Health Care Delivery Models in New York State
A Study of Retail Clinics, Urgent Care Providers and Major Physician Practices

September 2017
Contents

I. Introduction: Entities Examined under the Health Care Delivery Models Study Act ........ 1

II. Background ........................................................................................................................................ 2

A. The Changing Health Care Environment.................................................................................... 2

   1. The Affordable Care Act ............................................................................................................. 2

   2. The Medicaid Redesign Team and the Delivery System Reform Incentive Payment Program .......................................................... 2

   3. The Prevention Agenda ............................................................................................................ 3

   4. The State Health Innovation Plan ............................................................................................. 3

   5. Accountable Care Organizations ............................................................................................... 4

B. The Existing Regulatory Structure for Health Care Providers ................................................. 5

   1. The Corporate Practice of Medicine ......................................................................................... 5

   2. PHL Article 28 and the Certificate of Need Process ................................................................. 6

   3. Article 28 Regulatory Requirements and Surveillance ............................................................. 6

   4. Oversight of Physician Practices .............................................................................................. 7

   5. Article 28 vs. Non-Article 28 Providers and Section 600.8 Title 10 ...................................... 8

C. PHHPC Recommendations and Proposed Statutory Changes .............................................. 9

III. Model Analysis ............................................................................................................................. 9

A. Retail Clinics .................................................................................................................................. 10

   1. The Retail Clinic Landscape ...................................................................................................... 11

   2. Retail Clinic Quality .................................................................................................................. 11

   3. Retail Clinic Cost Impact ......................................................................................................... 12

B. Urgent Care Providers .................................................................................................................. 14

   1. The Urgent Care Provider Landscape ...................................................................................... 14

   2. Urgent Care Provider Quality .................................................................................................. 15

   3. Urgent Care Provider Cost Impact ......................................................................................... 16

C. Major Physician Practices .......................................................................................................... 17

   1. The Major Physician Practice Landscape ............................................................................... 17

   2. Major Physician Practice Quality ............................................................................................ 18

   3. Major Physician Practice Cost Impact ..................................................................................... 19

IV. Conclusion ..................................................................................................................................... 20
I. Introduction: Entities Examined under the Health Care Delivery Models Study Act

Pursuant to Chapter 369 of the Laws of 2013, which enacted the “Health Care Delivery Models Study Act,” the New York State Department of Health (“Department”) has undertaken a study of current innovations in the delivery of health care services not presently required to undergo state Certificate of Need processes nor required to obtain authorization to conduct office-based surgery (“OBS”). Specifically, this report examines retail clinics, urgent care providers and major physician practices whose physicians are linked directly or indirectly in an economic relationship.

- Retail clinics, also referred to as “limited services clinics,” are defined by their placement within pharmacies, supermarkets and other large retailers with multiple locations, their limited scope of services to treat minor acute ailments, and by their unscheduled walk-in hours which extend beyond the typical weekday hours of 9 AM to 5 PM, and often include weekend hours.

- Urgent care providers provide ambulatory care to patients with acute illness or minor traumas that are not life-threatening or permanently disabling. They too are characterized by unscheduled walk-in hours that extend beyond the typical workweek schedule and include weekend hours.

- Major physician practices, also referred to as “megapactices,” and “enhanced physician practices,” take many forms. They can be single or multi-specialty practices, perform OBS, and have one or multiple locations. Further, the nature of the economic relationship between their practitioners can vary. There are no specific criteria thresholds that make a physician practice a “megapactice.” However, these practices are often characterized by their ability to accommodate growth, gain from economies of scale, and exercise market power.

Based on available information, this report explores the impact of these respective types of entities on the delivery, quality and cost of health care in the respective communities and regions in which they are found.

Retail clinics, urgent care providers, and private physician practices are not subject to the direct oversight of the Department and therefore information available to the Department is generally less robust than information about licensed providers. As such, information about these entities in New York State pertaining to matters such as location and staffing, as well as data pertaining to safety, quality and outcomes, for the most part is not available to the Department. This report draws from public reports, articles and other publications about these models, which are cited herein.

In addition, as noted below, the New York State Public Health and Health Planning Council undertook a review of various ambulatory settings in 2013 and made a number of recommendations that pertain to these providers. This report reflects those recommendations.
II. Background

A. The Changing Health Care Environment

This report comes at a time when the health care landscape is evolving, marked in particular by an overall shift toward the provision of primary care and medical care services in ambulatory settings. This movement has been supported by federal and state initiatives aimed at improving overall population health and outcomes of care, and creating more efficient delivery by promoting value throughout the health care delivery system.

1. The Affordable Care Act

At the federal level, the Patient Protection and Affordable Care Act (“ACA”) called for the development of multiple pilot projects designed to promote integrated delivery systems and value based payment. These pilot projects encourage payment bundling and other episodic payment mechanisms, as well as integrated delivery models, medical homes and other collaborative programs that are not anchored in institutional inpatient settings.

The Center for Medicare and Medicaid Innovation (“CMMI”) was established by section 1115A of the Social Security Act as added by section 3021 of the ACA. CMMI was created for the purpose of testing “innovative payment and service delivery models to reduce program expenditures… while preserving or enhancing the quality of care” for individuals who receive Medicare, Medicaid, or Children’s Health Insurance Program benefits. Multiple health systems in New York State are participating in programs sponsored by CMMI.

2. The Medicaid Redesign Team and the Delivery System Reform Incentive Payment Program

In 2011, Governor Cuomo established the Medicaid Redesign Team (“MRT”) to engage stakeholders to make recommendations regarding the Medicaid program for the purpose of improving quality and outcomes and incorporating efficiencies. The MRT developed recommendations for reforms in the Medicaid program, most of which have been incorporated into the State’s budget, laws, regulations and administrative practices.

The Delivery System Reform Incentive Payment (“DSRIP”) Program is a major component of the Medicaid waiver agreement approved by the federal Centers for Medicare and Medicaid Services (“CMS”) in 2014 that allowed New York State to reinvest $8 billion of Medicaid savings generated as a result of MRT initiatives over a five-year period. Under DSRIP, participating providers collaborate as part of a Performing Provider System (PPS) to carry out projects designed to help reduce avoidable hospital use and achieve other health care and public health improvements.

---

3. **The Prevention Agenda**

The New York State Prevention Agenda 2013-2018 is the Department's five-year strategic plan for population health improvement.² The Prevention Agenda seeks to improve health status and reduce health disparities in five priority areas:

- Prevent Chronic Diseases;
- Promote a Healthy and Safe Environment;
- Promote Healthy Women, Infants and Children;
- Promote Mental Health and Prevent Substance Abuse; and
- Prevent HIV, Sexually Transmitted Diseases, Vaccine Preventable Diseases and Healthcare Associated Infections.

The Prevention Agenda is a call to action for stakeholders to collaborate at the community level to assess health status and needs, identify local health priorities and plan and implement strategies for local health improvement. The goal is improved health status of New Yorkers and a reduction in health disparities through increased emphasis on prevention and collaboration. The Prevention Agenda serves as a guide to local health departments and hospitals as they work together with their community to identify needs through Community Health Assessments/Community Health Needs Assessments and develop and implement Community Health Improvement Plans, required of local health departments, and Community Service Plans required of hospitals.

4. **The State Health Innovation Plan**

The State Health Innovation Plan (“SHIP”) is the strategic roadmap to achieve the Triple Aim of better care, better population health and lower health care costs. The SHIP outlines a multi-faceted approach that builds on the work of the MRT, the Prevention Agenda and other ongoing initiatives. The SHIP identified five strategic pillars as the foundation for New York’s efforts to achieve the Triple Aim:

- Improving access to care for all New Yorkers, without disparity;
- Integrating care to meet consumer needs seamlessly;
- Making health care cost and quality transparent to enhance consumer decision making;
- Paying for value, not volume; and
- Promoting population health.

The SHIP also identified three enablers:

- Workforce strategy;
- Health information technology; and
- Performance evaluation and measurement.

With funding from CMMI in the form of a State Innovation Model grant, the SHIP is focusing on the concept of advanced primary care (“APC”). APC is an integrated care

---

² The Prevention Agenda 2013-2017 was extended to 2018 to align its timeline with other state and federal health care reform initiatives.
delivery and payment model that ties together a service delivery model and reimbursement to promote improved health and health care outcomes that are financially sustainable.

5. Accountable Care Organizations

Accountable Care Organizations (ACOs) are groups of doctors, hospitals and other health care providers who form a relationship to provide coordinated care and share in savings with a health insurance plan for a specific patient population. As part of its goal of testing new innovative care delivery models in conformance with the ACA, CMS established several ACO programs under Medicare. These include: (1) the Medicare Shared Savings Program, designed to provide incentives for ACOs to improve the quality of care for Medicare fee-for-service enrollees and reduce unnecessary costs by allowing the participants to share the resulting savings; (2) the Pioneer ACO Model, available to organizations with experience in offering coordinated, patient-centered care in ACO-like arrangements, which uses a “shared savings and losses” model; and (3) the Next Generation ACO Model, which will allow Medicare ACOs to assume higher levels of financial risk and reward than under either the Medicare Shared Savings Program or the Pioneer ACO Model.

In New York, based upon a recommendation of the MRT, Public Health Law (PHL) Article 29-E was enacted to require the Commissioner of Health to establish a program governing the approval of ACOs in New York State. The statute authorized the Commissioner to issue certificates of authority to ACOs that meet conditions to be set forth in regulations. Further, the statute authorized the Commissioner to issue a certificate of authority to a “Medicare-only ACO” that documents its approval by CMS to operate as an ACO under Medicare, without the need to meet all of the criteria applicable to ACOs receiving other sources of payment. Regulations implementing PHL Article 29-E are within Part 1003 of Title 10 New York Codes, Rules and Regulations (“NYCRR”).

As a general matter, these initiatives, and others not outlined here, emphasize or support community-based care and services versus traditional institution-based care, and while coordination with hospitals is important, these initiatives strive to build a system of care that promotes wellness and prevents people from needing the level of inpatient care provided in hospital settings.
B. The Existing Regulatory Structure for Health Care Providers

To examine the impact of emerging models of care on the communities and regions where they are located, it is useful to take into consideration the way in which the Department oversees other health care providers. PHL Article 28 gives the Department broad authority to oversee hospitals, nursing homes and diagnostic and treatment centers. Private physician practices, however, are not within this purview, and are governed by the professional standards of the individual practitioner.

1. The Corporate Practice of Medicine

In New York State, as a general matter, 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.

Consistent with the doctrine prohibiting the corporate practice of medicine, licensed physicians may organize their practices as:

- Sole proprietorships;
- Partnerships or Registered Limited Liability Partnerships in which each partner is a professional licensed to conduct the specific practice of medicine in which the partnership is engaged; and
- Professional Service Corporations under section 1503 of the Business Corporation Law in which every shareholder, director and officer is a professional licensed to conduct the practice of medicine in which a PC is engaged.

A professional corporation may only provide services in its field. Except where specifically authorized, a general business corporation may not provide physician services to the public, exercise any judgment over the delivery of physician services, employ physicians to provide physician services, or share profits or split fees with licensed physicians. Licensed physicians and their professional firms are prohibited from sharing the fees earned for providing medical services with anyone other than members of their own professional firm.

---

3 See Education Law § 6512, § 6513.
6 Education Law, Title 8, Article 130, Section 6507; Regulations of the Commissioner of Education, Part 59, Section 59.10; Board of Regents Rule 29.1 http://www.op.nysed.gov/title8/part29.htm#29.1.
Exceptions to the corporate practice doctrine are explicitly set forth in the law. General hospitals are business corporations that may employ or otherwise engage the services of physicians by credentialing and privileging them as members of the medical staff. A self-governing organized medical staff provides oversight of the quality of patient care, treatment and services. Ambulatory surgery centers, diagnostic and treatment centers and other licensed entities regulated under PHL Article 28 may also employ physicians. Faculty practices are a non-profit model as set forth in section 1412 of the Not-For-Profit Corporation Law.\(^8\)

As the health care system continues to evolve, there may be opportunities for collaborative arrangements with the potential to promote innovation and improve patient outcomes which currently do not fall within one of the exceptions to the prohibition upon corporate practice. In such cases, the pursuit of an appropriate statutory exception should be explored.

2. **PHL Article 28 and the Certificate of Need Process**

The Certificate of Need ("CON") process governs the establishment, construction, renovation and major medical equipment acquisitions of Article 28 facilities which include hospitals, nursing homes, home care agencies, and diagnostic and treatment centers. The objectives of the CON process are to achieve alignment of health care resources with community health needs to ensure high quality health care. CON limits investment in duplicate beds, services and medical equipment and curbs excess health care capacity that drives unnecessary utilization and spending. CON, however, is not an all-purpose regulatory tool, and is not intended to redirect resources to areas of need.

Entities wishing to establish an Article 28 facility are required to submit a CON application to the Department in order to obtain approval from the Department and the Public Health and Health Planning Council ("PHHPC"). Establishment applicants must demonstrate a need for the facility, the character and competence of the proposed operators, and financial feasibility of the plan. As per PHL § 2801-a, PHHPC has the authority to look at these as well as other factors deemed pertinent on a case by case basis when reviewing CON applications.

Non-Article 28 settings such as retail clinics, urgent care providers operating as private practices, private physician offices that perform OBS and large private practices, are not subject to these controls.

3. **Article 28 Regulatory Requirements and Surveillance**

Article 28 facilities are required to comply with the Department’s physical plant standards and operational requirements before they are issued an operating certificate under the certificate of need process. For example, Part 405 of Title 10 NYCRR provides operational oversight requirements for general hospitals, and Parts 750 through 759

\(^8\) See *Albany Medical College v. McShane*, 66 N.Y.2d 982 (1985). In addition, employee and school health programs, where physicians and nurses are on salary and premises to perform health services for employees or students, are permitted, and businesses may hire physicians to serve in advisory or consultation roles where no direct patient care is provided.
provide operational standards for diagnostic and treatment centers, which includes ambulatory surgery centers.

To promote implementation of effective safety systems that reduce the likelihood of future errors and improve quality, Article 28 facilities are required to report adverse events, as defined in PHL Article 28, to the Department through the New York Patient Occurrence Reporting and Tracking System (NYPORTS). The Department has adopted the National Quality Forum Serious Reportable Events as the adverse events that Article 28 facilities must report via the NYPORTS system. Private medical practices that provide radiation therapy also are required to report adverse events to NYPORTS. Private practices performing OBS must report adverse events identified in PHL § 230-d to the Patient Safety Center of the Department.

Another reporting system within the Department into which Article 28 facilities submit data is the Statewide Planning and Research Cooperative System (SPARCS), which collects patient level detail on patient characteristics, diagnoses and treatments, services, and charges for hospital, ambulatory surgery, and emergency department services in New York State.

The Department also has accreditation standards for Article 28 facilities, and has a collaborative agreement with the Joint Commission to accept accreditation by the Joint Commission as evidence of compliance with the minimum operating standards for hospitals and diagnostic and treatment centers. Ambulatory surgery centers must become accredited by a national accrediting organization within two years of opening. Private medical practices that perform office-based surgery must become OBS accredited by one of the three accrediting agencies designated by the Department.

To assure compliance with the regulatory requirements, the Department is responsible for the ongoing surveillance of regulated facilities. PHL Article 28 provides broad powers to the Commissioner to oversee regulated facilities. This includes but is not limited to the ability to inspect and to review adequacy of the facility's premises, equipment, personnel, rules or bylaws, standards of medical care, hospital services, and finances. In addition, any complaints submitted to the Department regarding patient care or environmental concerns against a licensed facility are reviewed and followed-up as appropriate by Department staff.

4. Oversight of Physician Practices

Private physician practices are governed by the professional requirements of the individual practitioner. New York authorizes physicians to practice medicine, regardless of the type of entity in which they practice, via the professional licensing requirements of the State Education Department. PHL Article 2, Title 2-A, outlines the Department’s role in investigating, reviewing and identifying appropriate action regarding cases of suspected professional medical misconduct. Suspected professional medical misconduct by licensees, including physicians, physician’s assistants, and specialist’s assistants are investigated by the New York State Department of Health’s Office of Professional Medical Conduct (OPMC). OPMC then presents its findings and recommendations to various committees of the Department's Board of Professional

---

9 See § 2805-l and Title 10 Section 405.8 and Section 751.10.
10 See § 2816 and Title 10 Section 400.18.
Medical Conduct. The Board of Professional Medical Conduct makes the final determination as to whether professional misconduct took place and if so, the magnitude of the appropriate penalty.

Traditionally, New York State has relied on professional requirements, and has also imposed restrictions on the structure and ownership of physician practices, to ensure that medical decisions are controlled by licensed professionals exercising their professional clinical judgment. Requirements are imposed on individual practitioners, but not at a practice-level. Private physician practices are not required to comply with the Department’s physical plant standards and operational requirements and have limited reporting requirements to the Department.

5. Article 28 vs. Non-Article 28 Providers and Section 600.8 Title 10

Physician practices are subject to far less regulation and oversight than Article 28 facilities. Private physician practices are not required to go through a CON process, may freely add services, and are less likely to be subject to oversight by the State, although physician owned practices may voluntarily include a compliance program to prevent or correct any potentially inappropriate conduct. Private physician practices that perform invasive and/or surgical procedures are an exception, and must become OBS accredited and report adverse events.

As some private physician practices have become larger and more complex, they increasingly take on the characteristics associated with Article 28 diagnostic and treatment centers (“D&TCS”), which are licensed by the state. According to section 600.8 of Title 10 NYCRR, Criteria for Determining the Operation of a Diagnostic or Treatment Center under Article 28, health care entities that are privately physician owned and are not called “center” or “clinic,” may still be considered a D&TCC, at the judgment of the Department, upon review of certain criteria. These criteria include the nature of patient contact, decisions regarding patient admissions, patient choice of physician, patient care, and organization and management. Section 600.8 relies on Department discretion, stating that criteria are not “the sole determining factors, but indicators to be considered with such other factors that may be pertinent in particular instances.” Classification as a D&TCC brings a health care provider under the purview of PHL § 2801 which establishes Department regulatory authority and license requirements.

As advances in technology continue to allow more services to be safely provided in outpatient settings that were once only provided in hospitals, and as more services that historically were delivered only in licensed institutional settings are now being provided in physician offices, questions about what degree of licensure and oversight is needed to ensure adequate infection control, patient safety, quality of care, and a level playing field across care settings are being raised. In particular, the disparity in oversight between Article 28 facilities and non-Article 28 providers is prominent in discussions on retail clinics, urgent care providers, OBS providers and major physician practices.
C. PHHPC Recommendations and Proposed Statutory Changes

During 2013, the PHHPC Health Planning Committee undertook a review of ambulatory settings and issued a series of recommendations which were then approved by the full PHHPC at a special Council meeting on January 7, 2014. In particular, PHHPC recommended that statutory changes be pursued with respect to retail clinics, urgent care providers, and OBS providers.11

Consistent with these recommendations, the 2013-14, 2014-15, 2015-16 and 2016-17 Executive Budgets included proposals to establish a regulatory process for the approval and minimal oversight of retail clinics, allowing the Department to help assure that retail clinics continue to provide safe, high quality health care services and connect to the larger health care delivery system. The 2014-15 and 2015-16 Executive Budgets also included proposals to define urgent care services and restrict use of the term “urgent care” to providers that meet specified criteria, including accreditation. These proposals were not included in the final enacted budgets.

Changes were made with respect to OBS reporting and accreditation as a result of the 2015-16 budget to enhance the Department’s ability to monitor patient safety and quality in the OBS setting. First, the deadline for reporting adverse events to the Department was extended from one to three days, which was a more realistic timeframe. Second, the types of adverse events that need to be reported to the Department were expanded, so that adverse events that result in observation stays in hospitals and unplanned emergency department visits, if they occur within three days of OBS, must also be reported. Third, the Department was given the authority to gather additional data from OBS practices, which will help it evaluate adverse events. Fourth, changes were made to the provisions applicable to OBS accrediting agencies, so that accrediting agencies must utilize specific criteria in evaluating credentialing and privileging of OBS practitioners, carry out surveys and complaint investigations of OBS practices and share the results with the Department upon request. In addition, accrediting agencies also must have Quality Assurance and Quality Improvement programs, which provide confidentiality protections to data shared with the OBS accrediting agencies and the Department. Information and data authorized by these amendments is still being collected and analyzed, but is expected to offer insight in evaluating OBS performance and informing future-decision-making.

III. Model Analysis

For purposes of evaluating the potential impact of retail clinics, urgent care providers and large physician practices on the delivery, quality and cost of health care in their communities, several considerations should be taken into account.

First, it is necessary to take into consideration the landscape of entities that are providing health care services. This includes an understanding over time of the operations, workforce patterns, economic relationships, referral patterns, competition and market share of the different entities. This information is necessary in order to identify trends and identify potential causal

relationships between provider actions and changes in the delivery system landscape (the entities operating in a given geographic area, the services offered, their operations, etc.). Workforce patterns are key to understanding this landscape, and recognizing shifts in workforce migration are indicative of the sustainability and need for different health care services and settings.

Second, quality is multi-faceted. Data pertaining to patient safety, outcomes, patient satisfaction, care coordination and the use of evidence-based practices all factor into overall quality of health care services.

Third, in evaluating cost impact, it is necessary to understand competitive relationships in a given geographic area, service charges and reimbursement rates for services, and measure findings against statewide and national trends for these service lines in an effort to isolate the change agent(s).

The entities included in this report are not subject to direct oversight by the Department. As such, the number of such respective entities, their operations, locations, staffing and workforce patterns, claims data and data pertaining to safety, quality and outcomes are not readily available to the Department. As the Department continues to build an All Payer Database (APD), information regarding cost will become more readily available. The APD effort will compile data from health care providers and multiple payers in a way that will allow for meaningful analysis of health care utilization and cost trends on a statewide basis or at a sub-state level such as region, payer, service type, etc. Until then, without these types of data sets, any analysis of the impact of these emerging care models on the delivery, quality and cost of care in New York State is incomplete, but may serve as a starting point for policy discussions.

The following sections on each of the models studied in this report summarize the Department’s current knowledge of each model and, given the current data limitations, what can be considered about their impact on health care delivery, quality and cost. In order to reach even partial conclusions, the Department relied on information collected during the PHHPC 2013 review of ambulatory settings and studies conducted on these models in other states.

A. Retail Clinics

Retail clinics, typically located in pharmacies, supermarkets and other large retailers with multiple locations, 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 conditions such as diabetes and hypertension. Retail clinics are often referred to as “limited services clinics,” because they are limited in the scope of service they provide, and are intended for minor, episodic care. They typically offer extended business hours and are often open seven days a week, including evening hours. They are marketed as offering consumers a convenient, easily accessible option for obtaining basic health care.

Retail clinics often operate under corporate chains and are staffed primarily by licensed, non-physician health care practitioners, mostly nurse practitioners and physician assistants. To legally operate in New York State without violating the doctrine against the corporate practice of medicine, these sites are operated by private physician practices through an arrangement, such as a lease agreement with the retailer, rather than by the retailer itself. Operating as a private physician office that leases space within a retail setting, these retail
clinics are not subject to Department oversight and the Department does not have the authority to require data reporting.

1. The Retail Clinic Landscape

A March 2016 Health Affairs journal article noted that there are almost 2,000 retail clinics in the United States, receiving more than 6 million patient visits per year. To the Department’s knowledge, based on information offered through the PHHPC and information readily available online, there are at least 25 operational retail clinics in New York State, mostly concentrated in large urban areas such as New York City.

In 2010, of states with retail clinics, New York State ranked among the lowest in retail clinic incidence per 100,000 residents, with just 0.1 clinics per 100,000 residents, and when looking at New York City specifically, the incidence of retail clinics per 100,000 residents remained similarly low. In 2013, there were approximately 16,000 primary care physicians, more than 17,000 nurse practitioners and over 11,000 physician assistants in New York State, and an unknown number of private practices providing primary care services. While in 2016 the exact percentage of practitioners working in retail clinics and the proportion of retail clinics compared to all primary care settings cannot be exactly determined, with approximately 25 retail clinics statewide, the percentages would be very small.

2. Retail Clinic Quality

With the first retail clinics opening around 2000, peer-reviewed studies of their quality and potential effect on the overall health care system are limited in number. Without data specific to retail clinics in New York State, an analysis of quality of care within New York State cannot be conducted. However, studies that have been conducted in locations other than in New York State have shown that the care provided in retail settings is of sufficient quality for the limited set of illnesses treated, and for most measures of quality is comparable to or exceeds that of treatment received in other care settings, including urgent care, ambulatory care facilities, or emergency care providers, for the same illnesses. While it has been suggested that operating within a retail setting may bring potential conflicts of interest that could impact quality of care, for example, prescribing medications

---


more readily to increase pharmacy sales, there is no evidence to suggest that this occurs, and retail clinics are reported as adhering to best practice guidelines.\textsuperscript{16,17,18}

Not much is known about the use of retail clinics for pediatric care, however parents report preferring the use of retail clinics for minor childhood ailments due to convenience and avoiding appointment wait times.\textsuperscript{19} Many retail clinics self-limit their scope of services and clientele, not seeing children younger than the age of 24 months, recognizing the importance of the patient-physician relationship and continuity of care during the earliest years.

Retail clinics serve as a care option for patients with minor acute ailments. RAND Corporation research on retail clinics indicates that they typically serve younger adults who do not have a primary care provider.\textsuperscript{20} There may be an opportunity for retail clinics to connect patients to a source of regular primary care, serving as a gateway to the health care delivery system.

There is no evidence that retail clinics pose a risk to quality of care due to unintentionally undermining patient and primary care provider relationships.\textsuperscript{21} For example, by drawing patients away from regular primary care providers for episodic needs (removing opportunities to develop patient-physician relationships), not sharing patient records with the patient’s regular provider, or not connecting patients to regular providers when patients do not already have an existing patient relationship.

3. Retail Clinic Cost Impact

With so few retail clinics currently operating in New York State, an analysis of their current impact on health care spending is not feasible. However, it is widely known that, for those services provided in a retail clinic, it is significantly less expensive to deliver those services in the retail clinic than in other settings such as primary care offices, clinics, or Emergency Departments, with studies from 2009 and 2008 demonstrating savings anywhere between 30 to as much as 64 percent for common conditions that are seen in retail settings.\textsuperscript{22} For those retail clinics that take insurance, co-pays may be similar to those for primary care providers. Retail clinics are considered a low-margin provider. One potential concern is that retail clinics serve as a draw for consumers to enter the retail setting and make convenience purchases.

Retail clinics may provide benefit to the overall health care system by redirecting minor acute health care needs away from Emergency Departments, which would have the potential to significantly decrease overall health care spending. The extent to which this has


\textsuperscript{20}RAND Corporation. \textit{The Evolving Role of Retail Clinics}. 2016, available at \url{http://www.rand.org/pubs/research_briefs/RB9491-2.html}.

\textsuperscript{21}Reid, Rachel, et al. “Retail Clinic Visits and Receipt of Primary Care.” Journal of General Internal Medicine \url{http://link.springer.com/article/10.1007%2Fs11606-012-2243-x}.

started to occur, however, is unclear. The RAND Corporation argues in a 2016 report that the key to cost savings from retail clinics is substitution, and notes that despite potential, the availability of retail clinics in proximity to emergency departments across the United States has not been proven to result in reduced emergency department visits.\textsuperscript{23}

A different 2016 study indicates that retail clinic visits for low-acuity conditions may in fact increase health care utilization, and subsequently, increase spending, due to individuals engaging with a retail clinic due to convenience, accessibility and/or affordability who previously would not have accessed the health care system for a minor ailment.\textsuperscript{24} However, increased utilization of retail clinics may have benefits that over time counter any potential short-term costs.

Reducing avoidable emergency department use is a top priority for New York State, and a primary goal of the DSRIP Program is to reduce avoidable emergency department volume by 25 percent in five years. According to a nationwide study conducted by RAND Corporation researchers, as many as 27 percent of emergency department visits could take place in either a limited services or urgent care setting, suggesting that retail clinics could contribute to health care savings.\textsuperscript{25} If this were true for New York State, that could mean significant savings. In 2010, the New York State Health Foundation estimated savings from the use of alternative care settings, including retail clinics, to potentially be as much as $350 million over five years.\textsuperscript{26} In addition to the potential to reduce avoidable emergency department use, retail clinics also have the potential to contribute savings under value-based payment models, with providers being more willing to partner with retail clinics to serve as a cost-effective extension of primary care services.\textsuperscript{27}

Operating as a private physician’s office is not the model preferred by retailers, particularly since they are unable to share in the practice’s revenues, and further means that the Department has no regulatory oversight thereof. At the same time, as noted above, retail clinics are likely to displace more expensive visits to emergency rooms for non-emergency services, resulting in savings for consumers and payers. For these reasons, PHHPC in 2013 recommended that retail clinics be recognized in statute as a new type of Article 28 provider, which was proposed in several subsequent Executive Budgets. These proposals would have authorized regulations incorporating PHHPC recommendations such as serving the goal of expanding access to basic primary care by offering convenience for consumers with extended hours and walk-in visits and be required to commit to opening locations in medically underserved areas. Private physician practices would not have been precluded from offering health care services in a retail setting but would not be able to operate under a name that suggests any equivalency to a “clinic.”

\textsuperscript{23} RAND Corporation. \textit{The Evolving Role of Retail Clinics}. 2016, available at \url{http://www.rand.org/pubs/research_briefs/RB9491-2.html}.


\textsuperscript{27} Copeland, Bill; Raynor, Michael; Elsner, Natasha; and Carter, Ryan. \textit{Beyond the Acute Episode}. 2016. Deloitte University Press. Available at \url{http://edit.modernhealthcare.com/assets/pdf/CH1080221121.PDF}. 
Past Executive Budget proposals to authorize retail clinics also sought to promote quality by requiring retail clinics to demonstrate experience and expertise in delivering high quality health care services, attain accreditation and timely report if accreditation is lost, retain a medical director at the corporate level of the retail organization, and meet operational and physical plant standards set forth in regulation. Further, in recognition of PHHPC’s call to support primary care, these proposals would have: (1) required retail clinics to ask if patients have primary care providers and provide a list of local providers to those that do not; (2) prohibited retail clinics from serving patients that appear for the same issue three times in a year; (3) prohibited retail clinics from serving children under 24 months of age so that they are seen by pediatricians during that time; and (4) required retail clinics to share patient information with patients’ primary care and other providers by electronic means and participate in the Statewide Health Information Network for New York (“SHIN-NY”). Finally, retail clinics should be required to post signage advising patients that prescriptions and over the counter supplies can be purchased from any business and do not have to be purchased on-site.

B. Urgent Care Providers

Urgent care providers serve ambulatory patients with acute illness or minor traumas that are not life-threatening or permanently disabling. Because urgent care providers operate on an unscheduled walk-in basis with extended hours, urgent care providers may provide an efficient 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. Urgent care providers are not intended as resources for ongoing management of chronic conditions, although urgent care providers will treat acute care needs resulting from a chronic condition, as appropriate.

There is variation in the scope of services offered by urgent care providers. For example, some urgent care providers offer onsite one or more imaging services such as x-ray, ultrasound and CT scans, while others do not. Typical urgent care services include a medical history, physical examination and treatment services, and certain urgent care providers offer intravenous hydration, suturing of lacerations, EKG, and in-house lab services for immediate point-of-care testing.

Urgent care is not intended for emergency care of critical, major trauma, life threatening or potentially disabling conditions, and should not be confused with a freestanding emergency department. While some urgent care providers operate twenty-four hours a day, seven days a week, similar to emergency departments, most are open during normal business hours (9 AM to 5 PM weekdays) plus extended weekday hours and weekend hours.

1. The Urgent Care Provider Landscape

As of April 2017, the Urgent Care Association of America (UCAOA) website states that there are nearly 7,400 urgent care providers in the United States, and the American Academy of Urgent Care Medicine states that there are approximately as many as 9,300.28,29 The

---

UCAOA reports that in 2015, 96 percent of urgent care providers said the number of patient visits had increased, with 90 percent anticipating growth in 2016 and 73 percent expanding by acquiring or building a new location.\(^\text{30}\)

As for urgent care in New York State, the UCAOA reports in their 2016 benchmarking report that New York State ranks among the top five states with urgent care centers.\(^\text{28}\) A 2015 report of the United Hospital Fund indicated that there were as many as 366 urgent care providers in New York State.\(^\text{31}\) The Department currently has no mechanism for confirming this number, however the available information suggests that urgent care settings are growing in New York as they are across the United States. Urgent care providers may be a particularly important source of care in Health Professional Shortage Areas across the state.

Urgent care providers operate under a number of different models that include hospital-owned extension clinics, D&TCs, and physician-owned independent, chain or network affiliated private practices. Urgent care providers that operate as hospital-owned extension clinics or as freestanding D&TCs are considered “Urgent Care Centers” or “Urgent Care Clinics” (“UCC”). Urgent care providers that operate as private physician practices are often termed “Urgent Care Practices.” Urgent care services may also be provided as a component of a primary care practice, with designated hours for walk-in acute care. The UCAOA reports that 13 percent of urgent care providers offer ongoing primary care or specialty urgent care.\(^\text{28}\) “Urgent care providers” is generally used as an all-encompassing term, although some call all forms of urgent care “Urgent Care Centers.”

Urgent care providers in New York State that operate as hospital-owned extension clinics or as freestanding D&TCs are subject to operational oversight by the Department under Article 28. However, urgent care providers that operate as private physician practices are not subject to Department oversight. Urgent care practices are regulated by licensure and professionalism rules applicable to all individual physicians through State Education Law. This creates an uneven playing field among urgent care providers, however the consequences of this on care delivery, quality and cost, if any, are not clear. The vast majority of urgent care providers are private practice providers that do not have direct oversight by the Department and therefore are not required to provide data that would provide information on their numbers and locations and aid in gaining insight into their impact on the community.

2. Urgent Care Provider Quality

The urgent care industry has demonstrated a commitment to standardized quality, encouraging urgent care accreditation and urgent care recognition as a unique specialty of care for practitioners, distinct from primary care or emergency care. There are several urgent care accrediting bodies that accredit urgent care providers, including the Joint Commission, the Accreditation Association for Ambulatory Health Care, and as of 2014, the UCAOA. The American Board of Urgent Care medicine and American Board of Physician Specialties offer urgent care professional board certifications.

Similar to retail clinics, there is no evidence that retail clinics pose a risk to quality of care due to unintentionally undermining patient and primary care provider relationships. The Center for Health System Change conducted a study that looked at urgent care centers in six locations in the U.S. As part of the study findings, the report stated, “[a]lthough UCC’s were not seen as a major disruption to care coordination, they do not appear to emphasize care coordination.”32 The study found, however, that hospital-owned or affiliated urgent care providers that were connected to electronic health records were more likely to facilitate referrals to other providers than those that were not hospital-owned or affiliated and connected to Electronic Health Records.29

Some urgent care providers call themselves “urgi-care,” “convenient care,” and variations that play off of the word “emergency” such as “emergi-care,” and “emergent care,” among others. Although not marketing themselves as emergency departments, these naming conventions at times may create confusion, particularly when the urgent care provider is a hospital extension clinic, or otherwise affiliated with a hospital, which may suggest full-scale emergency services. The UCAOA reports that patients do not inappropriately present to urgent care providers when more advanced emergency services are needed at any higher rates than such patients present to primary care practices (about 1-2%), indicating that this is no greater of a concern for urgent care providers than it is for any health care provider.33

3. Urgent Care Provider Cost Impact

Services offered by urgent care providers cost significantly less than Emergency Department services. Similar to retail clinics, urgent care providers may provide savings to the overall health care system by redirecting patients from Emergency Departments who can be appropriately treated in a different setting, which would have the potential to significantly decrease overall health care spending. Cited earlier, a 2010 nationwide RAND study found that up to 27 percent of Emergency Department visits could take place in a limited services or urgent care setting, and noted significant savings for urgent care as compared to an Emergency Department visit.34 If this were true for New York State, that could mean significant savings, however given data limitations in New York State, an analysis of urgent care providers’ current impact on emergency department use and overall health care savings cannot accurately be performed.

A further consideration with regard to the potential reduction in avoidable emergency department use, however, is that urgent care providers are not subject to the Emergency Medical Treatment and Labor Act (EMTALA). Consequently, urgent care providers are not required to accept patients without regard for the ability to pay, and it is unclear how many urgent care providers accept Medicaid. This could potentially curb the potential for reducing avoidable emergency department visits and health care spending in the Medicaid population.

The PHHPC’s 2013 recommendations regarding urgent care providers took into consideration the uneven regulatory playing field and concerns regarding their potential for impact on health care delivery, quality and cost. Recommendations, which were incorporated into past Executive Budget proposals, sought to enact statutory changes to include a proposal to create a standardized naming convention for urgent care providers, and establish criteria for urgent care classification, including minimum scope of service, consumer disclosure, accreditation, and health IT requirements. These types of recommendations support the urgent care industry and alleviate the potential for consumer confusion, and promote continuity of care and connectivity to the larger health care delivery system.

C. Major Physician Practices

In 2013, the New York State Department of Health issued a letter seeking comments on the topic of enhanced physician practices. In part, the letter stated as follows:

One of the salient characteristics of our evolving health care delivery system is the growing market presence of single- and multi-specialty ‘mega’ physician practices, physician practices that provide highly-specialized and capital-intensive services, and physician practices with close ties to corporate entities (henceforth collectively referred to as ‘enhanced physician practices’). These practices may employ hundreds of physicians, and they may operate surgery, advanced diagnostic imaging, urgent care and/or radiation therapy centers.

The terms “major physician practice,” “enhanced physician practice,” or “megapractice” are not defined by statute, regulation, or standard in the health care industry. There are no specific criteria thresholds that make a physician practice a major/enhanced physician practice or megapractice. However, major physician practices may be characterized by their ability to accommodate growth and gain from economies of scale, and a potential to exercise market power. They generally are considered large group practice sizes (high numbers of physicians, high patient volume), with multiple locations and a wide scope of services. They may be single- or multi-specialty and can vary in organizational structure.

The lack of clear thresholds that make a large physician practice a major physician practice, the unique circumstances that may exist in one local health care market versus another, and a lack of oversight over physician practices makes it difficult to cast a net over physician practices that could be considered major physician practices. What may be considered a major physician practice in one local health care market may not be considered a major physician practice in another larger market. While the aforementioned characteristics are not exhaustive and do not lead to a specific definition of major physician practices, they are demonstrative of the profile for a major physician practice.

1. The Major Physician Practice Landscape

It is generally understood that there has been increased growth of practices that fall into this loosely defined category, and with this growth an increased potential for these entities to play an influential role in local health markets. Large physician group practices, for
example, are leading two-thirds of the ACOs designated by CMS in New York State. This is indicative of the high level of clinical integration, resource and capital capacity that some physician practices are able to achieve that had traditionally been seen only in hospitals.

The shift in care from inpatient to outpatient settings, emerging technologies, improving medical care techniques and evolving payment models have created conditions that support the formation of large, multi-specialty group practices with integrated care delivery models. Ambulatory care settings potentially offer patient convenience through flexible scheduling of services, proximity and at-home recovery.

As previously indicated, private physician practices generally are not subject to Department oversight. To some extent, this may permit them advantages over institutional providers that are subject to such oversight and may further contribute to less desirable outcomes for the overall health system. For example, private practices may be able to undertake expansions of their physical infrastructure more quickly than Article 28 providers, which must obtain CON approval for various construction projects. In addition, many private practices do not accept Medicaid while their Article 28 counterparts do. Factors such as these may contribute to an uneven playing field, or at least the perception thereof, which would be exacerbated in the case of the larger practices. Moreover, such dynamics could lead to situations in which the private practice displaces Article 28 providers and adversely impacts access to care for New York’s vulnerable populations.

An additional trend that has been observed over the last several years is the integration of physician practices into Article 28 health systems, including larger and multi-specialty practices. To some extent, this may reflect a desire to support the development or growth of integrated systems and/or accountable care models, including the ability to share referrals more broadly within the resulting system. Such arrangements may minimize the concerns outlined above, and have the potential to create efficiencies and help the health care system reach the triple aim of improving the quality of care, improving health and reducing costs. In particular, the integration of practices into Article 28 systems is likely to support the use of uniform, evidence-based standards, measurement capability and quality improvement infrastructure which the practices, particularly those of smaller size, may not have been able to institute on their own.

2. Major Physician Practice Quality

Larger physician practices that may be considered major physician practices market their third party recognitions. Although most private medical practices are not required to seek accreditation by a third party accrediting organization (aside from office-based surgery practices), larger physician practices will often take it upon themselves to seek accreditation and certification from third party accrediting bodies such as the Joint Commission, in order to measure the quality of services against nationally-recognized standards. Accreditation


helps these practices conduct assessments of their efficiency and competence and support improvements in the quality and safety of patient care provided.

Some practices that may be considered major physician practices are National Committee for Quality Assurance (NCQA) recognized Patient Centered Medical Homes (PCMH). As of March 2016, there were 1,327 practices in New York State with NCQA PCMH recognition, 38 percent of which had between 4-10 health care practitioners (HCPs), 8 percent of which had 11-25 HCPs, and 2 percent of which had 26+ HCPs. How many of these are considered major physician practices cannot be determined.

As indicated above, the integration of private practices into Article 28 health systems has the potential to support improvements in quality by enabling reliance upon systems that may have been beyond the reach of smaller physician practices.

3. Major Physician Practice Cost Impact

In general, fiscal pressures from increasing costs for office space, equipment, malpractice insurance, staff, and electronic health records, are making it a challenge for smaller practices to keep pace with patient demand and stay financially viable. What is emerging is a national shift of physicians from solo and small group practices to employed positions and larger-group practices that may be considered major physician practices, so as to benefit from savings through economies of scale.

In addition, evolving payment models have helped to drive physician practice aggregation. For example, the growth of managed care and capitated payment models has provided an incentive for specialists to partner with primary care physicians to form large multi-specialty practices in order to maintain a patient base, leverage negotiating power with health plans, and better manage financial risk across the practice. Preferred provider organizations (PPOs) provide an incentive for specialists to form large single-specialty practices and gain negotiating power with increased market share. Many physician practices have found mutual benefits to affiliating with hospitals, hospital networks or other Article 28 facilities. These relationships often include referral pathways and may also facilitate the sharing of electronic health records and educational resources. Some arrangements provide administrative and management benefits to the practices and increase negotiating power with suppliers and health plans.

The current health care delivery system often relies on hospitals to provide New York’s vulnerable population access to primary care. Hospitals that serve vulnerable populations have a critical role in providing health care to low-income, medically vulnerable patients. Given increased financial pressures from competition, costs and shrinking payments, the viability of the state’s safety net institutions has come into question. As services continue to shift from inpatient to outpatient settings, and if specialty care providers increasingly gain market share for more profitable services, hospital safety-net providers may not be able to subsidize socially important but less profitable services. An additional risk that results from this shift is that free-standing facilities and physician practices may not serve Medicaid patients, the uninsured or the underinsured, leaving the burden of uncompensated care on general hospitals.

As shared savings models continue to grow and further encourage the growth of major physician practices, these practices will be in a position to significantly impact hospital patient activity and market share as a result of their growing referral power. This may support improved hospital quality standards and patient outcomes, with the best hospitals winning referrals and forcing further evolution of remaining providers. However, in order to evaluate the impact of major physician practices on safety net providers, the entire provider landscape in a market must be understood, and consistent criteria must be used to identify when forces are driving quality, efficiency and cost reductions, and when instead they are creating risk for destabilization.

Larger physician practices are in a position to commit resources to clinical integration. Clinical integration is the integration of clinical information and services across a continuum that can span across service lines (preventive/wellness care, outpatient, inpatient acute hospital care, post-acute follow-up care, etc.) and potentially streamline administration and improve the value of the care provided. Clinical integration allows larger practices to take advantage of certain economies of scale. For example, shared administrative services across departments and practice locations create operational efficiencies and reduce costs. In addition, aggregating revenue and spreading costs over larger practices makes investments in equipment and information technology, such as electronic health records, more financially feasible than for smaller practices. Larger practices with scale also have the capacity to “…employ systems to collect, analyze, and compare data on their providers’ performance, compared to that of their peers, and to external benchmarks using evidence-based measures of quality and performance.” These types of tools help enable larger physician practices to better manage the care of not only individuals, but of communities, and support the needs of the wider care management and service delivery system.

Group practices may be able to provide services at a lower cost and may enhance efficiency due to economies of scale, but as well-reimbursed services continue to migrate to ambulatory care settings, hospitals and other safety net providers may have unfair cost disadvantages because these providers may lose healthier patients and receive patients with medical complexities. Without the ability to cross-subsidize services, preserving access to critical services becomes more difficult.

Major physician practices have emerged as a health care model with the potential to critically impact both the provider community and consumers, however the extent of their current impact cannot easily be determined. There are currently no PHHPC recommendations or regulatory proposals regarding major physician practices, but it is an area for further investigation and policy discussion.

IV. Conclusion

While conclusions regarding the impact of these entities such as retail clinics and urgent care on health care delivery, quality and cost in New York State are very limited, these models have the potential for creating a beneficial impact by increasing access to services in convenient, community-based settings, using evidence-based methods, and in some cases providing care at lower cost than traditional alternatives. When well-defined, these models have the potential to empower New Yorkers to successfully self-triage and seek an appropriate source of care that fits their needs, budget and preferences.
PHHPC’s recommendations regarding retail clinics and urgent care providers have yet to be adopted into statute or regulation, but establish a framework for continued policy discussion regarding these emerging models of care. The Department will continue to consider the evolution and growth of these and other models and propose action as appropriate.