Addressing Health Care Cost Growth — Why and How States Should Lead

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With health care affordability high on U.S. voters' minds, the upcoming election and subsequent legislative sessions offer an opportunity to make the case for restraining cost growth while addressing the increasing financialization of the U.S. health system, which poses a serious threat to the public good and undermines physicians' ability to live up to their professional values.[1] Turning concrete proposals into an election issue can render subsequent legislative success more likely.[2] And, because the prospects for needed federal reforms are poor and states are better positioned than the federal government to precisely and comprehensively address the drivers of low-value spending, we believe that action at the state level is essential.

Rising health care costs are like a balloon: as policymakers constrain spending in one area, affected organizations simply seek additional revenues elsewhere. Since spending is the product of volume and price and since new services and products add to rather than supplant existing ones, policymakers need to see the full picture, establish systemwide constraints, and address the drivers of low-value spending and monopoly pricing (see table).

Without comprehensive oversight of money flows, sources and magnitude of waste, and opportunities for change, improvement will not be possible. Economists have long called for firm limits on spending growth. A key step forward has been the establishment of agencies charged with both these tasks: nine states have launched programs to track and analyze statewide health care spending and establish reasonable spending-growth targets. Targets can and sometimes do include goals for increased spending on primary care. The targets are set by a public process and with the intention of achieving growth rates no greater than that of the economy as a whole. Reducing spending growth to just 1 percentage point below projected trends would lead to annual savings of more than $1 trillion by 2037. Because targets are aspirational, states also need to implement specific policies that can directly address the major drivers of spending growth.

Despite declining utilization, hospitals still represent the largest single component of U.S. health care spending. Hospitals provide the technologies that are essential for the effective and timely treatment of medical emergencies and the diagnosis and treatment of many diseases. Some subset of services must be geographically accessible to all. High fixed costs make duplication wasteful and providing access in rural regions challenging. Currently, hospitals can avoid the hard work of cost cutting by maximizing margins in other ways: expanding profitable services in wealthy neighborhoods, avoiding Medicaid, Medicare, and uninsured patients, or simply raising prices, as many do. If they are well designed and implemented, global hospital budgets can set firm limits on the total cost of hospital care (volume and price) while aligning incentives with community health goals by encouraging prevention and outpatient care. With input from regulators over time, budgets can be gradually adjusted to reduce duplication among facilities and improve efficiency within them. Global budgets have been adopted in Maryland and for rural hospitals in Pennsylvania; the Maryland model fosters hospitals' engagement by giving them a share of the savings achieved. The result has been significant reductions in preventable admissions, readmissions, and the total cost of care, with no diminution of the quality of care, according to patients' assessments.[3]

Population-based payment models such as accountable care organizations (ACOs) have demonstrated their potential for reducing costs for patients who are under the ACO contract while improving quality, especially when they are led by physicians, focused on primary care, or both. Fee for service, however, remains the dominant U.S. payment model, accounting for the vast majority of physician revenue. Because the adoption of the team-based care models essential for effectively treating patients with chronic conditions requires most patients to be covered under population-based payment arrangements, no one should be surprised that the impact of ACOs has been limited so far. Shifting to all-payer standard-

State Policies That Could Collectively Slow Cost Growth and Improve Health and Care.

Policy	Justification
Comprehensive oversight and spending-growth targets: Each state should establish and adequately fund a state agency to track systemwide cost and quality performance, set spending-growth targets, identify drivers of cost growth and opportunities for improvement, and implement or recommend needed reforms.	Systemwide oversight, sound data, and understanding of state-specific drivers of cost growth provide the foundation for effective policy. Having the statutory authority to achieve spending-growth targets makes agencies' actions more likely to withstand legal threats from groups and organizations that resist reform.
Hospital global budgets: States should work with Medicare to establish all-payer hospital global budgets that ensure both adequate local and regional access to needed facilities and services and their financial viability, gradually shifting resources to primary care and population health improvement, as possible.	All-payer hospital global budgets shift incentives by rewarding health improvements, reductions in avoidable utilization, and increased efficiency rather than volume growth for high-margin services. Implemented properly, they can strengthen safety-net and rural facilities while reducing duplication in overserved markets.
All-payer accountable care organizations: All payers should be required to adopt aligned global payment models for physician-led organizations that can deliver comprehensive, coordinated primary and specialty care with accountability for quality and the total cost of care.	Still the predominant payment model, fee-for-service payment rewards overuse and locates accountability at the level of the clinician, resulting in fragmented care. Clinicians and health care organizations that receive global payments for all their patients have powerful incentives to improve care and the necessary freedom to innovate.
Pricing power limited by means of effective regulation: States should adopt policies to preserve competition wherever possible. Where it is not possible, they should establish regulatory bodies authorized to review cost structures and effectively regulate prices as needed.	Consolidation and barriers to entry have led to decreased competition, lower quality of care, and monopoly pricing, especially for hospital services and prescription drugs. In such cases, regulation is essential for improving affordability and access to care.

ized contracts with identical and aligned performance measures and less gameable risk adjustment would reduce administrative burdens, strengthen the incentives to improve (because they would apply to all patients), and give practices the flexibility to pay for innovations in care that are not reimbursed under current fee-for-service billing codes. State (and federal) policies requiring a transition to these payment models could both improve quality and reduce costs if applied to all patients. Direct contracting by governments and employers with physician-led organizations could reduce the layer of financial extraction by intermediaries such as health plans, hospitals, or other entities.[1]

Meanwhile, lack of competition in health care markets leads to higher prices and often lower quality of care. Many U.S. markets — 90% of hospital markets, 65% of specialist markets, 57% of insurer markets, and 39% of primary care markets — are already too concentrated to support meaningful competition.[4] To preserve the competitive markets that remain, we believe states should adopt policies that increase transparency and oversight of mergers, acquisitions, and investments in hospitals and physician practices. States can broaden the scope and standards for health insurance rate setting, as Rhode Island has done for 20 years. Maryland has long regulated prices charged by provider organizations, and some states have established caps on price increases (e.g., Rhode Island) or limits on the degree to which prices can exceed Medicare rates (e.g., Oregon).

Resistance to reforms that threaten the profits of large corporations and health systems will be fierce and well funded, and opponents of reform can legitimately point to the limited impact of each approach up to this point. Current state approaches to making prescription drugs more affordable do not address the underlying drivers of drug prices. Opponents will also cite ideological reasons to prefer market forces to government intervention or argue that any reduction in spending will harm patients. And slowing cost growth in a handful of states won't solve health care's threat to the federal budget.

Nevertheless, state-level reform is both possible and, we believe, the most promising path forward. Some states have already implemented many of these reforms and are thus well positioned to adopt the comprehensive, mandatory approach we recommend. The Centers for Medicare and Medicaid Services already has the authority needed to test new Medicare payment models and Medicaid waivers that would make an all-payer approach to global budgets and ACOs possible. If Congress is willing to act, reform of drug-patent laws and increased

funding for technology assessment would both help. To address concerns about ineffectiveness or harms to patients, state oversight agencies must be well funded, be supported by analytics and broad community engagement, and have the authority to impose any reforms that demonstrably improve health and care while slowing cost growth. And if these efforts are successful in some states, others are likely to follow.

Nearly 50 years ago, when health care accounted for only 7% of the gross domestic product (as compared with 17% now), Howard Hiatt called on physicians to work with government to put in place the data systems and policies needed to reduce wasteful and harmful care while improving health.[5] Since that time, the financialization of health care has increased dramatically, to the detriment of the public and the medical profession. But reform that advances Hiatt's vision appears within reach in many states. With stronger leadership by health professionals, effective community organizing,[2] and the right mix of policies, that vision could be attainable.

The views expressed are those of the authors and do not necessarily represent the views of the Green Mountain Care Board.

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Confirmatory Trials of Accelerated Approval Drugs — Will Imposing Fines Reduce Delays?

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In 1992, patient-advocacy groups convinced the Food and Drug Administration (FDA) to develop an accelerated approval program, which allowed new drugs to be approved on the basis of changes to surrogate measures, such as reductions in HIV viral load, that are reasonably likely to predict actual clinical benefits. Accelerated approval was later expanded to cover cancer drugs and corresponding end points such as tumor response rate. The goal was to expedite approval of promising new drugs for which definitive evidence of patient benefit was lacking. As part of the deal, manufacturers were charged with conducting postapproval studies to show that the drug does in fact benefit patients. If they failed to demonstrate clinical benefit, or to complete these confirmatory trials, the FDA could withdraw the approval.

In the 30-plus years since, accelerated approval has proven useful, but its implementation has revealed a persistent problem: manufacturers of drugs granted accelerated approval have limited incentive to complete confirmatory trials in a timely fashion. Indeed, for some drug manufacturers, the uncertainty resulting from a lack of definitive evidence may be financially preferable to the risk of a negative trial. As a result, multiple studies have revealed delays in completion of confirmatory trials, with some trials delayed by years.[1] Some delayed trials are ultimately negative, as with hydroxyprogesterone caproate (Makena), which was approved for preterm labor and then withdrawn 12 years after approval. In other cases, such as the cancer drugs pralatrexate and belinostat, the agents remain on the market without confirmatory evidence more than 10 years after approval. Meanwhile, patients incur costs and medical risk from drugs for which conclusive evidence of clinical benefit is lacking.[2]