anced-budget requirement, cuts of 40% would still be required by 2022. It is difficult to contemplate federal health spending reductions at such unprecedented levels. As Kaiser Family Foundation tracking polls show, public support for Medicare and Medicaid surpasses 80%, with strong support even among Republican and Tea Party–identified voters.

Which brings us back to Romney's record. His fundamental policy proposal is to undo the ACA, the nation's most consequential health care reform law. His replacement proposals would provide no meaningful security to people who would lose the law's coverage protections. His Medicare and Medicaid proposals would irrevocably transform these programs. His budget and tax proposals would threaten the country's basic health infrastructure as few in living memory have done. One can only hope that if elected President, Romney would surprise the United States as he did Massachusetts.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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The Shortfalls of "Obamacare"

Gail R. Wilensky, Ph.D.

U.S. health care suffers from three major problems: millions of people go without insurance, health care costs are rising at unaffordable rates, and the quality of care is not what it should be. The Affordable Care Act (ACA) primarily addresses the first — and easiest — of these problems by expanding coverage to a substantial number of the uninsured. Solutions to the other two remain aspirations and promises.

The ACA's primary accomplishment is that approximately 30 million previously uninsured people may end up with coverage — about half with subsidized private coverage purchased in the mostly yet-to-be-formed state insurance exchanges and the other half through Medicaid expansions.

The law's most controversial provision remains the individual mandate, which requires people either to have insurance coverage or to pay a penalty. The objective is to "encourage" people who might have decided not to buy insurance to do so. Unfortunately, the mechanisms put in place may instead encourage people to postpone buying insurance until they're sure it will be needed. Insurers will not be able to refuse coverage to anyone and cannot charge higher rates to people who wait until they clearly need care. The penalty for not having insurance is very small, particularly for younger people with modest incomes. Given the choice, many people may put off buying insurance to save thousands of dollars in premium payments.

A mandate cannot work without a credible threat that noncompliance will be costly. It would have been smarter to mimic Medicare's policies: seniors who don't purchase the voluntary parts of Medicare covering physician services and outpatient prescription drugs during the first year in which they lack comparable coverage must pay a penalty for every month they have gone without coverage whenever they finally do purchase it. This system has produced high rates of Medicare enrollment without creating the firestorm generated by a mandate.

Moreover, although the ACA expands coverage, it ignores the structural problems in the organization and reimbursement of care — a limitation that is disappointing but not surprising: adding more people to the insurance rolls is politically and technically easier than finding a way to ensure that care is effective, high-quality, and affordable for both the recipients and taxpayers.

Despite widespread recognition that fee-for-service reimbursement rewards providers for the quantity and complexity of services

and encourages fragmentation in care delivery, the ACA retains all the predominantly fee-for-service reimbursement strategies currently used in Medicare. Much of the coverage expansion is financed through Medicare budget savings, which are produced by reducing the fees paid by Medicare to institutional providers such as hospitals, home care agencies, and nursing homes — but using the same perverse reimbursement system currently in place. Reducing payments to institutional providers should not be confused with lowering the cost of providing care.

The ACA also provides Medicare "productivity adjustments," which assume that inflation adjustments can be reduced over time because institutions will become more productive, whether or not hospitals and other providers actually find ways to increase their productivity. Unless these institutions find ways to reduce costs, lower Medicare reimbursements will force providers to bargain for higher payments from private insurers. And eventually, seniors' access to services will be threatened. The Medicare actuary expects that 15% of institutional providers will lose money on their Medicare business by 2019, and the proportion will increase to 25% by 2030 — a situation that he calls unsustainable.[1]

Most troubling, the ACA contains no reform of the way physicians are paid, which is the most dysfunctional part of the Medicare program.[2] Through the Resource-Based Relative Value Scale, physicians are reimbursed on the basis of more than 8000 different service codes, and payment for each physician service is reduced whenever aggregate spending on physician services exceeds a prespecified limit. This system rewards the provision of highly reimbursed services without consideration of whether clinicians are providing low-cost, high-value care for patients. Given physicians' key role in providing patient care, it's impossible to imagine a reformed delivery system without a more rational way of paying physicians — one that encourages and rewards them for providing clinically appropriate care efficiently.

Some modest payment reforms, such as value-based purchasing and accountable care organizations (ACOs), are included in the legislation. Value-based payment bonuses are being phased in for hospitals and nursing homes in 2012 and 2013 and for physicians starting in 2016. In principle, tying payment to quality indicators could promote greater quality and efficiency, but the bonus payments are very modest, which reduces the chances that clinical and institutional behavior will be substantially affected.

ACOs allow hospitals and physicians who are not formally affiliated with each other to work together and share savings. It might have made more sense to pursue this model as a pilot project, since there are many uncertainties about how these organizations should be structured and whether they will produce the hoped-for outcomes.

Most of the payment- and delivery-system reforms in the ACA are part of pilot projects being initiated by the Center for Medicare and Medicaid Innovation (CMMI), a unit of the Centers for Medicare and Medicaid Services. CMMI initiatives include strategies for promoting primary care, as well as bundled-payment initiatives in which a single payment is made to cover more of the services delivered in an episode of care. Unfortunately and inexplicably, none of the initiatives focus on alternative reimbursement arrangements for physicians separate from institutional payments or on ways to promote the formation of multispecialty group practices, a known strategy for producing high-quality care.[3]

Pilot projects may seem like an attractive way to try out innovative ideas, but they have not led to much change in Medicare policy. Successful pilots may need to be repeated on a larger scale to see if the results are scalable and replicable — all of which takes time. The sense of urgency that should surround these activities has not seemed to be present thus far.

Finally, as Medicare has since its inception, the ACA focuses all its pressure to reduce spending and improve quality of care on clinicians and institutional providers through regulatory means, rather than trying to harness market forces. If the envisioned spending reductions don't materialize, the ACA authorizes an Independent Payment Advisory Board (IPAB) to reduce payments to clinicians and institutions until the desired spending levels are achieved. Although Congress can override the IPAB's recommendations, it can do so only if it acts within a limited time and comes up with comparable savings.

Some supporters of the ACA characterize it as "market-friendly" — presumably because it encourages exploration of a reimbursement system with better incentives than the current one — but they fundamentally misunderstand what it takes to be market-friendly.[4] Having Medicare choose which pilot project should become the law of the land or which bundled-payment strategy should be used to pay

for services does not bring market forces into play.

What is needed are reforms that create clear financial incentives that promote value over volume, with active engagement by both consumers and the health care sector. Market-friendly reforms require empowering individuals, armed with good information and nondistorting subsidies, to choose the type of Medicare delivery system they want. Being market-friendly means allowing seniors to buy more expensive plans if they wish, by paying the extra cost out of pocket, or to buy coverage in health plans with more tightly structured delivery systems at lower prices if that's what suits them. If market-friendly Medicare reform is your aim, a good place to look is the plan proposed by Senator Ron Wyden (D-OR) and Representative (and vice-presidential candidate) Paul Ryan (R-WI) — not the ACA.[5]

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From Project HOPE, Bethesda, MD.

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HISTORY OF MEDICINE

Reform, Regulation, and Pharmaceuticals — The Kefauver–Harris Amendments at 50

Jeremy A. Greene, M.D., Ph.D., and Scott H. Podolsky, M.D.

Fifty years ago this month, President John F. Kennedy signed into law the Kefauver–Harris Amendments to the Federal Food, Drug, and Cosmetic Act (see photo). With the stroke of a pen, a threadbare Food and Drug Administration (FDA) was given the authority to require proof of efficacy (rather than just safety) before approving a new drug — a move that laid the groundwork for the phased system of clinical trials that has since served as the infrastructure for the production of knowledge about therapeutics in this country. We often remember the Kefauver–Harris Amendments for the thalidomide scandal that drove their passage in 1962. But there is much we have collectively forgotten about Senator Estes Kefauver (D-TN) and his hearings on administered prices in the drug industry. Many parts of the bill left on Congress's cutting-room floor in 1962 — and left out of our memories since — have not disappeared but continue to confront those who would ensure access to innovative, safe, efficacious, and affordable therapeutics.

By the time Kefauver began his investigation into the pharmaceutical industry in the late 1950s, the escalating expense of lifesaving prescription drugs was illustrating that the free-market approach to medical innovation had costs as well as benefits. From the development of insulin in the 1920s, through the "wonder drug" revolutions of sulfa drugs, steroids, antibiotics, tranquilizers, antipsychotics, and cardiovascular drugs in the ensuing decades, the American pharmaceutical industry had come to play a dominant role in the public understanding of medical science, the economics of patient care, and the rising politics of consumerism. For Kefauver, the "captivity" of the prescription-drug consumer in the face of price gouging and dubious claims of efficacy underscored the need for the state to ensure that innovative industries worked to the benefit of the average American.

President John F. Kennedy Signing the 1962 Kefauver–Harris Amendments.

After 17 months of hearings, in which pharmaceutical executives were openly berated for profiteering and doctors were portrayed as dupes of pharmaceutical