Review Article

Redesigning the Regulatory Framework for Ambulatory Care Services in New York

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Policy Points:

- The landscape of ambulatory care services in the United States is rapidly changing on account of payment reform, primary care transformation, and the rise of convenient care options such as retail clinics.
- New York State has undertaken a redesign of regulatory policy for ambulatory care rooted in the Triple Aim (better health, higher-quality care, lower costs)—with a particular emphasis on continuity of care for patients.
- Key tenets of the regulatory approach include defining and tracking the taxonomy of ambulatory care services as well as ensuring that convenient care options do not erode continuity of care for patients.

Context: While hospitals remain important centers of gravity in the health system, services are increasingly being delivered through ambulatory care. This shift to ambulatory care is giving rise to new delivery structures, such as retail clinics and urgent care centers, as well as reinventing existing ambulatory care capacity, as seen with the patient-centered medical home model and the movement toward team-based care. To protect the public's interests, oversight of ambulatory care services must keep pace with these rapid changes. With this purpose, in January 2013 the New York Public Health and Health Planning Council undertook a redesign of the regulatory framework for the state's ambulatory care services. This article describes the principles undergirding the framework as well as the regulatory recommendations themselves.

Methods: We explored and analyzed the regulation of ambulatory care services in New York in accordance with the available gray and peer-reviewed literature

and legislative documents. The deliberations of the Public Health and Health Planning Council informed our review.

Findings: The vision of high-performing ambulatory care should be rooted in the Triple Aim (better health, higher-quality care, lower costs), with a particular emphasis on continuity of care for patients. There is a pressing need to better define the taxonomy of ambulatory care services. From the state government's perspective, this clarification requires better reporting from new health care entities (eg, retail clinics), connections with regional and state health information technology hubs, and coordination among state agencies. A uniform nomenclature also would improve consumers' understanding of rights and responsibilities. Finally, the regulatory mechanisms employed—from mandatory reporting to licensure to regional planning to the certificate of need—should remain flexible and match the degree of consensus regarding the appropriate regulatory path.

Conclusions: Few other states have embarked on a wide-ranging assessment of their regulation of ambulatory care services. By moving toward adopting the regulatory approach described here, New York aims to balance sound oversight with pluralism and innovation in health care delivery.

Keywords: health policy, ambulatory care, primary care, regulation.

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, millions of uninsured Americans will receive health coverage from both the expansion of Medicaid and the health insurance marketplaces created by the Affordable Care Act (ACA). Both government and private payers are driving this 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 important, the actual structures of the health care delivery system are changing. That is, while hospitals remain important centers of gravity in the health system, services are increasingly being delivered through ambulatory care.

The ambulatory care system also is being affected by the changes taking place among practicing physicians. In New York State, the stresses of the current environment are causing many private practitioners to

turn for employment to institutional providers, especially hospitals. At the same time, hospitals are moving from identifying themselves solely as acute-care facilities to comprehensive systems of care extending into the community.

In addition, many physicians are joining large, multispecialty groups offering a broad spectrum of services, often in multiple locations, thereby gaining sufficient market power to compete with area hospitals. This shift to ambulatory care is giving rise to new delivery structures, such as retail clinics and urgent care centers, as well as reinventing ambulatory care capacity, such as the patient-centered medical home model and the movement toward team-based care. To protect the interests of the public—that is, promote patient safety, quality, and judicious use of resources—the oversight of ambulatory care services must keep pace with these rapid changes.

Regulation of Ambulatory Care Services: The Charge

In 2011, New York Governor Andrew Cuomo, seeing an opportunity for both quality improvement and cost savings, undertook a fundamental reform of the state's largest single program, Medicaid, through his Medicaid Redesign Team. In January 2012, the New York Department of Health charged the Public Health and Health Planning Council (PHHPC) with developing a health planning framework that would improve the health system, affecting both private and public providers and payers. The PHHPC's December 2012 report, titled *Redesigning Certificate of Need and Health Planning*, examined changes in the organization of health care and tried to align the certificate of need (CON) and health-planning processes with these changes. The PHHPC recommended that regional, multistakeholder collaboratives conduct deliberations on health planning. Accordingly, by recommending retaining licensure requirements but eliminating need assessments for primary care facilities, it anticipated the expansion of capacity needed for the up to 1 million New Yorkers who would gain coverage under the ACA. Additional recommendations dealt with requiring regulatory oversight of physician practices, modifying the process of establishing new health care facility and home care agency operators, strengthening the review of

health system governance, supporting expanded access to hospice care, and incorporating quality and population health factors into the CON review. The December 2012 PHHPC report also laid the groundwork for strategically aligning regulatory oversight with new models of health care organization and payment.

In January 2013, the former New York commissioner of health (one of this article's authors, Nirav R. Shah) offered a new charge to the PHHPC—to address the changing structure of the delivery system itself. Through extensive consultation and deliberation, the PHHPC built the framework for public oversight of ambulatory care services, represented by a set of recommendations formally adopted by the PHHPC in January 2014. A subset of recommendations would require authorizing legislation not yet passed by the New York State legislature. Other recommendations, which require only regulatory authorization, have entered into the rule-making process (for a summary of regulatory recommendations, see Table 1; full recommendations are available online at http://www.health.ny.gov/facilities/public_health_and_health_planning_council/meetings/2014-01-07/docs/ambulatory_care_services_recommendations.pdf).

Three principles guided the PHHPC's work. First, the vision of high-performing ambulatory care should be rooted in the Triple Aim (better health, higher-quality care, lower costs), with a particular emphasis on continuity of care for patients, as we describe later. Second, there is a need to better define the taxonomy of ambulatory care services. From the state government's perspective, clarification requires better reporting from the new health care entities (eg, 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 consumers' understanding of rights and responsibilities. Third, the regulatory mechanisms employed—from mandatory reporting to licensure to regional planning to CON—should remain flexible and match the degree of consensus regarding the appropriate regulatory path. For areas where there is considerable uncertainty about the consequences of any new regulation, incremental steps—often beginning with reporting requirements—would help shed light on a prudent way forward.

Table 1. Regulatory Recommendations From the New York Public Health and Health Planning Council

Ambulatory Care Setting	Summary of Regulatory Recommendations
Retail clinics	<ul style="list-style-type: none"> • Allow corporations to provide professional services that are currently prohibited. Private physician offices are not precluded from providing professional services in a retail setting. • Retail clinics will be known as “limited services clinics.” Must use the term “limited services clinic” in their name at all sites and in materials in order to help consumer recognition of this model of care. • Define scope of services to cover basic services, including certain immunizations. Prohibit the following: <ul style="list-style-type: none"> • Prescription of controlled substances or conduct of any laboratory testing except for Clinical Laboratory Improvement Amendments—waived tests. • Services to patients 24 months of age or younger. • Childhood immunizations to patients under 18 years of age (excluding influenza vaccine and human papilloma vaccine [HPV]). • Secure third-party accreditation by a national accreditation organization approved by the Department of Health. • Require disclosures to consumers, including signage for consumers regarding services that are and are not offered and disclosures that prescriptions and over-the-counter medication are not required to be purchased on-site. • Procedures that support the medical home must be followed. A list of primary care providers accepting new patients must be provided to patients indicating that they do not have a primary care provider and encouraging the patient to establish a relationship with a provider.

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Table 1. *Continued*

Ambulatory Care Setting	Summary of Regulatory Recommendations
Urgent care providers	<ul style="list-style-type: none">• Require health information technology connections to the larger health care delivery system through electronic health records and other means.• Require private physician offices and institutional providers (as defined by Article 28 of New York Public Health Law) to apply to the Department of Health to use the name “urgent care.” Only approved providers may use the term “urgent care” in their name.• To be approved, private physician offices and Article 28 providers need to be accredited by a national organization approved by the Department of Health and to offer required minimum services.• Urgent care providers cannot use the word “emergency” or its equivalent in their names.• Requirements related to disclosures to consumers, support of the medical home, and health information technology also apply (see Retail clinics).
Freestanding emergency departments	<ul style="list-style-type: none">• Referred to as “hospital-sponsored off-campus emergency department (ED)” in regulation, but name given to the public will be the name of the hospital that owns the facility and “satellite emergency department.”• Restrict off-campus ED ownership to hospitals and prohibit non-hospital-owned off-campus EDs.• Subject to the same standards and requirements as a hospital-based ED and must demonstrate compliance with Centers for Medicare and Medicaid Services hospital condition of participation.• Hours of operation will generally be 24/7, but part-time operation will be allowed.• Need and approval methodology will be developed.

Continued

Table 1. *Continued*

Ambulatory Care Setting	Summary of Regulatory Recommendations
Office-based surgery (OBS) / office-based anesthesia (OBA) practices	<ul style="list-style-type: none"> ● Requirements related to disclosures to consumers, support of the medical home, and health information technology also apply. ● Require all physician and podiatry practices performing procedures (including noninvasive procedures) utilizing more than minimal sedation to become accredited and file adverse-event reports. ● Limit both procedural time to 6 hours and postprocedure time to discharge to 6 hours. ● Require registration with the Department of Health of all new and existing practices performing procedures with minimal sedation. ● Require submission of practice, procedure, and quality data as determined by the department. ● Require accrediting agencies to share with the department the outcomes of surveys and complaint/referral investigations and other requested information. ● Require accrediting agencies to survey OBS/OBA practices and carry out complaint/incident investigations at the department's request.
Upgraded diagnostic and treatment centers	<ul style="list-style-type: none"> ● Eliminate upgraded diagnostic and treatment centers (UD&TCs) from statute and regulation. 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. There is now no need for this model given the development of new models of care, including urgent care and hospital-based off-campus emergency departments.

The Triple Aim

The principles guiding the Affordable Care Act and the Medicaid Re-design Team's initiatives—the Triple Aim—remain a useful polestar for the changing health care services landscape, offering both a yardstick for what has been accomplished and a set of aspirations for the future.¹

Population Health

Ambulatory care should help shift the locus of health care from facilities to communities, with a concomitant focus 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 spread across domains of behavioral risk, social and economic circumstances, environmental exposures, and medical care.² The balance and effects of many of these determinants—for example, the 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 the Internal Revenue Service requirements for tax-exempt hospitals to demonstrate meaningful efforts to improve the health of the communities they serve.³ 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 5 priority areas and provides guidance for local stakeholders in assessing and improving community health and reducing 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.^{4,5} Improving population health will require the full participation of ambulatory care providers in the State Prevention Agenda.

Health Care Quality

New York has made progress in improving the quality of health care. For example, in the Medicaid program, the 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.⁶ New York's 1115 Medicaid waiver could help make even more progress. Yet health care quality improvement

efforts have not yet embraced the full spectrum of ambulatory care. The majority of outpatient quality measures focus on preventive care, chronic disease care, and patient experience, which, albeit important, leave out equally important measures such as diagnostic accuracy, appropriateness of testing, and rates of medication errors.⁷ 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.⁴ Again, Medicaid has been a bright spot, with reforms proposed by the Medicaid Redesign Team thus far saving between \$5 billion and \$10 billion. Still more can be done, though, particularly with the Medicare and commercially insured populations. A recent study by the Institute of Medicine of geographic variation in US health care spending identified 2 major cost drivers, both of which affect the organization of ambulatory care. Most of the variation in spending per beneficiary in the Medicare population was in postacute care (services provided by skilled nursing facilities, rehabilitation and long-term care hospitals, home health agencies, and hospices).⁸ In the commercially insured population, postacute care was only a minor contributor to the variation in spending. Instead, price variation was the predominant factor, accounting for about 70% of the total expenditure variation.⁹ In both cases, postacute care variation and price variation, careful regulation to help shape the ambulatory care market could make the broader health care system more efficient. As another cross-cutting strategy, redirecting inappropriate visits from emergency departments to other ambulatory care services would reduce costs through 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 one of the Triple Aim's fundamental metrics of interest.

Another principle, *continuity of care*, is as important as those of the Triple Aim when considering ambulatory services. Continuity of care is a "Triple Aim home run," as it helps bring about better health, improves health care quality, and lowers costs.¹⁰ While some patients, particularly younger patients with acute illnesses, may prefer better access over greater continuity, many more prefer continuity of care,

particularly older patients or those with multiple chronic conditions, that is, those patients who are most vulnerable to serious illness and whose care incurs the highest costs. For these people especially, their continuing relationship with a caring professional provides the needed context for shared decision making and responsibility to maintain and improve their health. A growing corpus of evidence demonstrates the systemic effects of continuity of care. For example, a study of more than 3 million Medicare beneficiaries showed an inverse effect between primary care continuity and preventable hospitalizations.¹¹ To the extent that new models of ambulatory care disrupt continuity of care, they may have negative implications for cost, quality, and health. Accordingly, the first step in resolving this may be for primary care practices to begin measuring their patients' continuity of care.

A Foundation of High-Performing Primary Care

A simple premise led to a breakthrough in deliberations on regulatory recommendations: High-quality ambulatory care depends on excellent primary care. Therefore, new models of care must not erode—but should bolster—high-quality primary care.¹² 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 the new models of ambulatory care may blur the boundaries of primary care, it was useful to base our discussions on 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."¹³ While superlative models of primary care are dependent on the particular community, they all share a few main elements.

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, and 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.”¹⁴ The American College of Physicians (ACP) recently defined team-based care further in a position paper: “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.”¹⁵ Importantly, the ACP’s position paper also advocates a cooperative, interprofessional approach to coping with the looming shortage of physicians.

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 matched to patient care management categories in order to allocate health care resources in a cost-effective manner. The US Department of Veterans Affairs, for example, risk-stratifies populations of patients and tailors interventions to specific risks. Based on longitudinal electronic health records (EHRs) covering up to 2 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.¹⁶ The CAN score therefore stratifies patients who are at greatest risk for major adverse outcomes, enabling enhanced care management services to be directed to those veterans.

High-Risk Patient Management

As popularized by Atul Gawande’s *New Yorker* article,¹⁷ “The Hot Spotters,” another Triple Aim home run could be addressing the needs of the sickest and most vulnerable patients. Nationally, just 10% of the population is estimated to account for about 64% of health care expenditures, often because of overutilization of the hospital, emergency

room, and other acute-care resources.¹⁸ Addressing care coordination, targeting intensive interventions, and ensuring greater access would enable this segment of the population to benefit from better health and would reduce costs. Many primary care practices are now testing high-risk patient management, in either an “ambulatory intensive care unit” or another designation. Preliminary evidence from programs for high-risk elderly patients shows modest reductions in hospital and emergency department utilization, although how generalizable these findings are to a broader (nonelderly) high-risk population is not clear.¹⁹

Rapid but Judicious Access to Specialty Expertise

The market for specialty services is different from different vantage points. For private providers who take care of affluent, generally commercially insured patients, the problem may be the supply-driven overuse of expensive specialty resources. Meanwhile, the supply and demand for specialty services are greatly mismatched for patients and providers in safety-net systems, leading to long wait times and delays in care. Innovations in accessing specialty expertise may help 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, which sometimes eliminates the need for in-person consultation.²⁰ Similarly, a national program known as Project ECHO has shown that with the right staffing and technology infrastructure, primary care providers and specialists can comanage patients with complex, chronic diseases like hepatitis C.²¹

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 2 or more disorders.²² New York has been a leader in incorporating behavioral health services into primary care, particularly through Medicaid Health Homes. More broadly, however, most primary care doctors are ill-equipped, lack the time, or are not reimbursed in a manner that allows them to fully address the psychosocial

issues underlying many patients' visits. In some cases, patients do not have access to dedicated behavioral health professionals, and rarely are physical health and behavioral health providers colocated to enable "warm handoffs" between them, although models for integrated or collaborative behavioral health and primary care are emerging.²³ In one example, the Southcentral Foundation's Nuka System of Care in Alaska, behavioral health has become a routine component of medical care, with integrated charts, care teams, and clinic design facilitating collaboration, from informal consultation to joint visits to more formal referrals.²⁴

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 Convenient Ambulatory Care

Across the United States, patients visit health care providers about 50 million times annually for low-acuity conditions such as sinusitis and urinary tract infections.²⁵ Some of these visits take place in emergency departments, though it is sometimes difficult to distinguish between low-acuity and urgent conditions *a priori*, and such visits can also reflect poor access to primary care rather than patients' poor judgment.^{26,27} Indeed, there might have been many more than 50 million annual visits if primary care appointments had shorter wait times, and the expansion of the Affordable Care Act's coverage may make wait times even longer rather than shorter. Partly in response to these demands, new ambulatory options, such as retail clinics (eg, CVS Caremark's MinuteClinic) and urgent care centers, have expanded rapidly in recent years. For example, between 2007 and 2009, the number of visits to retail clinics increased nationally fourfold and by 2012 were estimated to account for almost 6 million annual visits.²⁸ In rural areas, concerns about insufficient emergency care capacity have led to the promulgation of upgraded diagnostic and treatment centers (with limited emergency care capabilities) and the establishment of freestanding emergency departments.

The benefits of these convenient ambulatory care options remain conjectural, although the greater access and low-overhead cost structure intuitively seem to be an improvement. The risks of these options include less continuity of care and more fragmentation. While the care provided may be less expensive for each visit, better access may lead to

more patients seeking care, thereby increasing overall utilization and spending. Access also may be heavily weighted toward more affluent patients depending on payment sources accepted. For example, only about 60% of retail clinics in the United States accept Medicaid, and usually only in a limited form.²⁹ Finally, the reallocation of private revenue to convenient care options could threaten the viability of much needed primary care practices and hospital-based emergency departments.³⁰

Innovations in Specialty Ambulatory Care Services

New models of ambulatory care delivering specialty services over the past 2 decades have complicated the relationships between hospitals and physicians. Enhanced physician practices (so-called physician megagroups), nonhospital 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 risen 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.³¹ 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. But detractors contend that despite providing complex and costly services, the enhanced arrangements operate with insufficient oversight of safety and quality and cherry-pick the lower-risk, more affluent patients while delivering more lucrative services.

The amalgamation of “specialty ambulatory care services” has made each category of service even more complex. Although enhanced physician practices are in some ways the most natural accountable care organizations, they can also destabilize existing safety-net providers by luring away commercially insured patients. Nonhospital surgery spans care sites with drastically different cost structures and regulatory responsibilities, and there is little help to patients to find appropriate sites of care. As a result, 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, as defensive medicine, patient preference, and time constraints all likely play a role.³² Meanwhile, radiation therapy might be appropriately utilized as a whole, even

though the predilection toward costlier modalities of radiation therapy may warrant scrutiny.

Regulatory Tools

In New York State, medicine may be practiced in one of two modes: professional or institutional. The state's statutes and regulations for practicing medicine in both the professional and the institutional modes contain and use many regulatory tools to shape the delivery, monitor the quality, and define the cost of care, including formal licensing, registration with periodic re-registration, establishment through the CON process, close definition of allowed scope of services, use of third-party agencies for purposes of accreditation, posting requirements, naming conventions and restrictions, routine surveillance, investigation of complaints with imposition of sanctions as appropriate, requirements to accept certain insurance, and requirements to connect to information exchanges.

The aim of New York's regulatory approach is to value the pluralism of the state's health care delivery system and recognize in this diversity the numerous benefits, including greater choice for consumers, practice options for providers, ability to tailor service programs to the needs of different communities and populations, and, perhaps most beneficial of all, an opportunity for experimentation and innovation in order to create better models of caregiving.

A Vision for Ambulatory Care

Developing New York's regulatory framework required an in-depth study of the changes taking place in health care delivery. In the future, more care will be delivered in the outpatient setting and 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 shown in the evolution of some hospitals into full health care delivery systems, in the expansion of some federally qualified health centers into powerful regional providers of care, and in the emergence of large, multispecialty physician groups, with some of them assuming financial risk.

Risk-based contracts have shown promise in slowing the increase in medical expenditures for both private and public payers (eg,

Medicare).^{33,34} 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 366 Medicare Accountable Care Organizations (ACOs) operating in 2014, 25 are located in New York,³⁵ with a majority sponsored by physician groups rather than hospitals. The other categories of “disruptive innovators”—including retail clinics, start-up primary care networks, and ambulatory surgery centers—are testing models of care with the potential to up-end current payment and delivery paradigms. In this environment, the primacy of inpatient acute care as the financial driver of the health care system is challenged, and the role of chronic disease managed in ambulatory care settings is heightened.

The Way Forward

Grounded in this vision for advanced ambulatory care, the New York regulatory approach (for a summary of recommendations, see Table 1) has charted a path forward in an evolving market environment. The recommendations should be seen as an initial set of policy priorities meant to be applied in tandem, but also with built-in flexibilities to adapt to changing circumstances. The details of these recommendations flowed from 6 broader conclusions.

First, patient safety and quality standards for new models of care should equal or exceed existing clinical standards in currently regulated environments.

Second, the public’s awareness of novel ambulatory care services is paramount, so the standard nomenclature for services and public signage should be chosen to reduce, not increase, consumers’ confusion.

Third, continuity of care, particularly with patients’ primary care practices, should be preserved and promoted. Primary care is the robust and necessary foundation of all care, whereas episodic care, from minor care to serious emergencies, is supplementary and complementary and thus layered into, above, or around the foundation of primary care.

Fourth, a robust data infrastructure, implemented by means of interoperable health information technology systems, should support providers’ reporting requirements as well as patients’ continuity of care.

Over time, the availability of these data should enable further refinement of the state's own regulatory system.

Fifth, regulation should be directed to create conditions for fair competition in the ambulatory care market, particularly among institutional providers and independent professional practices. 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.

Sixth, regulatory recommendations are a work in progress, and additional changes will depend on the evolution of ambulatory care.

Finally, despite the broad penetration of novel ambulatory care options across the United States, few policy precedents pertain to comprehensive ambulatory care oversight. Massachusetts created a state-level health planning council to identify health care service needs, determine priorities for addressing those needs, and make recommendations for the appropriate supply and distribution of services. In its first phase, the council is addressing 6 areas: behavioral and mental health services, primary care resources, postacute care, ambulatory surgery, percutaneous coronary intervention, and trauma.³⁶ Only a few other states have embarked on a wide-ranging assessment of regulation of ambulatory care services. Therefore, by building on the foundation described in this article, New York aspires to become a trailblazer in sound oversight while encouraging innovation in health care delivery.

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