began in 2004 but were not widely reported to other states, and information about them was not transparently available to health care providers. If these steps had been taken, the NECC might have seen reduced sales in out-of-state markets, prompting improvements in quality control.

Massachusetts accepted primary regulatory responsibility for the NECC tragedy and has spent the past year on appropriate responses, with major reports and proposed legislation from both the governor and the legislature.[4,5] Since the federal government has essentially ceded much of the regulatory landscape to the states, it is all the more important to ensure that state regulations meet minimum quality standards while not triggering drug shortages. Key features of the proposed Massachusetts reforms are described in the table. Each of these reforms plays an important role in the quest to improve the quality of compounded drugs. For example, the out-of-state license is important because otherwise a compounder like the NECC could avoid the new Massachusetts rules by relocating to a more lightly regulated state. With an out-of-state license, all compounding pharmacies selling in Massachusetts must meet the same quality standards.

Second, the FDA now has clearer authority, especially over outsourcing facilities, but will be successful only if other stakeholders support the FDA. For example, the new law did not provide any additional budgetary appropriations for inspecting compounders that do not register as outsourcing facilities. Congress needs to adequately fund this mission. In addition, registration as an outsourcing facility is voluntary. For compounders that fail to register, the FDA relies on states to regulate and share information.

Finally, rather than being passive in this process, providers and health plans could act to improve the quality and availability of compounded drugs. Purchasers can demand that their sterile-compounded drugs be sourced exclusively from outsourcing facilities regulated by the FDA. This decision could also be included in accreditation standards and reimbursement contracts. Such a market-based response would force compounders to accede to their major customers' demands and register with the FDA. Alternatively, if providers constantly seek out the cheapest compounded drugs, then the unregulated compounders will have an unfair competitive advantage and we can expect few compounders to seek FDA approval.

The Drug Quality and Security Act may have been a good first step, but patients will not be protected unless states, the FDA, and health care providers and plans act quickly to fill in the gaps left by Congress.

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Accelerating the Adoption of High-Value Primary Care — A New Provider Type under Medicare?

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A bipartisan, bicameral proposal from the Senate Finance Committee and House Ways and Means Committee to repeal and replace the Medicare sustainable growth rate formula (SGR) for physician payment would begin to reform provider payment to reward high-value care.[1] It calls for replacement of the SGR with a 10-year freeze on physician payment levels and, beginning in

The Nine Comprehensive Primary Care Initiative Milestones to Be Achieved by the End of Year 1.*

- Annual budget including expenses associated with practice change
- Care management for high-risk patients — impaneled patients, patient risk status and tracking, care management services, personnel, and care management plans
- 24/7 patient access to physicians or nurses, with real-time access to medical records
- Assessment and improvement of patient experience based on patient surveys or patient and family advisory councils
- Use of data to guide improvement, including at least quarterly calculation and reporting of data on quality and utilization measures
- Care coordination, including timely communication pertaining to emergency department visits, hospital admission and discharge, medication reconciliation, and specialist referrals
- Shared decision making, including use of decision aids for high-priority conditions
- Participation in a learning community and sharing of knowledge, tools, and expertise
- Meaningful use of health information technology, including meeting requirements for Stage 1 EHR Incentive Programs

* From the Centers for Medicare and Medicaid Services (http://innovation.cms.gov/Files/x/CPC_PracticeSolicitation.pdf). EHR denotes electronic health record.

2016–2017, would provide a 5% bonus to physicians who receive a substantial portion of their revenue through an alternative payment model, such as a patient-centered medical home (PCMH), an accountable care organization, or a bundled-payment system.

The Senate Finance–House Ways and Means proposal would support an ongoing move toward advanced primary care practice (APCP). Stronger primary care is an important policy goal because primary care practices that have been redesigned to ensure the provision of patient-centered, coordinated care are considered the foundation of a high-performance health system. Evaluations of the early experience with advanced primary care offer systematic evidence of positive effects on the delivery of preventive care services, the experience of physicians and staff, and the rate of emergency department visits.[2]

Although the proposed Medicare physician payment reform is an important step in the right direction, we believe that a bolder approach is needed to accelerate the adoption of APCP. We propose that Medicare adopt APCP as a new provider category, with its own eligibility standards and accountability for performance on patient outcomes, care, and resource use, linked to a new payment approach.

As policymakers struggle to find pathways to accelerate transformation to high-value models of advanced primary care, they are challenged by two things: the lack of a clear definition of the clinical model they are trying to create and the transformed practices' need for a business case for deploying it. Current approaches to strengthening primary care included in the Affordable Care Act have focused on increasing reimbursement for primary care (e.g., increasing Medicare payment for primary care by 10%), and proposed recent changes in payment rules for 2014 include new non–visit-based codes (e.g., for care management services and care coordination) that may be used by primary care physicians as well as other clinicians providing these services. Though these changes do direct increased resources toward primary care, they do not drive practice transformation to any particular clinical model.

Our proposed new APCP category would be best thought of as a bundle of services provided by a team using a technology platform designed to support a variety of visit-based and non–visit-based activities rather than as a discrete cognitive service offered by physicians. Efforts to graft this new bundle of services onto existing primary care practices using visit-based fee-for-service payment will always face the challenge that much of what policymakers want to see delivered in primary care adds overhead to an existing primary care practice without offering any corresponding revenue source to support those activities. And in a fragmented payment system, if each payer specifies a different bundle of services and varying payment methods, the national rate of real practice transformation will be unacceptably slow.

As a standard setter in payment, the Centers for Medicare and Medicaid Services (CMS) plays a critical role in establishing new payment models for new services. Two multipayer pilots deployed by the Center for Medicare and Medicaid Innovation (CMMI) are informative.[3] In the Multi-Payer Advanced Primary Care Practice initiative, Medicare joined with approximately 27 private insurers and state Medicaid programs in eight states. States used their antitrust authority to create a safe harbor for private payers to collaborate on defining and determining how to pay for advanced primary care. CMS joined in later, once the states and payers had agreed on both the criteria for practice participation and the model for payment. Most states used the PCMH credential offered by the National Committee for Quality Assurance (NCQA), and they offered a payment model typically comprising a combination of fee-for-service payment,

monthly per-person care management fees, and rewards for performance on quality metrics, shared savings, or both.

Under the Comprehensive Primary Care Initiative (CPCI), 44 private payers and state Medicaid agencies joined with Medicare in seven market areas, engaging 500 high-performing primary care practices including more than 2000 providers. Under this 4-year program, Medicare specified the clinical model before the private payers chose to sign on. Practices applying to participate had to commit to achieving a set of milestones by the end of the first year (see box). In addition to Medicare fee-for-service payment, the initiative provides a payment of $20 per Medicare beneficiary per month in years 1 and 2 (almost 40% more than what Medicare now pays for primary care) and the opportunity for shared savings starting in year 2. All the participating commercial payers agreed to offer similarly structured payment and shared-savings opportunities, but they varied in amount.

Though both these programs are in process and clinical and financial results are not yet available, the programs have already demonstrated several important things: payers are willing to pay more for advanced primary care, practices are willing to transform to a new model if they're assured of a revenue stream to support such change, and the private market is willing to partner with Medicare in defining the clinical model and the payment approach.

Several common features of the programs could lay the foundation for designing a payment system for advanced primary care under Medicare: a clinical model specifying practice capacities and a payment model offering care management fees that flow on behalf of a defined population in a predictable way, incorporating accountability for population health outcomes and opportunities for shared savings.

Creating a new APCP provider category would give policymakers multiple tools for accelerating the broad availability of enhanced primary care. Medicare already recognizes different categories of providers, and it administers both "Conditions of Participation" (specifying the infrastructure and capacities that must be in place to make a provider eligible to bill using that provider type) and a fee schedule unique to each category of provider (designed to support requisite infrastructure). Both the NCQA PCMH credential and the CPCI milestones could inform the criteria that Medicare would require for participation. The APCP category could be open to all providers meeting requirements on eligibility, reporting, performance, and accountability. It would have its own payment method — a blend of fee-for-service payment, a monthly care management fee per Medicare beneficiary served, and the opportunity for shared savings — similar to the method used in the CPCI.

Establishing the APCP as a provider category would accelerate the deployment of care teams (including such health care professionals as nurses, care managers, health educators, social workers, and pharmacists[4]) and would foster the development of the information infrastructure for delivering patient-centered, coordinated primary care. To encourage broader use of this coordinated care model, Medicare beneficiaries enrolling in APCPs should have their primary care services covered with no deductible and no copayment for the care management payments, along with reduced coinsurance (e.g., 10% rather than the usual 20% coinsurance) for specialist care obtained through referral from their APCP. We believe that the combination of Medicare payment reform for APCPs and financial incentives for beneficiaries to seek this form of high-value care would induce most primary care providers to embrace practice transformation to ensure the best possible patient outcomes and experiences.[5] Ongoing support for CMMI pilots and demonstrations can help to refine this approach over time, but the time for committing to advanced primary care has come.

The views expressed in this article are those of the authors and do not necessarily represent those of the American Board of Internal Medicine.

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