRC) regulations for federal facilities. In addition, recent DOH regulations require ALL providers be accredited by national accrediting bodies such as the American College of Radiology (ACR) and American College of Radiation Oncology (ACRO). If a provider loses its accreditation, it would be required to report such change to the Department of Health in a timely fashion.
- DOH would still have operational oversight for RT in Article 28 facilities as per the general requirements of 10 NYCRR Part 405.15 and Part 16.

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Non-Hospital Surgery in New York

Ambulatory Surgery Centers and Office-Based Surgery

Background

The migration of medical and surgical care to ambulatory settings is undeniable. Ambulatory surgical care occurs in a variety of settings with various levels of oversight and regulation. Non-hospital surgery performed in ambulatory surgery centers (ASC) is highly regulated at both the state and federal level. In contrast, oversight of private practices of medicine is limited to those that perform invasive and/or surgical procedures involving more than minimal sedation or local anesthesia that must become office-based surgery (OBS) accredited and report adverse events. Surgical care provided in non-hospital settings is generally considered safe and of sufficient quality. The cost of non-hospital surgery is lower than hospital-based surgery; with regulated facilities receiving higher reimbursements for the same procedures as offices - primarily due to receipt of a facility fee.

Regulated facilities, including free standing ambulatory surgery centers pay New York Health Care Reform Act (HCRA) surcharges; office-based surgical practices do not. HCRA is a major component of New York State's Health Care financing laws and addresses a broad range of issues including mechanisms for hospital reimbursement, graduate medical education finance, and subsidies for care provided to the uninsured. The law requires that certain third-party payors and providers of health care services participate in the funding of these initiatives through the submission of authorized surcharges and assessments. Health care providers that offer services subject to HCRA surcharges include: general hospitals, comprehensive diagnostic and treatment centers, diagnostic and treatment centers that provide ambulatory surgical services, and clinical laboratories,. Also included are extension clinics affiliated with hospitals and comprehensive diagnostic and treatment centers.

There are a number of policy issues of relevance to the subject including: ongoing migration of surgical and procedural care to non-hospital settings, appropriate site of care, quality and safety of care delivered in non-hospital surgical settings, disparate oversight of settings providing similar services, cost of care and current reimbursement practices, public good including contribution to HCRA and responsibility to provide care to the under and uninsured as well as persons on Medicaid. Based on analysis of OBS adverse events and in response to the ever-evolving landscape of

healthcare, changes to the OBS statute supported by the OBS Advisory Committee are currently under review by the Department.

Issues

Migration of Care to Outpatient Settings

The literature is replete with reports the migration of invasive and surgical procedures to ambulatory settings, including non-hospital affiliated ambulatory surgery centers (ASC) and physician offices.

A 2004 MedPac report to Congress reported that 60-70% of invasive and surgical procedures were being performed in an ambulatory setting (hospital outpatient department, freestanding ASCs and office-based surgery practices), with the expectation that these numbers would only increase. In 2009 KNG Health Consulting, a health economics and policy firm, published a report titled “An Analysis of Recent Growth in Ambulatory Surgery Centers” commissioned by the ASC Coalition noting that almost all Medicare growth in ambulatory surgery services from 2000-2007 was primarily due to growth in the number of services per beneficiary. KNG estimated that 70% of growth in service volume per beneficiary during this period could be attributed to migration of services from hospital outpatient departments to ambulatory surgery centers and other non-hospital surgical settings.

Quality and Safety

According to Agency for Healthcare Research and Quality (AHRQ) only about 10% of patient safety studies are conducted in outpatient settings. In addition, the research on the quality/safety of outpatient surgery is confusing. The terms ambulatory surgery, outpatient surgery, and office-based surgery are used interchangeably and findings for all settings are frequently grouped together or not clearly differentiated from each other. The lack of a standardized definition of terms illustrates the need to clarify taxonomy and definition of terms.

In 2011 the American Medical Association published, “Research in Ambulatory Patient Safety-A Ten Year Review” which reviewed patient safety data from 2000-2010 for all types of ambulatory care, including surgery. The authors concluded that “though some very high-quality work on ambulatory safety took place between 2000 and 2010, research and initiatives in ambulatory safety were remarkably limited, both in quantity and in the ability to generalize from the studies that were reported...Even using relaxed criteria, the peer reviewed literature on ambulatory patient safety was often limited and publications of research on safety interventions were almost non-existent.”

Ambulatory Surgery

NYS Department of Health longitudinal surveillance of freestanding ASC's has not identified any undue occurrence of adverse events or poor outcomes for this category of provider. In addition, the NYPORTS system has not received reports in numbers that would indicate that freestanding ASCs pose any unusual risk for poor surgical outcomes or substandard quality of care. It should be noted, however, that incidents documented in NYPORTS may be subject to underreporting. Therefore, this favorable picture for ASCs may be biased.

The NYS experience is consistent with the research literature on ASCs that shows few differences in quality between freestanding ASCs and hospital-based ambulatory surgery services (Chukmaitov et al, 2008). Although critics often contend that freestanding ASCs select lower-risk patients ("cherry-picking"), resulting in favorable outcomes, studies adjusted for differences in co-morbidity have found no significant differences in outcomes between hospital-based and freestanding ASCs. Like other Article 28 providers, freestanding ASCs are required to implement quality assurance programs.

Office-Based Surgery

In the 2011 American Medical Association report, "Research in Ambulatory Patient Safety-A Ten Year Review", the authors concluded that overall the published research on office-based surgical safety has been characterized by small studies using varied methods, as well as other significant limitations. Lack of the availability of denominator data is generally identified as a challenge in carrying out studies of OBS safety. Most of the research referenced on office-based surgery has examined adverse events of plastics and dermatologic procedures.

Perhaps because of these limitations, different authors have arrived at different conclusions regarding the overall safety of OBS. Some investigators have concluded that office-based surgery is generally safe. Others have concluded that office-based surgery is safe only for certain procedures or if certain conditions are met. Others have concluded that office-based surgery or anesthesia may expose patients to additional risk. Still others have concluded that more information would be needed to establish the safety of office-based surgery.

Factors identified in the literature as being important to patient safety such as patient selection, co-morbidity, nature and complexity of procedure, and peri-operative management have been identified as issues of concern when reviewing OBS Adverse Event Reports received by the DOH Patient Safety Center.

Appropriateness of Site of Care

Though a number of factors are taken into consideration when scheduling a patient for a procedure in a one surgical care setting versus another, patient safety is primary. The risks and benefits of each procedure and associated sedation and/or anesthesia and each individual patient's medical history are evaluated. Based on this evaluation, the involved practitioners make the decision as to the setting most appropriate for the patient.

Periodically Medicare publishes a list of ambulatory surgery procedures that they will reimburse. The current list includes approximately 2000 procedures. Office-based surgery practices take this list into consideration when establishing the practices' scope of services. There is clear overlap in the procedures performed in ASC and OBS practices. Appropriateness of patient selection is an area of concern identified by Department staff and the OBS Advisory Committee in reviewing OBS adverse event reports.

Appropriate use of procedures is generally guided by professional standards in the diagnosis and/or treatment of disease. Adherence to appropriate use criteria varies among practitioners and has been identified as a contributing factor to over utilization of certain procedures, including colonoscopies. There is no appropriate use data regarding procedures performed in OBS settings currently available to the DOH.

Reimbursement and Cost of Care

Freestanding ASCs, like hospitals, receive a "facility fee" from public and private payers to reflect their more elaborate operations, staffing and physical plant compared to office-based settings. Physicians performing procedures in freestanding ASCs and hospital settings are reimbursed a professional fee that is lower than they would receive for the same procedures performed in an office setting (site of service differential). Physicians performing procedures in ASC in which they have full or partial ownership also receive some component of the facility fees paid to the facility in addition to a professional fee.

Public and private payers routinely reimburse private practice physicians professional fees for covered procedures performed in OBS offices. Physicians performing procedures in private OBS office practices do not routinely receive a facility fee, though this is a matter of negotiation between the physician and private payers. Neither Medicare nor Medicaid pays a facility fee to OBS practices.

Overall, the cost of surgical care in non-hospital settings is less costly than that delivered in hospital settings primarily due to reduced or non-payment of facility fees to outpatient and office settings, coupled with reduced professional fees for services rendered.

June 1, 2013 the New York Times published an article, “The \$2.7 Trillion Medical Bill; Colonoscopies Explain Why U.S. Leads the World in Health Expenditures.” The article notes that colonoscopies were largely an office procedure when widespread screening was first recommended and have “moved to surgery centers....a lucrative step down from doctors’ examining rooms—which are billed like a quasi-operation.” It identifies colonoscopies as the most expensive screening test that healthy Americans routinely undergo and the average cost of a colonoscopy in the U.S. as \$1,185, much more expensive than in other developed countries.

The Times reported their findings as:

- In 2011, Medicare paid gastroenterologists an average of \$531 for a colonoscopy—this did not include payments for a facility fee or anesthesiologist care.
- A Long Island woman underwent 2 colonoscopies, one in a hospital outpatient surgery department-- billed as \$ 9,143 (\$5,743 reimbursed including a facility fee) and a second in a doctor’s office—billed as \$5,323 with \$2,923 reimbursed.
- Also on Long Island, a woman underwent a colonoscopy in an ambulatory surgery center. She was billed \$6,385 including \$1,075 for the gastroenterologist, \$2,400 for the anesthesiologist and \$2,910 for the facility fee.

The Times, and many other authors, raise questions about the differences in charges and reimbursements; why the same tests are billed, and reimbursed, at such different amounts per setting; if hospital and ambulatory surgery center care (and costs) are needed for certain, in most instances, low risk procedures; and if “anesthesia services” are required for routine procedures that can be performed using different (non-anesthetic) medications, doses or practitioners to administer them.

Public Good and the Health Care Reform Act(HCRA) Surcharges

As previously discussed, ASCs are subject to HCRA surcharges; office-based surgical practices are not. HCRA imposes a charge of 9.63% on payments to freestanding ASCs from commercial insurers, Blue Cross, HMOs, self-insured plans and other non-governmental payers to support the HCRA pools, which aid hospitals in providing safety net services. A charge of 7.04% is also assessed on the ASCs’ Medicaid revenues (State share portion). In 2012, these combined assessments on the revenues of freestanding ASCs resulted in payments of \$3.3 million to the HCRA pools.

OBS practices do not pay surcharges into the HCRA pool, no matter their size or service provision.

The proportion of Medicaid and self-pay clients treated by freestanding ASCs is lower than that of hospital-based ASCs. Many private physicians participate in the Medicaid program, however, the amount of care provided to Medicaid recipients by OBS practices is unknown.

Current Oversight of Non-Hospital Surgery

Under current New York State law, surgery performed in non-hospital settings is categorized and overseen according to the setting in which it occurs: 1) freestanding (i.e. not owned, operated or sponsored by a hospital) ambulatory surgery centers (ASCs) and 2) office-based surgery practices (OBSP).

Ambulatory Surgery

Ambulatory surgery is defined in the regulations of Article 28 of the Public Health Law as “those surgical procedures which need to be performed for safety reasons in an operating room on anesthetized patients requiring a stay of less than 24 hours' duration. These procedures do not include those outpatient surgical procedures which can be performed safely in a private physician's office or an outpatient treatment room.” (10 NYCRR Section 755.1)²

ASCs must comply with the staffing and other operational requirements set forth in Parts 405 and 755 of Article 28 regulations. In addition, NYS law and regulation require ASCs to submit adverse event to NYPORTS and to report procedure and payer information to SPARCS. Freestanding ASCs must become accredited by a national accrediting organization within two years of PHHPC approval.

Like hospitals, freestanding ASCs are subject to Certificate of Need (CON) review, for public need, financial feasibility and operator character and competence. Like other Article 28 facilities, they are also subject to review for compliance with the architectural and engineering requirements of Parts 711 and 715 of the State's medical facilities construction code. The Department solicits comments from neighboring hospitals to evaluate whether a proposed ASC would have an adverse effect on the hospitals' surgical cases and revenues and on their community-oriented programs.

ASCs, whether freestanding or hospital-operated, are subject to the need methodology set forth in 10 NYCRR Section 709.5. This regulation states that need for an ASC is demonstrated through the ASC applicant's documentation that the capacity of the proposed ASC will be utilized sufficiently to be financially feasible, as demonstrated by a three-year analysis of projected costs and revenues associated with the program, based on expected demand and expected patient referral and use patterns.

ASC are also required to comply with Medicare Conditions of Participation.

² Surgical procedures carried out in a procedure room, such as endoscopy, are also defined as ambulatory surgery for reporting purposes and must be reported as ambulatory surgery under Section 400.18. of the SPARCS regulations

Office-Based Surgery

Office-based surgery in NYS is governed by PHL 230-d Office-based Surgery and 2998-d Reporting of Adverse Events in OBS. PHL 230-d, and related OBS legislation signed into law in 2007, require private physician practices performing invasive or surgical procedures involving more than minimal sedation (moderate sedation, deep sedation and general anesthesia) or liposuction of greater than 500 ml to become accredited and report select adverse events identified in the law. No OBS regulations have been written to date. To date, practitioners and others have been guided by Frequently Asked Questions posted to the OBS website and correspondence to individuals.

In 2012 the OBS Advisory Committee began discussion about the need for revisions to the OBS law and arrived at a series of recommended statutory changes. These are OBS Advisory Committee generated changes to PHL 203-d are listed below in number one.

On October 28, 2013 members of the OBS Advisory Committee met to review the OBS regulatory reform options generated as part of the work of the PHHPC Planning Committee including:

- a. Require all OBS/OBA practices to register with the DOH, provide practice specific information* and utilize certified EHR with submission of data to RHIOs and SHIN-NY.**

Registration with the submission of select data would enhance the Department's knowledge of the amount and types of care being provided in private offices. Requiring utilization of certified ERH's seeks to assure use of medical record systems that have inter-operability; submission of EHR data to the RHIO's and participation in the SHIN-NY seeks to improve sharing of patient information, quality of care and care coordination.

*Information to include: # of MDs & other LIP's providing services, types of services provided (including specifics such as # and type of surgical/invasive procedures performed); number of patients seen, payer mix, quality indicator information, accreditations/certifications held by office/practice.

**Assumes continuation of current requirements for accreditation and adverse event reporting as well above noted statutory changes.

- b. Require licensure (operational oversight) of OBS practices by the DOH when the following criteria are met*:
 - i. When 4 or more patients rendered incapable of self-preservation without assistance at one time (regardless of ASA class), or
 - ii. When administering greater than local anesthesia or minimal sedation to ASA 4 or unstable ASA 3 patients, or

- iii. When performing level 2 or level 3 surgeries as defined by the American College of Surgeons with expected duration of 6 hours or greater, or
- iv. When post-procedure time to meet discharge criteria extends beyond 6 hours.

Requiring a greater degree of oversight as patient risk increases is a regulatory scheme common in NYS and in other states. Architectural and other standards set by both the National Fire Protection Association and the National Guidelines Institute increase when more than three or four patients are rendered incapable of self-preservation, respectively. Risks to patients increase as the degree of impairment of their baseline health status increases (ASA classification) and as the length of sedation/anesthesia time increases. Patients not attaining discharge criteria within six hours of the completion of OBS indicate the need for ongoing care that private offices were not designed to deliver.

*Assumes continuation of current requirements for accreditation and adverse event reporting as well above noted statutory changes.

Committee members revisited the purpose and mission of the Advisory Committee, previously known as the Committee on Quality Assurance in OBS, commissioned in 1997 and again in 2005 by the then Public Health Council to assure quality of care and patient safety, facilitate establishment and adherence to standards of practice and delivery of appropriate care in the OBS setting. To that end, the Committee authored Clinical Guidelines for Office-based Surgery in 2000 and the 2007 Report of the Committee on Quality Assurance in OBS recommending the current OBS statute.

Committee members acknowledged that both the "registration option" and the "licensure option" presented are reasonable in some ways; each having pros and cons associated with them.

The Committee strongly supports establishment and implementation of processes, even requirements that will help and support physicians, giving them tools, such as evidenced based guidelines, accreditation, etc., to accomplish the delivery of safe, quality, appropriate, efficient and cost-effective care to patients.

The Committee strongly supports the use of data, information and evidence to advance and guide the evaluation of the quality of health care delivered by practitioners as well as health care delivery systems, regulated and unregulated, and the health care planning responsibilities of the NYS DOH and the PHHPC.

The Committee strongly supports mandatory reporting of the number and type(s) of procedures performed and number and type of complications associated with each type of procedure for each practitioner for all OBS accredited office practice locations.

The Committee supports accreditation as the preferred method to achieve quality and standardized care in OBS including:

- Via submission of procedure, complication, quality and other data identified by the Department, and,
- To address patient selection, appropriateness of procedures performed in OBS and appropriate training/credentials for physicians performing procedures in OBS settings.
 - Appropriate credentials to perform procedures should be determined by ABMS board certification, hospital privileging or other equivalent determination of competency method(s).

The Committee endorses consumer access to information to assist in healthcare decision making as well as physician/provider accountability for care delivered. Members note that physician comfort with making quality improvement and peer review data and information available may be enhanced by providing them protection from potential litigation associated with discovery similar to the protection afforded in Article 28 facilities.

If statutory changes were required to strengthen the ability of accrediting agencies to carry out these requirements, Committee members would support such statutory changes.

The Committee recognizes that registration and/or licensure may be perceived by physicians as additional hardship or unfunded mandates, which may add to their resistance to change and contribute to a further decline in physician morale. This can negatively impact quality and safety of patient care despite statutory or regulatory programs that have beneficent goals. Any registration and/or licensure programs need to be designed to minimize this risk while still achieving salutary outcomes. In addition, the Committee expressed concern that to be effective any registration and/or licensing program would require the commitment of additional resources.

The Committee is split on the idea of granting DOH the authority to go in and survey OBS settings outside of the existing Office of Professional Medical Conduct (OPMC) authority. A number of members oppose any change in the current level of oversight and encourage enhanced utilization of the Patient Safety Centers' current authority to share adverse event related information with OPMC.

Recommendations

Ambulatory Surgery

- Maintain current regulations and oversight.

Office-Based Surgery

1. Changes to PHL 230-d Proposed and Supported by the OBS Advisory Group

Guided by a number of years of adverse event data and the evolution of health care, the OBS Advisory Group supports the following changes to the OBS laws to continue to address patient safety and quality of care concerns in OBS.

- Broaden premise of the law to include office-based sedation/anesthesia (OBA) greater than minimal sedation or local anesthesia when accompanying any medical or surgical procedure performed to diagnose or treat patients.
- Broaden licensees included in the law to podiatrists and others whose scope of practice includes or evolves to include OBS or OBA.
- Limit expected procedural and post-anesthesia time to meet discharge criteria to six hours.
- Lengthen time to report adverse events from 24 hours to 72 hours.
- Expand list of reportable adverse events to capture “observation” admissions to the hospital of greater than 24 hours and discharge of patients to the emergency department.
- Require accrediting agencies to share specific information with DOH upon request, including findings of survey(s) and complaint investigations, available quality data.
- Require accredited OBS practices to respond to requests for information and data when requested.

2. Changes to PHL 230-d Supported by the OBS Advisory Group

The OBS Advisory Committee felt that the following additional changes to the OBS law, derived from options presented to the PHHPC Health Planning Committee, best accomplished the objectives of improving patient safety, making data available to the department, and not adding to the ever-increasing demands on practicing physicians. These endorsed recommendations are proposed in lieu of potential options requiring registration or licensure (operational oversight), as discussed above.

- Mandatory reporting of procedure and quality data identified by the Department by OBS practices to the OBS accrediting agencies.
- Require accrediting organizations to base credentialing of practitioners to perform procedures in OBS on ABMS Board certification, hospital privileging or other equivalent determination of competency.
- Require accrediting agency inspection and follow-up on DOH referrals upon Department request.
- Require accrediting agency release of information to the DOH upon request.

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