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C O N T E N T S

VOLUME 46:4 • WINTER 2018

Symposium Articles

SYMPOSIUM

Next Steps
in Health
Reform

Guest Edited by
Lindsay F. Wiley

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*Letter from
the Editor*

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Introduction

Lindsay F. Wiley

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The Simple Reality of Our Complex System: The Future of Health Care

Sylvia Mathews Burwell

The incredible complexity of the United States health care system can be connected to three simple outcomes: access, affordability, and quality. We should measure our progress against these three measures. While historic progress on access was made through implementation of the Affordable Care Act, the next area of focus for more results across all three measures is delivery system reform.

829

Getting Health Care Right

Daniel J. Hilferty

The author, a health insurance industry leader and a prominent voice in the national reform debate, shares his perspective on attempts to transform health care over nearly a decade. He advocates for a bipartisan solution to stabilize the health insurance market in the near term, and for private sector innovation in partnership with government to create sustainable long-term change. He encourages ASLME members to continue to lend their expertise to the process of transformation.

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Myths, Misperceptions, and Policy Learning: Comparing Healthcare in the United States and Canada

Gregory P. Marchildon, Capri S. Cafaro, and Adalstein Brown

The U.S. and Canadian health care systems are more similar than is commonly believed. This article debunks some of the powerful myths about these health care systems and opens up the discussion for greater policy learning from both sides of the border. Cross-border comparisons can yield a number of lessons from common policy challenges such as cost control, physician organization and payment, and the organization of health coverage and services for Native Americans and Indigenous Canadians.

838

The Future of Health Equity in America: Addressing the Legal and Political Determinants of Health

Daniel E. Dawes

There is much discourse and focus on the social determinants of health, but undergirding these multiple intersecting and interacting determinants are legal and political determinants that have operated at every level and impact the entire life continuum. The United States has long grappled with advancing health equity via public law and policy. Seventy years after the country was founded, lawmakers finally succeeded in passing the first comprehensive and inclusive law aimed at tackling the social determinants of health, but that effort was short-lived. Today the United States is faced with another fork in the road relative to the advancement of health equity. This article draws on lessons from history and law to argue that researchers, providers, payers, lawmakers and the legal community have a moral, economic and national security imperative to address not only the negative outcomes of health disparities, but also the imbalance of inputs resulting from laws and policies which fail to employ an equity lens.

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Health Care Federalism and Next Steps in Health Reform

Abbe R. Gluck and Nicole Huberfeld

The next steps in health reform, like all such efforts before it, will have to engage the issue of American health care federalism – the relationship between the federal and state governments in the realm of health law and policy. Since its enactment in 2010, the Patient Protection and Affordable Care Act (ACA) has offered a robust example of modern federalism and revealed new complexities. This article recounts the findings of our five-year study of the federalist and nationalist features of ACA implementation. Contrary to the claims of ACA opponents that the law marked a federal “takeover,” the ACA’s governance structures have advanced rather than suppressed state power. But we also found that the advances in state power occurred seemingly independently of the statute’s structural arrangements; that is, the ACA’s nationalist and federalist features *both* enhanced state power over health policy. These findings raise questions about whether cherished American federalism values are unique to federalist structures; they also raise the question of what exactly health care federalism is for, and why we continue to design health policy with federalism front and center. It is not clear that enhanced state power has brought better health policy. If it has not, is federalism for its own sake worth the trade-off?

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Health Reform and Theories of Cost Control

Erin C. Fuse Brown

Health care costs and affordability are critical issues to consumers. Just as we assess the coverage impacts of a health reform proposal, we should be able to evaluate how the plan will constrain health care costs: its theory of cost control. This essay provides a framework to assess health reform plans on their theories of cost control, identifying the key policy tools to constrain health care costs organized in a two-by-two matrix across the following dimensions: price vs. utilization and public vs. private payers. It then applies the framework to the Affordable Care Act (ACA) and the Republican's 2017 legislative efforts to repeal and replace the ACA to identify their general theories of cost control, revealing on the plans' strengths, blind spots, and incoherence.

857

Controlling Health Care Costs under the ACA — Chaos, Uncertainty, and Transition with CMMI and IPAB

Gwendolyn Roberts Majette

This article addresses two components of the new governing architecture (NGA) that help to reform the delivery of health care and to control costs of the health care system: the Center for Medicare and Medicaid Innovation (CMMI) and the Independent Payment Advisory Board (IPAB). The republican controlled federal government has partially disassembled these two components, threatening the effectiveness of federal delivery system reform and cost control initiatives.

862

The Tortuous Journey of the Health Insurance Marketplace

Jeanne M. Lambrew

This article examines the past, present, and future of individual market policies in the Affordable Care Act (ACA). It does so, first, by reviewing the law's goals, scope, and set of individual market policies, collectively called the Health Insurance Marketplace. The Marketplace, along with the ACA's Medicaid expansion, was designed to fill in gaps to provide all Americans with accessible, affordable coverage. Second, it reviews evidence on the law's impact to date, including changes under a new administration. Third, it discusses the three main policy options for the Marketplace: do nothing, build on it, or replace it. Lastly, it discusses the factors which could determine which pathway policy makers follow.

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Cost-Sharing Reductions, Technocrat Tinkering, and Market-Based Health Policy

Allison K. Hoffman

The Trump Administration has exposed both the durability and vulnerability of the Patient Protection and Affordable Care Act's insurance reforms. One of the Administration's first strikes at "Obamacare" was to discontinue federal government payment of cost-sharing reductions, which insurers pay to low-income enrollees on the exchanges to reduce their out-of-pocket share of medical spending. The states struck back with a clever solution that could hold insurers and enrollees harmless. This article examines this strategy and why, while impressive, it reaffirms larger problems with the ACA's market-based approach to health reform and the need for new pathways forward.

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The Private Insurance Market: Not Very Big and Not Insuring Much, Either

Jacqueline Fox

Creating a single national health insurance pool is not likely to destabilize the economy by supplanting the private health insurance industry. This industry insures a relatively small percentage of the population and holds very little of the risk such insurance implies. In effect, insurance companies function as middlemen, bundling risk packages to distribute to other, larger companies and so serve a limited purpose. Were insurers to handle claims for a national pool as they do for the Medicare program, any destabilization to the economy more broadly would be further minimized.

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The Irreplaceable Program in an Era of Uncertainty

Sara Rosenbaum and Elizabeth Taylor

In 2017, Medicaid faced a near-death experience, the third of its 53-year history. Its survival and resilience is a testament not just to its size but to the multiple, vital roles Medicaid plays in the health care system, and its ability to adapt to emerging population health needs. It can take an existential threat to make these indispensable qualities clear.

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Medicaid, Work, and the Courts: Reigning in HHS Overreach

Sidney D. Watson

Work requirements are the centerpiece of HHS's Trump Administration strategy to undo the ACA expansion for low income working age adults. This article examines the June 29, 2018 trial court opinion in *Stewart v. Azar* which held that HHS's approval of Kentucky's Section 1115 work demonstration was "arbitrary and capricious." The purpose of Medicaid is to provide health coverage and HHS may not ignore the loss of coverage that will result from a work requirement.

892

Medicaid Waivers: Courts Must Step in When the Exception Becomes the Rule

Leonardo Cuello

Section 1115 of the Social Security Act is misconstrued as a mechanism to foster state flexibility, when in fact it is a narrow pilot program authority. HHS has exceeded the scope of this authority to approve harmful projects. Courts will not grant the agency broad deference when reviewing this abuse of authority.

897

Medicaid's Role for Children with Special Health Care Needs

MaryBeth Musumeci

This commentary explores Medicaid's role for children with special health care needs today and considers how changes to Medicaid's federal financing structure under a per capita cap or block grant could affect coverage for these children.

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Next Steps in Health Reform: Hospitals, Medicaid Expansion, and Racial Equity

Dayna Bowen Matthew

The confluence of racial unrest and Medicaid expansion in Virginia should inspire a national reimagining of how health care can contribute to health equity. Hospitals in particular can leverage their role as economic drivers in communities to equalize health and social outcomes for all. The urgent need for innovative opioid intervention presents a fertile proving ground for new ways that hospitals can act to reduce the impact of racial inequity. Inspired by the role hospitals played to achieve desegregation during the Civil Rights era, this essay proposes an integrated approach to use Medicaid expansion to advance health and racial healing in America.

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Considering the ACA's Impact on Hospital and Physician Consolidation

Lawrence E. Singer

The Affordable Care Act did not start the consolidation rapidly occurring with hospitals/health systems and medical groups, but it most definitely accelerated the movement to combine. In the last five years, the number and size of consolidations have been at an all-time high. This comment reviews the degree to which consolidation has occurred and explores the key reasons behind these consolidations. It then posits that consolidations should be evaluated in light of the Triple Aim goals of enhancing access to care, reducing cost, and strengthening quality, and looks at the evidence to date in light of these goals.

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The New Health Care Merger Wave: Does the "Vertical, Good" Maxim Apply?

Thomas L. Greaney

This essay questions the wisdom of adherence to an indulgent approach to vertical integration in health care. It first critiques the bases for antitrust law's traditional tolerance of vertical integration and describes contemporary economic learning that supports more robust antitrust enforcement. It goes on to dispute arguments urging extra caution in dealing with the health care sector and concludes with several justifications for close scrutiny of vertical health sector mergers.

927

Payors, Data, and Nudges to Improve Care

Wendy Netter Epstein

Unnecessary health care is a tremendous problem that negatively impacts individuals and also increases health care costs across the system. While much scholarly attention has been paid to the role of patients and providers, payors' role in contributing to the problem is underexplored. The article recommends that payors should nudge providers away from unnecessary care by requiring electronic alerts intended to deter unnecessary care.

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An Unintended Consequence of Payment Reforms: Providers Avoiding Nonadherent Patients

Jessica Mantel

Payment reforms that link health care providers' reimbursements to their performance on various metrics incentivize providers to improve the quality and efficiency of care they provide to patients. Unfortunately, these reforms also create strong incentives for providers to reject patients who do not adhere to medical advice. This commentary argues that providers' avoidance of non-adherent patients flouts the medical profession's commitment to patients' best interests, undermines patients' trust in health professionals, and aggravates disparities in health. Moreover, the economic incentives under payment reforms that encourage quality and efficiency gains are weakened when providers can escape the financial penalties for poor outcomes by simply firing their non-adherent patients.

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Regulatory Pathways to Promote Treatment for Substance Use Disorder or Other Under-Treated Conditions Using Risk Adjustment

Matthew J. B. Lawrence

This commentary provides a legal analysis of the extent to which changes proposed by scholars to promote care for substance use disorder or other under-treated illnesses through risk adjustment could be implemented administratively, without legislation, in federal risk adjustment systems: Medicare's privatized component, Medicare's pharmaceutical component, and the individual and small group market. As the article explains, federal laws governing risk adjustment provide broad discretion to regulators and can reasonably be interpreted to permit (or in the case of Part C even compel) full and final implementation through the administrative process of almost all of the changes that scholars have proposed.

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Public Health and Health Care: Integration, Disintegration, or Eclipse

Peter D. Jacobson and Wendy E. Parmet

Many observers have argued that the US health care system could be more efficient, and achieve better outcomes if providers focused more on improving the community's health, not just the welfare of individual patients. The passage of the Affordable Care Act (ACA) in 2010 seemed to herald the promise of such reforms, and greater integration of the health care and public systems. In this article, we reassess the quest for integration, a quest we call the "integration project." After examining the modest steps taken so far toward integration, we consider some conceptual barriers to integration as well as some of the risks it might portend for the public health system. Our assessment contributes to wide-ranging debates among public health advocates, practitioners, and policymakers as to the health care system's role in protecting public health, and how the public health system can best be organized to meet expected population health challenges.

Independent Articles

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Can Outcomes-Based Pharmaceutical Contracts Reduce Drug Prices in the US? A Mixed Methods Assessment

Elizabeth Seeley, Susan Chimonas, and Aaron S. Kesselheim

To improve the value of pharmaceutical spending, some manufacturers and payers have introduced outcomes-based contracts, where rebates are tied to specified outcomes. We reviewed the literature and interviewed key experts to assess these contracts' potential to slow pharmaceutical spending. We found that while outcomes-based contracts are increasingly common in the US, they are still limited by multiple factors — including the lack of meaningful outcomes data. Moreover, there is no evidence to date that they slow pharmaceutical spending or increase access. Experts favored having CMS test and rigorously evaluate this model to achieve a better understanding of the implications.

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COMMENTARY

Nirosha Mahendraratnam and Stacie B. Dusetzina

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A Decision Aid May Offer Liability Protection for a Bad Obstetrical Outcome: Results of Mock Trials

Suzanne Brodney, Pamela H. Wescott, Benjamin W. Moulton, Katherine Hartmann, Yuchiao Chang, and Michael J. Barry

The objective of this study is to evaluate if use of a patient decision aid (PDA), when choosing between a repeat cesarean or a trial of labor after a cesarean (TOLAC), reduces medical liability exposure. The authors conclude that use of a PDA conferred liability protection when potential jurors were presented with a hypothetical malpractice claim against an obstetrician following a TOLAC.

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COMMENTARY

David M. Studdert

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Overcoming the Balkanization of State Advance Directive Laws

Charles P. Sabatino

State law requirements for health care advance directive documents were reviewed in every state and the District of Columbia to determine whether they are consistent and/or flexible enough to permit the utilization by the public of "universal" advance directive forms, specifically a health care power of attorney, that would be valid under every state's advance directive statutes. Such documents would have to overcome the wide variability of state legal formalities for validity. If this could be accomplished, the public would benefit from having a variety of multi-state or truly universal forms available that could be used with confidence in their validity.

The review found that a basic, multi-state health care power of attorney appears to be feasible in 41 States and the District of Columbia, compared to 36 states and the District in 2005. Only nine states prevent recognition of a truly universal form. Some barriers were surmountable, including differing agent and witness requirements, execution requirements, and effectiveness triggers. Other barriers were insurmountable, including mandatory forms, mandatory disclosures, and decision-specific language requirements. The strategies identified for overcoming some barriers can be used by lawyers in drafting true multi-state directives. More importantly, states should simplify state advance directive laws to facilitate a more meaningful communication model of advance care planning.

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C O N T E N T S

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A Symposium
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by Amy McGuire,
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COMMENTARY

*Brian L. Block, Alexander K. Smith, and
Rebecca L. Sudore*

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**Untangling the Promises of Human
Genome Editing**

Katherine Drabiak

This article traces the rapid progression of policy pertaining to human genome germline modifications using genome editing. It provides an overview of how one fertility physician implemented and advertised experimental techniques as part of his fertility clinic services, examines US law and policy, and assesses the impact of rhetoric influencing global policy and interpretation of the law. This article provides an in-depth examination of the medical rationale driving the acceptance of genome editing human embryos in two contexts: to cure disease and treat infertility. It describes complexities in genomics and outlines risks currently associated with genome editing, asserting the available evidence fails to demonstrate genome editing constitutes a curative therapy.

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