HEALTH CARE POLICY OUTLOOK FOR 2016

In 2016, the Affordable Care Act will continue to be a contentious issue involving opposing legislative efforts and presidential debates. Clients and industries affected by health care regulations can, however, expect the emphasis of this debate to shift this year. Brownstein Hyatt Farber Schreck's Health Care Outlook for 2016 provides insight on what to expect.

Topics:

Presidential Campaigns; Candidates' Positions on Health Care System

Since the presidential election of 2012, many of the major provisions of the Affordable Care Act (ACA) have taken effect. Of the people who were not covered by health insurance when President Obama was elected to his second term, an estimated 20 million now have coverage through the ACA, either through Medicaid or through state exchanges. The positions of the two parties on the ACA are well known. The administration will likely spend 2016 defending "Obamacare" and marketing its accomplishments so that continuing and expanding the ACA will be part of the message of the Democratic candidates for president. Conversely, Republican candidates will likely endorse the repeal efforts and some of the replacement proposals introduced by the Republican-led Congress. Currently, the leading candidates in both parties have started to outline their health care positions as they prepare for debates in the 2016 election.

Both former Secretary of State Hillary Clinton and Sen. Bernie Sanders have made health care a central component of their campaigns early. Secretary Clinton released a platform statement regarding health care affordability and prescription drugs in September 2015. In it she details several proposals, including placing monthly caps on prescription drug copays and legalizing the importation of prescription drugs from Canada. Sen. Sanders also has discussed affordability of health care and is an adamant proponent of a single-payer health care system like Medicare to serve all Americans.

Both candidates have also raised the issue of prescription drug pricing, with Sen. Sanders long championing his "Prescription Drug Affordability Act" and the "Medicaid Generic Drug Price Fairness Act," which would require Medicaid rebates for generic drugs whose prices rise faster than the rate of inflation. Secretary Clinton also has criticized the pharmaceutical industry for restricting competition in the market, which she believes leads to actions like that of Turing Pharmaceuticals when it increased the price of one of its drugs by 5,000 percent.

Of the Republican candidates, many have been focusing their health care policies around ideas for dismantling Obamacare. Donald Trump, the Republican frontrunner, has not released a specific health care policy plan, but has made several statements both in the campaign and historically that would suggest that he supports "universal" health care. He believes that opening the insurance market to allow for more competition by selling plans across state lines would result in millions more people being insured. In 2000, Trump authored a book, *The America We Deserve*, and suggested in it that the Federal Employees Health Benefits Program could serve as a model of a centralized health care system that provides choice and is market-based. Breaking from the traditional Republican support of the market-based approach of the Medicare Part D program, Trump has signaled support for negotiating the price of prescription drugs, claiming it would result in $300 billion annual savings. However, his statements did not specifically reflect support for the government negotiating rates. Rather, he signaled his disapproval of drug companies, especially those engaged in "inversions," merging with smaller, foreign companies and relocating their headquarters overseas, thereby paying lower corporate taxes.

Ted Cruz, who has been seen as Trump's closest opponent in the polls, has said that he would not repeal Obamacare on his first day in office because he would not have the constitutional authority to do so. However, Cruz has led the charge to repeal Obamacare in the U.S. Senate, and has cosponsored the "Health Care Choice Act" (S. 647) as an alternative. This legislation repeals Title I of the ACA, which includes the law's insurance mandates, and also amends the Public Health Service Act to allow for insurance policies to be sold across state lines provided that the plan and insurer comply with basic requirements.

Of the "establishment candidates" in the race, Jeb Bush and Marco Rubio have revealed their plans for replacing Obamacare. Bush unveiled a plan that included a transition plan for the millions receiving coverage under Obamacare into private plans and gives states more flexibility in designing Medicaid programs. The plan calls for higher tax credits for individuals choosing "catastrophic" health coverage coupled with higher limits on contributions to health savings accounts for out-of-pocket medical expenses. Rubio has also called for advanceable, refundable tax credits to enable individuals to purchase health insurance and transition Medicare to a block grant, premium support system.

The Cost of Prescription Drugs

In 2015, the administration held a summit on the rising costs of prescription drugs, congressional Democrats wrote letters to Republican committee chairs requesting hearings, and the Senate Aging

Committee conducted oversight investigations that targeted the rate of price increases for both branded and generic pharmaceuticals. As the issue begins to poll higher and perhaps become one of the priorities of American voters, candidates also are taking positions and elevating the issue. Yet, the question remains what, if anything, can Congress or the administration do about the issue?

Health and Human Services (HHS) has taken the initial step to inject transparency into the debate by publishing the "dashboard" detailing the highest-cost drugs in Medicare, and it plans to release the data for Medicaid in 2016.

The proposals most likely to be considered by Congress to address this issue in 2016 seem to focus on speeding up approvals for generic drugs to compete with off-patent branded medications that have been targeted for substantial price increases by companies like Valeant and Turing. This approach has bipartisan support and has met with little resistance, even from Pharmaceutical Research and Manufacturers of America (PhRMA). Currently, the Food and Drug Administration (FDA) has acknowledged that it has a large backlog of applications for generic drugs, and the nominee for FDA commissioner has said that addressing the backlog will be a priority for the agency.

Additionally, the Centers for Medicare and Medicaid Services (CMS) will likely engage in activities under its jurisdiction to attempt to bring down the cost of prescription drugs by adopting payment-reform demonstrations. In December, a group of senators wrote to CMS Acting Administrator Andy Slavitt to request additional information on how CMS could use the Center for Medicare and Medicaid Innovation (CMMI) "to examine the potential of alternative payment mechanisms, including examining methods to increase use of and access to competitive generic medications, and alternatives to the current 'ASP+6%' model." The letter also asked how CMS could use the comparative-effectiveness information being produced by the Patient Centered Outcomes Research Institute (PCORI) and the Institute for Clinical and Economic Review (ICER) "to improve beneficiary outcomes and lower program spending." The senators questioned how CMS would use its authority to ensure that people in the individual private insurance market have access to prescription drugs. It is likely that the response by CMS to this letter, as well as proposals in the president's budget, will outline the drug-pricing actions that the administration may take in 2016.

The ACA: Repeal or Embrace?

House Republicans, having voted to repeal the ACA 62 times without receiving a sufficient Senate response, finally succeeded with their 63rd vote and sent repeal legislation to the president's desk. Senate Republicans were able to send the legislation to the House because the use of the budget reconciliation process prevented Democrats from launching a filibuster to stop the legislation. The legislation repeals fundamental portions of the ACA, such as the individual mandate, but does not entirely repeal the law because of limitations on the use of the reconciliation process in the Senate.

The president, as expected, quickly vetoed the legislation. The decision whether to attempt to override the president's veto was up to the House because the reconciliation legislation originated in the House. The Republican leadership scheduled the House vote for February 2. The required threshold is that two-thirds of those present and voting support overriding the veto, and the House, by a vote of 241-186, failed to meet that requirement. The legislation, therefore, will not go to the Senate. Even if House Republicans had prevailed, Senate Republicans were not expected to be able to muster enough votes to override the veto. Nevertheless, this vote is significant in the role it plays in electoral politics as Speaker Paul Ryan (R-WI) has set a goal of offering proposals on replacement of the ACA early in the year in order to highlight a distinct difference between the candidates in both parties seeking the presidential nomination.

2016 will be significant in the life of the Affordable Care Act as participating insurers continue to lose money on the newly enrolled. The exchanges set up by the law have been threatened by plans reevaluating their participation. More than half of the 23 insurance co-ops established by the law have closed; many with outstanding debt. CMS has been limited in its risk corridor payments to plans participating in the exchanges, and risk corridors remain an attractive political target for opponents of the law.

Much of premium increases expected for individual plans in 2016 can be attributed to the difficulty insurers have faced in signing up those who are healthy and young and therefore will offset the coverage of older, more costly individuals. This year could see a shift in this demographic makeup as the penalties for individuals increase. For 2016, the penalty under the ACA for failing to obtain essential minimum coverage rises to $695 per adult and $347.50 per child. For families, the penalty is $2,085 or 2.5 percent of family income, whichever is greater. This economic driver could provide the stability the individual exchanges have been seeking; however, the law will continue to be targeted by detractors as the political rhetoric heats up in 2016.

CMS and Reimbursement-Related Activities

Senate Finance Committee's Chronic Care Working Group

Building on the bipartisan "Better Care, Lower Cost Act," a bill introduced in the House and Senate in the 113th Congress, Sens. Johnny Isakson (R-GA) and Ron Wyden (D-OR), the original sponsors of the legislation, along with Sen. Mark Warner (D-VA) and Chairman Orrin Hatch (R-UT), led a working group of senators on the Finance Committee tasked with developing an additional proposal aimed at comprehensively improving health care for Medicare beneficiaries who have multiple chronic conditions. The bipartisan goals of this working group included seeking proposals from stakeholders that would improve care coordination for these beneficiaries, lower costs to Medicare, and improve the outcomes for Medicare beneficiaries with chronic conditions.

Following months of meetings with stakeholders, in December the working group released the "Bipartisan Chronic Care Working Group Policy Options Document," which contains 24 proposals the working group believes have the potential to achieve the goals of the committee and improve care. Among these proposals are recommendations that would increase care in the home setting, including access to hemodialysis in the home; strategies to increase coordination and team-based care for beneficiaries managing multiple chronic conditions; submissions to expand the use of technology for these populations, including the use of telehealth; initiatives that would empower these beneficiaries and their caregivers to have more participation in their care management; and plans to study the impact of medication synchronization and obesity medications on this population.

The most significant outcome of the Policy Options document, in addition to its bipartisan support, is the working group's acknowledgement that while the Congressional Budget Office will determine the impact that these proposals will have on the Medicare program, the working group is committed to producing a bipartisan legislative proposal stemming from this activity. While there is no associated time frame for the consideration of such a proposal, staff has plans to share and shepherd these proposals through the Ways and Means Committee in the House. Many of these proposals are similar to stand-alone House legislation and could therefore receive early support on the House side. The likelihood for legislative movement on these proposals in 2016 will increase as these bicameral talks begin.

Hospital Payment Reforms

Prior to assuming the gavel of the Ways and Means Committee, Chairman Kevin Brady (R-TX) and the health subcommittee were preparing legislation that would include several payment reforms affecting hospitals. With that package said to include a number of legislative provisions that had previously been introduced as part of the committee's broader effort on comprehensive Medicare reform, and with Chairman Brady's ascension to the chair of the full committee, it is likely that these reforms will be an early priority of the committee in 2016.

One of the provisions likely to be included in this package of proposals is a "technical fix" that would exempt hospital outpatient departments currently under construction from the "site-neutral" Medicare payment provision. The bipartisan budget agreement enacted in November (the Bipartisan Budget Act of 2015) included an offset that aligns payment rates for hospital outpatient departments and hospital-owned physician offices. This offset provision is aimed at hospitals that may have been acquiring physician practices and submitting reimbursement claims under the outpatient prospective payment system (OPPS), rather than under the Medicare physician fee schedule, which has lower reimbursement rates.

Existing outpatient departments that are currently billing Medicare are grandfathered under this new provision; however, the provision denies OPPS reimbursement to facilities built or acquired after November 2, 2015, that are not on or within 250 yards of the hospital's main campus. Currently, facilities in planning stages or under construction that do not meet that deadline will not be able to bill under the OPPS. Concerned that there is not enough time to comply with the existing regulation, lawmakers have introduced legislation exempting those buildings currently under construction. While it is unclear what

vehicle could be used for a technical "fix" such as this, the fix seems to be a priority of lawmakers on the Ways and Means Committee, including its new chairman, Kevin Brady.

In late December 2015, the Government Accountability Office (GAO) released a report entitled "Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform." This report was requested by Rep. Jim McDermott, the ranking member on the Ways and Means Subcommittee on Health and a physician. This study examined how consolidation—specifically, the purchasing of physician practices by hospitals—impacts the practice of medicine and overall Medicare spending. GAO's recommendations in the report were to harmonize payments, as enacted in the Bipartisan Budget Act of 2015, between physician practices and hospital outpatient departments.

Rep. McDermott has indicated his desire to hold a hearing on this report early in 2016 to further examine the impact of consolidation in health care. While this report will certainly serve as a foundation of the hearing, it is possible that other entities in the health care marketplace that are experiencing consolidation could also become a target, as the committee seeks to understand the impact of this consolidation on patients and Medicare spending.

FDA-Related Issues

House 21st Century Cures; Senate Innovations for Healthier Americans

In 2015, the House passed the "21st Century Cures Act" (H.R. 6) developed by the Energy and Commerce Committee. With over 350 pages, this legislation is intended to accelerate the drug development and approval process to help find treatments for thousands of diseases, particularly rare and serious diseases. Concurrently, the Senate HELP Committee began developing its related Innovation bill, but a draft was not released to the public. A wide variety of stakeholders presented proposals to Congress and advocated for their inclusion in the House and Senate bills.

As the Cures bill developed in the House, several proposals were offered to incentivize drug development through new or expanded market-exclusivity programs. Ultimately, one such proposal was included in the House-passed bill. It is unclear whether any market-exclusivity provision will be included in the Senate Innovation bill.

The drafting process in the Senate HELP Committee is taking longer than anticipated. One challenge is finding budget "pay-fors" (offsets) in order to avoid adding to the federal debt, as the Cures pay-fors are generally not available to HELP. A key issue is whether, as in the Cures bill, the National Institutes of Health (NIH) will receive mandatory funds in addition to its discretionary appropriations. Another challenge is that the committee hoped to produce a bipartisan bill (as was done in the House with the Cures bill). It can take significant time to determine whether bipartisan consensus can be reached on potentially controversial provisions. If negotiations break down, it is possible that Republicans on the committee will proceed without support from Democrats.

On January 19, Chairman Lamar Alexander (R-TN) announced a plan to move a number of individual health-related bills through the committee, rather than a single package. Three separate markups will be held, one in each of February, March and April. Apparently, there was bipartisan agreement on the list of bills to be marked up in February, but not on the list for the March markup. The list for the April markup has not been announced. It remains possible that, after these markups, a single Innovation package could be assembled and passed by the Senate, setting up negotiations with the House to produce a final version.

Although there is a possibility that various provisions of the Cures/Innovation bills could be enacted in 2016, it seems likely that some of the issues involved will spill over to 2017, when developing and enacting the User Fee legislation will be a priority. The current statutory reauthorization cycle will expire for the Prescription Drug User Fee Act (PDUFA) (innovator prescription drugs/biologics), Medical Device User Fee Amendments (MDUFA) (medical devices), and Biosimilar User Fee Act (BsUFA) (biosimilars) on October 1, 2017. The majority parties in the House and Senate historically have not included controversial provisions in the UFA reauthorization bills because the failure to enact the legislation on time would result in layoffs of FDA employees. The overall situation is therefore challenging for legislative proposals with any degree of controversy—such as proposals on laboratory developed tests (LDTs) and on off-label uses—although such proposals potentially could make progress as separate bills.

Given that any final Cures/Innovation bill would have to be carefully balanced as to pay-fors, Republican priorities and Democratic priorities, and that a similar balancing act will be necessary for the UFA legislation, the question is whether there is sufficient time and energy to enact two separate bills.

Biosimilars

There were important biosimilars-related developments in 2015. The FDA approved the first-ever biosimilar (Zarxio, Sandoz's biosimilar of Amgen's Neupogen). The agency also issued its first denial of a biosimilar application (Hospira / Pfizer's biosimilar of Amgen's Epogen and Janssen's Procrit). The Federal Circuit issued its first decision on the "patent dance" negotiation process (*Amgen v. Sandoz*), and the court in part held that the patent dance is not mandatory. An appeal to the Federal Circuit was filed in a separate but related case (*Amgen v. Apotex*). The FDA issued four final guidance documents and two draft ones, including draft guidance on nonproprietary naming, which was criticized by the Federal Trade Commission (FTC). On the reimbursement front, CMS issued a final rule on Medicare Part B to reimburse all biosimilars of a given reference product at the same rate, notwithstanding that a bipartisan group of House members sent a letter to CMS criticizing the proposed rule.

The new year promises to be just as active on issues related to biosimilars. In 2016, the FDA is expected to issue biosimilar guidance on demonstrating interchangeability and on labeling, both of which may be controversial. An important labeling issue is that the approved labeling for the first biosimilar (Zarxio) does not provide any notice that it is a biosimilar. Moreover, the labeling is virtually identical to the reference product's labeling. As to interchangeability, an important issue is whether, with respect to reference products with multiple approved indications, the FDA will permit a biosimilar to be marketed as

interchangeable for a particular indication of the reference product when the biosimilar has not been demonstrated to be interchangeable for all indications of the reference product. The FDA is also expected to issue guidance on statistical evidence, which will help clarify the evidence needed for approval. The debate over the "naming" draft guidance will continue, and the FDA may issue final guidance on it. Per report language for the omnibus appropriations bill enacted in December, the FDA must submit to Congress, by mid-February, a timeline for finalizing pending guidance and regulations.

Regarding patent-dance litigation, the Federal Circuit will likely decide *Amgen v. Apotex*, which will clarify whether a biosimilar company that has followed the patent-dance process is, after approval of the biosimilar, required to give the reference product sponsor a notice of at least 180 days before beginning to market the biosimilar. The next question will be whether the patent-dance cases decided by the Federal Circuit will be appealed to the Supreme Court. Meanwhile, five biosimilar applications are publicly known to be pending at the FDA, and the BsUFA performance goal of approving or denying a majority of such applications within 10 months of receipt has not been met for three of these applications. If most of these pending applications are not approved by the FDA in 2016, it will raise significant issues about when the biosimilars program will meet expectations.

Medical Devices

In 2015, various private organizations released legislative proposals on the regulation of laboratory developed tests (LDTs), which took different approaches as to the role of the FDA. The House Energy and Commerce Committee released a discussion draft of a bill that would create a new regulatory program for LDTs—separate from devices—and would create a new center within the FDA to administer that program. The omnibus appropriations legislation enacted in December suspended the device tax under the Affordable Care Act for two years.

In 2016, the debate over reforming the LDT regulatory process will continue in Congress. The guidance documents the FDA has scheduled for release in 2016 include final guidance on regulating LDTs as medical devices. On Capitol Hill, however, the chairman of the Senate HELP Committee plans to try to prevent the agency from following the LDT guidance and may try to block it using procedures under the Congressional Review Act (which involve a resolution of disapproval). The FDA has also scheduled the release of draft guidance on 510(k) modifications, on the 510(k) third party review program, and on companion diagnostics co-development. The recent draft guidance on notifying the public of clinical-use "emerging signals" will likely be controversial because the notifications can be based on information that is not yet fully validated or confirmed. The FDA has also announced that its priorities for 2016 include partnering with patients and promoting a culture of quality and organizational excellence.

Other FDA-Related Matters

Early in 2016, Dr. Robert Califf is expected to be confirmed as FDA commissioner by the Senate, although several senators have placed holds on the nomination. There likely will be further developments on the issue of manufacturers' rights to make statements about off-label uses of their products. The FDA may issue new draft guidance on unapproved uses of already-approved products.

This guidance—originally scheduled for 2015—may address some of the issues involved in the recent litigation concerning off-label uses (the *Amarin* and *Pacira* cases). Regarding generic drugs and (b)(2) drugs, the comment period on the Hatch-Waxman proposed rule closed in June 2015, and it is possible that the FDA could submit a final rule to the Office of Management and Budget in 2016. Beginning on March 1, the requirements of the Drug Supply Chain Security Act (track and trace) will apply to dispensers (pharmacies).

Other Health-Related Topics

Mental Health Legislation

The House Energy and Commerce Committee has expressed interest in extending the discussion on legislation sponsored by Rep. Tim Murphy (R-Pa.) that would address mental health needs. Though this legislation has a number of bipartisan co-sponsors, the bill was strongly debated in the subcommittee in 2015 and did not receive much support from Democrats on passage. In the Senate there are several potential legislative vehicles that address mental health issues that could result in a combination in order to match the efforts of the House. It is expected that the recent controversy over gun control measures announced by the administration, coupled with the expectation that mental health legislation should address the requirement for a mental health component for gun purchases, will continue to complicate this debate.

Trans-Pacific Partnership

After five years of negotiations, a deal has finally been reached on the Trans-Pacific Partnership Agreement (TPP). While a number of issues were addressed in this 12-country trade agreement, a hotly debated topic was intellectual property protections for biologics. In the United States, the Biologics Price Competition and Innovation Act of 2009 (BPCIA) grants 12 years of data protection for innovator biologics. Other partners in the agreement, especially Australia, do not provide the same level of regulatory protection. In the TPP negotiations, many members of Congress as well as the biopharmaceutical industry requested that U.S. negotiators hold firm and maintain consistent policy with U.S. law. However, in the final agreement, the negotiating countries reached a “compromise” involving a period of data protection of five years, with potentially an additional period of up to three years of monitoring. While the agreement will not impact the data protection period in the United States, there is concern that holding those countries in the TPP to a different standard, the level of global investment could fall and the development could slow in areas of high therapeutic need.

The administration has targeted early 2016 for approval of what it considers to be the most progressive trade deal in history. They believe that they have achieved several of their policy goals through the TPP, including reducing tariffs on U.S. goods being exported to these countries and requiring more on environmental and labor protections in a rapidly expanding region of the world. However, many in Congress have signaled skepticism and even opposition to the agreement, making passage early in

2016 questionable. Should this issue stretch into the fall, it will most certainly be an issue President Obama seeks to achieve during a lame duck session.

Veterans Health Care

In 2015, the Department of Veterans Affairs sent a plan to Congress to establish the New Veterans Choice Program, or New VCP, designed to combine the department's community health care programs, including the newly established VA Choice program, into one program that would improve the delivery of community-based care. The goal of the plan is to improve veterans' access and eligibility for care received outside of the traditional VA facilities, and better coordinate the networks and providers of that care. This sweeping new plan will add an additional $1 billion to $2.4 billion in implementation costs, in addition to the almost $7 billion per year that the recently enacted VA Choice program costs to run current non-VA community-based care. Also, the VA anticipates expanding emergency and urgent care services as well, costing an additional $2 billion.

The VA cannot implement this plan through regulatory authority. Many of the proposals outlined in the report will require action on the part of Congress. At least 10 pieces of legislation currently introduced would begin implementation of this proposal, while amendments to existing law and additional legislative "fixes" may also be a necessary initial step. It is unclear whether this large legislative plan will see full realization in the shortened 2016 legislative session; however, comments from members of the House and Senate Veterans Affairs Committees indicate general support for the goals of the proposal to ensure that veterans receive quality care in a timely manner.

The "Moonshot" to Cure Cancer

In October, a group calling itself the National Immunotherapy Coalition met with Vice President Joe Biden to outline their mission to harness the newest technologies and combinations of therapies with the potential to treat, cure and eradicate cancer. This group, led by billionaire Patrick Soon-Shiong, included major pharmaceutical companies invested in cancer research, including Amgen, Celgene, and GlaxoSmithKline, biotech companies including those led by Soon-Shiong, oncology researchers and physicians, and large insurers and self-insured companies like Blue Cross and Bank of America was first to outline a strategy now commonly referred to as the Cancer Moonshot 2020. This collaboration will enable large scale testing of new combination therapy protocols by identifying and overcoming regulatory obstacles that currently disrupt the creation of cancer cures.

In January at his State of the Union Address, President Obama tasked the vice president with leading a governmental task force to enhance the efforts of the private sector. Convening this group now with the goal of laying groundwork for years of activity, the vice president's group will focus on new technologies and the regulatory obstacles they face, the availability of big data and data sharing as a catalyst in the discovery of a cure, and increasing patients' access to therapy. It is unclear at this point what role the governmental coalition will play, as no new money has been appropriated for this effort. The FY2017

budget will be the first indication of how the task force will be funded. However, the existence of this working group and the potential for additional funds to drive the research forward will certainly influence the overall health policy landscape in 2016.

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