

2017 Presages Dramatic Change For Federal Health Care Policies

Republicans Are Likely to Face Hiccups Along the Way

Stephen Barlas

Donald Trump's election as president poses a real challenge to elements of the U.S. health care policy framework. But it is not yet clear whether the changes will reach seismic proportions or resemble ripples in a pond. Despite repeated statements during the campaign that he would repeal Obamacare immediately upon taking office, the president-elect said a few days after his election, once he had chatted with President Barack Obama, that he wants to keep a couple of its key reforms, such as prohibiting insurance companies from discriminating based on existing illnesses.

Trump will have a strong ally in congressional Republicans, who have a much broader, more complete agenda that includes important changes to Medicare and Medicaid as well as a restructuring of health insurance. Depending on the extent to which those changes morph into law, the "new order" will likely affect every corner of health care, from hospitals to physicians to all sectors of the pharmaceutical industry.

The pharmaceutical industry, theoretically, has a lot at stake, having drawn Trump's reproach during the campaign. For example, at a March GOP primary debate in Miami, Trump said, "They have a fantastic lobby. They take care of all of the senators, the congressmen." That sounded as if it were part criticism and part compliment. During the campaign, he supported letting Medicare negotiate drug prices with pharmaceutical companies, anathema to the industry. He also blessed importation of drugs from abroad, also condemned by the industry.

Trump's presidential campaign website appears to send veiled warnings to the industry. It includes, in the same paragraph, these statements: "Though the pharmaceutical industry is in the private sector, drug companies provide a public service," and "Congress will need the courage to step away from the special interests and do what is right for America."¹ If Trump takes on the pharmaceutical industry, he will find willing allies among the Democrats. At a meeting with reporters on November 17, Senator Bernie Sanders (I-Vermont), who caucuses with the Democrats, argued that he and Trump could forge a common cause on drug pricing.

In September 2015, Sanders introduced legislation (S. 2023) called the Prescription Drug Affordability Act.² It would make numerous changes, such as allowing Medicare to negotiate lower drug prices in Medicare Part D, accelerating closure of the Part D "doughnut hole," requiring drug companies to issue additional rebates under various circumstances, and more. However, that

bill never received a hearing in the Senate Finance Committee, despite high-visibility hearings in both the House and Senate during 2016 that featured drug-pricing horror stories. Senator Amy Klobuchar (D-Minnesota) introduced a narrower bill (S. 31) authorizing Medicare to deal directly with drug companies on price.³ That bill also went nowhere. Neither Sanders' nor Klobuchar's press offices responded to requests concerning the senators' chances of enlisting Trump's support for their efforts in 2017.

Some of Trump's promises and threats will become history once he occupies the White House; perhaps some already have. Mary Jo Carden, Vice President of Government and Pharmacy Affairs for the Academy of Managed Care Pharmacy (AMCP), says Trump appeared to backtrack during the campaign on his support for direct negotiation between Medicare and drug companies, morphing from that position to one supporting importation of foreign drugs. The AMCP opposes direct negotiation by the government. "But drug prices are still an issue on American minds," Carden states. She believes that value-based purchasing of drugs is more likely to be the avenue that Congress and the Trump administration take to ease the cost of specialty drugs to payers such as Medicare, Medicaid, and hospitals.

Pharmaceutical companies generally don't have a problem with value-based pricing, as long as it conforms to their formula. They have strongly opposed the work done by the Institute for Clinical and Economic Review (ICER), which has published a series of monographs estimating what a reasonable price would be for high-profile drugs such as sofosbuvir (Sovaldi, Gilead Sciences) and the proprotein convertase subtilisin/kexin type 9 inhibitors. "The reason we oppose the ICER methodology is because it does not give enough weight to patient experience," one industry insider explains. "We do believe we need as an industry to bring greater evidence to payers to demonstrate they are getting value."

With a view toward congressional legislative efforts on drug pricing in 2017, the drug industry is backing an ICER rival called the Innovation and Value Initiative, which is a new program of Precision Health Economics, a research consulting firm to the health care industry. Its website states: "Our view is that ICER currently emphasizes a short-term budget impact approach based on concepts of affordability. Our research will focus more on the longer term, looking at health care spending as an investment in the vitality of the system as well its cost."⁴

The Future of the PPACA

For Trump and congressional Republicans, the marquee issue, of course, is "repeal and replacement" of the Patient Protection and Affordable Care Act (PPACA) insurance market-



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place, where more than 20 million individuals and employees of small businesses not covered by employer health care have been able to obtain insurance. The majority of those individuals are in the 31 states that have expanded their Medicaid programs. About 80% of the policies purchased by individuals (outside of Medicaid) are heavily subsidized by the federal government. Trump and GOP allies have promised immediate repeal, though they haven't laid out a replacement except to endorse some general solutions such as allowing consumers to cross state lines to buy insurance policies and greater access to health savings accounts (HSAs).

The blueprint for repeal of some key elements of the PPACA is already in place. Last year Congress passed a budget reconciliation bill (H.R. 3762) that annulled key portions of the exchanges, such as the subsidies, the requirement to buy insurance, and the Medicaid expansion, which is financed up to 90% until 2020 by the federal government.⁵ There was a transition period of two years before the disappearance of the PPACA marketplaces as presently constituted. That would give policy-holders and insurance companies a chance to adjust to the changes, which would likely cause a mass exodus from marketplace policies both by consumers and insurance companies. President Obama vetoed that bill.

But the provisions of H.R. 3762 are likely to be the starting and perhaps ending point for a repeal bill in 2017. Unlike most bills, a budget reconciliation bill needs only 50 votes to pass the Senate, not 60. There will be 52 GOP members in the Senate in 2017. House passage of a bill such as H.R. 3762 in 2017 is a foregone conclusion. But a bill like H.R. 3762 cannot eliminate all aspects of the PPACA exchanges, just those dealing directly with federal spending and taxes. So that legislation can eliminate tax penalties on those not buying policies (i.e., the individual mandate) and subsidies for 80% of policy-holders.

Though a successor to H.R. 3762 could pass Congress quickly and receive President Trump's signature, that will not happen immediately. Trump has already said that President Obama convinced him to keep the requirement that insurance companies not discriminate in terms of premiums charged to people with pre-existing conditions. He also wants to allow adults 26 years of age or younger to stay on their parents' policies. The GOP will have to come up with some workarounds to last year's bill to accommodate Trump's statements (unless he repudiates them).

Negotiations between the congressional GOP and the Trump White House should be relatively smooth given Trump's appointment of Representative Tom Price, MD (R-Georgia), to be Secretary of the Department of Health and Human Services. Dr. Price was chairman of the House Budget Committee and a senior member of the Health Subcommittee in Ways and Means. An orthopedic surgeon, he has deep knowledge of federal health programs and was a leading theoretician for the House GOP in its drive to end the PPACA and reform Medicare and Medicaid.

"It's simply too soon to respond to anything that may or may not be proposed," says Kristine Grow, Senior Vice President for America's Health Insurance Plans, the health insurance industry's lobbying group. But her comments indicate the insurance industry's desire to keep all the facets of current PPACA policies. "The demands of consumers haven't changed,"

she states. "They want affordable coverage, the control to choose a plan that best fits them, high-quality care that gets them well when they're sick and keeps them well when they're healthy, and financial protection, peace of mind, and value that insurance provides."

Trump and other Republicans have some of the same ideas for the "replace" part of PPACA elimination. House Speaker Paul Ryan (R-Wisconsin) headed an effort in 2016 to produce a game plan called "A Better Way" for changes to federal health plans.⁶ Trump's transition website echoes many of these GOP ideas. A bushel of the prescriptions are long-term Republican tenets, such as expansion of HSAs tied to high-deductible health insurance plans. The Ryan blueprint argues that the PPACA put a number of roadblocks in the way of HSAs that should be ditched. Rather than subsidizing individual health insurance plans, as the PPACA does, the GOP would provide a universal, advanceable, refundable tax credit for individuals and families. The new fixed credit would be large enough to purchase the typical pre-PPACA health insurance plan. The GOP "Better Way" also advocates allowing consumers to buy insurance across states lines, a longtime Republican concept that Democrats have shunned whenever it was broached.

What May Await Medicare

Changes to Medicare and Medicaid are also in the offing. "A Better Way" includes a number of prescriptions for change in the Medicare Part B physician care, Part C Medicare Advantage, and Part D outpatient drug benefit programs. President-elect Trump said during the campaign that he didn't want to touch Medicare. Still, no one has ever accused him of consistency, as he has shown by pledging adherence to a couple of PPACA precepts.

Here again, expect the GOP members of Congress to take the lead. "A Better Way" strategy would bend Medicare policies away from fee-for-service toward both a premium-support program and Medicare Advantage, the health maintenance organization option that has been around since 2003. In premium support, a senior would get a fixed amount with which to buy an insurance plan on the private market. Republicans think Medicare Advantage has more cost savings built in than fee-for-service, and from the senior's perspective has the advantage of an annual ceiling on out-of-pocket costs, which Part B plans do not have. Hardly anyone disputes that Medicare costs are unsustainable over the long term. The Congressional Budget Office estimates the Part A Hospital Insurance Trust Fund will be insolvent in 2026.

The Medicare Part D outpatient drug benefit, established in 2003, has been something of a roaring success. But like the PPACA marketplace plans and state Medicaid plans, it has been hurt by high drug prices. Trump has advocated for direct negotiations between the Medicare program and drug companies. But when that kind of proposal has come up in Congress in past years, Republicans and pharmaceutical companies have opposed it. The industry insider says that Part D plans negotiate rebates from drug companies on the order of 20% off the list price, so negotiation takes place in the program already. Moreover, Medicare has no desire to establish a national formulary. "Is Medicare going to deny every Part D

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plan the right to carry a specific drug on their formulary?” he asks. “Formulary setting is not their expertise.”

The Prospects for Medicaid

Republicans want to convert Medicaid into a block grant program in which states would have more freedom to determine what they cover, including which drugs they pay for.⁶ Trump has nominated a true believer on behalf of Medicaid reform to head the Centers for Medicare and Medicaid Services (CMS). Seema Verma was one of the architects of Indiana’s Healthy Indiana Plan (HIP) 2.0, which opened for business in February 2015. It won a Medicaid waiver from the Obama administration, which enabled Medicaid expansion to Indiana’s higher-income poor. Recipients are required to make monthly payments—equal to 2% of income—to an HSA in exchange for a more expansive HIP Plus benefit package. Residents with incomes under 100% of the poverty line who cannot make those contributions are placed in a HIP Basic plan with limited benefits. A study by Lewin Associates based on one year of the plan’s operation found that upwards of 70% of members of HIP Plus and Basic were satisfied with their coverage.

However, Verma’s work with both Kentucky and Ohio in 2016 failed to gain a Medicaid exemption for either of those two states. Verma is the owner of a health care consulting company in Indianapolis. Her general philosophy fits in with the beliefs of Dr. Price and other Republican legislators that federal dollars can be saved by turning Medicaid into a block grant program without sacrificing access to care, all by turning Medicaid into a managed care program where members have what Vice President-elect and former Indiana Governor Mike Pence calls “skin in the game.”

Some of the 31 state Medicaid expansions created under the PPACA may be jeopardized if federal subsidies are ended. The 100% of new enrollee costs the CMS is paying today in expansion states drops in stages to 90% by 2020. Ending those subsidies, which may force states to drop a large percentage of the 12 million people added under the expansion, would definitely hurt hospitals. For hospitals, the majority of those 12 million were formerly nonpaying customers. Pharmaceutical companies could be hurt, too, but not all of them. The impact would depend on the extent of the rebate a drug company is paying, with those paying high rebates not being affected as much. Companies paying the highest rebates make less money than drug companies paying smaller rebates. Generally, older drugs pay higher rebates. “Our new net Medicaid sales are very low,” reports one industry executive from a major manufacturer that is among those that would not suffer, sales-wise, from the end of the expansion.

The Medicaid rebate structure is as arcane as any policy in Washington. It has been around for decades and is ripe for reform, which may be on the agenda for 2017 if the National Association of Medicaid Directors (NAMD) and others, perhaps even the pharmaceutical industry, have their way. Last March the NAMD sent a letter to the leaders of the Senate Finance Committee saying: “We continue to believe that the policy levers available to state Medicaid programs are not designed to address fundamental sustainability issues posed by high-cost, high-impact products. Currently, there is little insight into how pharmaceutical manufacturers price new therapies entering the market and, more specifically, the potential value for Medicaid populations.”⁷

Possible Changes at the FDA

Drug companies argue that their prices reflect research and development costs, which are unnecessarily high because of Food and Drug Administration (FDA) approval requirements. The Trump campaign website seems to agree with this sentiment. It supports this step: “Remove barriers to entry into free markets for drug providers that offer safe, reliable, and cheaper products.”¹ That may or may not be a call to change FDA rules. If it is, it fits hand-in-glove with the congressional GOP’s “A Better Way,” which says: “Translating research into therapies is an incredibly risky, cumbersome, and expensive process. ... We must improve how new treatments are developed, tested, and ultimately approved by the FDA. Our plan would streamline clinical trials and modernize data collection activities by cutting through red tape, using drug development tools like biomarkers and patient-reported outcomes, and harnessing the wealth of information in electronic health records and other troves of real-world data.”⁶

There is some regulatory relief in the 21st Century Cures bill signed by President Obama in December 2016. But those measures were probably just a down payment on a much broader attempt to eliminate regulatory barriers during reauthorization of the Prescription Drug User Fee Act (PDUFA), which expires at the end of September 2017. The PDUFA sets the fees that drug companies pay the FDA to fund staff working on drug approvals. It also contains FDA commitments on the speed of application review and policy changes to the approval process. User fees in fiscal year (FY) 2016 stood at \$851 million—about two-thirds of the FDA’s FY 2016 budget for human drugs, which is \$1.4 billion. The FDA has already met with interested parties to gather input on how it can improve its approval process in the context of the PDUFA reauthorization Congress is expected to pass in September 2017.

In July, the FDA released its PDUFA VI Goals Letter for FYs 2018 to 2022.⁸ It includes commitments in areas such as additional staffing and post-market surveillance, which are of prime importance to various pharmaceutical sectors. In terms of staffing, the agency has committed, for example, to establishing a dedicated unit within the Office of Medical Products and Tobacco charged with the continuous recruiting, staffing, and retention of scientific, technical, and professional staff for reviewing human drug applications. The agency sets specific numbers for professional hires in each of the five years covered by the commitment letter.

In another area, the FDA promises to buff up its Sentinel System, which looks at adverse reactions to drugs once they enter the market. Improving the Sentinel System is a top priority of pharmacy groups. The FDA says it will “use user fee funds to conduct a series of activities to systematically implement and integrate Sentinel in FDA pharmacovigilance practices. These activities will involve augmenting the quality and quantity of data available through the Sentinel System, improving methods for determining when and how that data is utilized, and comprehensive training of review staff on the use of Sentinel.”

The Sentinel System of post-market surveillance was authorized by Congress in 2008, remained a pilot program until 2014, and has only recently blossomed into a wider-ranging drug adverse effects monitoring system. It relies on the FDA’s

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database of individuals' medical claims and looks for abnormalities rather than depending, as the FDA has for decades, on physicians and drug companies voluntarily reporting problems caused by drugs. Pharmacy groups sent a letter to the FDA after its PDUFA VI commitment letter was published saying: "Our organizations commend the FDA for its commitment to develop a more robust and rigorous Sentinel program. Our organizations agree that performing active, diligent post-marketing pharmacovigilance is critical for proactively identifying possible areas of concern for medications and ensuring the ongoing safety of medications post-approval."

Antitrust Concerns About Health Care

Elsewhere in the bureaucracy, the Justice Department looms large because of its policing of mergers and other antitrust issues, such as pricing agreements between pharmacy benefit managers (PBMs) and drug manufacturers. David Balto, a Washington attorney who specializes in health care issues, doesn't expect a Trump Justice Department to take a much different approach to mergers than the Obama Justice Department, which contested the Aetna/Humana and Anthem/Cigna health care merger proposals. What may get added scrutiny are complaints from pharmacies alleging predatory practices by PBMs. Past administrations have pursued such allegations. For example, Novartis and AstraZeneca have agreed to pay fines and penalties to settle allegations that they had offered a *quid pro quo* to PBMs for preferred formulary status.

Balto notes that Representative Tom Marino (R-Pennsylvania) is taking over as chairman of the House Judiciary Committee's antitrust subcommittee. "He is a foe of PBMs," Balto explains. Marino introduced a bill called the Preserving Our Hometown Independent Pharmacies Act in past Congresses (though not in the last one) that would have exempted independent drugstores from antitrust laws prohibiting them from banding together to buy medication.⁹ Community pharmacies will also have a strong supporter in Senator Jeff Sessions (R-Alabama), nominated to be the next Attorney General. "Sessions has advocated allowing pharmacies to collectively negotiate with PBMs," Balto adds.

Expect the Republican Congress to begin reining in health care spending in 2017 and laying out a broad selection of changes, many of which won't happen overnight. This time, no threatened presidential veto will stand in their way. None of the GOP reforms are likely to make any sector within the pharmaceutical industry jump for joy. But if it's any consolation, hospitals, physicians, and other associated health care sectors won't be partying either.

REFERENCES

1. Donald J. Trump for President. Healthcare reform to make America great again. Available at: www.donaldjtrump.com/positions/healthcare-reform. Accessed November 29, 2016.
2. Sanders B. S.2023—Prescription Drug Affordability Act of 2015. 114th Congress (2015–2016). September 10, 2015. Available at: www.congress.gov/bill/114th-congress/senate-bill/2023/text. Accessed November 29, 2016.
3. Klobuchar A. S.31—Medicare Prescription Drug Price Negotiation Act of 2015. 114th Congress (2015–2016). January 6, 2015. Available at: www.congress.gov/bill/114th-congress/senate-bill/31/text. Accessed November 29, 2016.
4. Innovation and Value Initiative. How is IVI related to organizations like ICER? 2016. Available at: <http://thevalueinitiative.org/search/section/general/string/icer>. Accessed November 29, 2016.
5. Price T. H.R.3762—To provide for reconciliation pursuant to Section 2002 of the concurrent resolution on the budget for fiscal year 2016. 114th Congress (2015–2016). February 2, 2016. Available at: www.congress.gov/bill/114th-congress/house-bill/3762. Accessed November 29, 2016.
6. A Better Way. Health care. June 22, 2016. Available at: http://abetterway.speaker.gov/_assets/pdf/ABetterWay-HealthCare-PolicyPaper.pdf. Accessed November 29, 2016.
7. Salo M. Letter to Senators Ron Wyden and Charles Grassley, Senate Finance Committee. National Association of Medicaid Directors. March 4, 2016. Available at: <http://medicaiddirectors.org/wp-content/uploads/2016/03/NAMD-Response-to-SFC-on-drug-value-03-04-16.pdf>. Accessed November 30, 2016.
8. Food and Drug Administration. PDUFA reauthorization performance goals and procedures, fiscal years 2018 through 2022. Available at: www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf. Accessed November 30, 2016.
9. Marino T. H.R.1188—Preserving Our Hometown Independent Pharmacies Act of 2013. 113th Congress (2013–2014). March 14, 2013. Available at: www.congress.gov/bill/113th-congress/house-bill/1188/cosponsors. Accessed November 30, 2016. ■