

Health Care ADVISORY

November 12, 2012

Post-Election Health Care Outlook

On November 6, 2012, President Barack Obama was re-elected for a second term, while Democrats gained two seats and retained control of the U.S. Senate and Republicans retained control of the House of Representatives (with some races still being recounted).

The following advisory provides a brief post-election outlook of key health care issues that we expect to be considered during the Congressional "lame duck" session and beyond.

(1) Congressional "Lame Duck" Session

While the policy agenda for President Obama's second term is still being developed, critical work remains for the President and the current Congress during the Congressional "lame duck" session, as a number of tax, spending and health care policies either expire or start at the end of the calendar year—each with significant economic and budgetary impacts. Meanwhile, this all hangs under a cloud of an expiring debt ceiling and a likely emergency supplemental package for states affected by "super storm" Sandy.

a. Fiscal Cliff

The first of these issues is the "fiscal cliff"—the term used to describe, among other things, the expiration of the tax cuts initially enacted during the George W. Bush Administration and the across-the-board spending cuts ("sequestration") mandated by the Budget Control Act of 2011. The election did not bring added clarity to the legislative stalemate on fiscal cliff deliberations, as the same players will deliberate over the same contentious issues.

With regard to sequestration, the sequester would result in \$109 billion in automatic, across-the-board spending cuts in fiscal year 2013, including \$55 billion from defense. While most lawmakers say they would like to find a way to avoid the cuts, Republicans and Democrats are at an impasse over how to replace the savings that result from these cuts. Republicans generally favor substituting other spending cuts, aimed at domestic programs. The House passed a reconciliation bill in May that would replace about \$94 billion of the cuts with reductions in mandatory spending spread out over 10 years. Congressional Democrats and President Obama, however, have insisted on a plan that includes additional tax revenue. Any agreement to delay or replace the sequester is likely to be tied to broader negotiations related to the expiration of some or all of the Bush-era tax cuts.

On November 9, President Obama announced that he has invited Congressional leaders to the White House next week to begin negotiations over resolving the issues presented by the fiscal cliff. He added that the election results had proven support for "higher taxes for the wealthy" and called for the immediate extension of middle class tax cuts. Earlier, on November 7, Speaker of the House John Boehner (R-OH) called the fiscal cliff a "tremendous" challenge and urged

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Congress and the President to solve the problem within the context of a broader tax reform effort. Ultimately, we do not expect that President Obama and Congress will agree on a comprehensive deficit reduction package in the lame duck session. Rather, we believe that an agreement will be made to delay both the sequester and the expiration of the Bush-era tax cuts for a short period (e.g., six months) while agreeing on a framework for deficit reduction—with the details to be worked out by Congressional committees next year.

b. Physician “Doc-Fix”

Another likely focus of the “lame duck” session will be the regular extension of relief from the severe cuts in Medicare payments to physicians required under the Sustainable Growth Rate (SGR) formula—a process that has preoccupied Congress every year for more than a decade. The latest physician payment extension was included in the Middle Class Tax Relief and Job Creation Act of 2012, and is set to expire at the end of December. The “doc-fix” and other Medicare payment adjustments (see below) included in the law were offset by modifying Medicare payments plus a \$5 billion reduction in the Affordable Care Act’s (ACA) preventive health services fund. The current political environment generally requires all spending extensions to come with provisions that cut spending or raise revenue elsewhere in the federal budget. The one-year cost to fix the SGR is approximately \$18.5 billion, and we believe offsets will be “health for health” and thus mostly impact Medicare providers; however, expect efforts by House Republicans to include some previously offered ACA-oriented pay-fors in lieu of more hits to providers. We believe Congress will likely pass a short-term “doc-fix” of up to one year, but that shorter term alternatives of three or six months might also be possible if tied to other aspects of the fiscal relief “package.” It would not be a complete surprise if the “doc-fix” becomes a short-term casualty of the lame duck tensions and physicians and other Medicare providers were left to face the 26.5 percent reduction in reimbursements for the first few weeks of 2013 or longer.

c. Medicare “Extenders”

In addition to a “doc-fix,” the Middle Class Tax Relief and Job Creation Act of 2012 also extended the authorization of four Medicare payment policies (all of which had been subject to previous annual extensions) through the end of 2012: (1) the so-called “geographic practice cost index (GPCI) floor” payment policy; (2) the “exceptions process” to the \$1,880 per-beneficiary, per-year cap on Medicare coverage for outpatient therapy services; (3) the “outpatient hold harmless” provisions; and the (4) “ambulance add-on” payment provisions. When combined, the budgetary cost of one-year extensions for these four provisions is estimated to be \$1.7 billion. An extension of up to one year (or a shorter period connected with the length of the “doc-fix”) for some, but not all, of these temporary Medicare payment policies may be included in “doc-fix” legislation that Congress will likely pass during the lame duck.

(2) Long-Term Budget Outlook

Upon resolution of the fiscal cliff issues, the President and Congress will again need to raise the federal debt ceiling, at some point in early 2013. It remains to be seen if House Republicans will again insist that any legislative package increasing the debt ceiling must include deficit reduction levels that equal the amount by which the debt limit is being increased. Such a demand by House Republicans could bring entitlement reform—and negotiations over Medicare and Medicaid savings—to the forefront very early in 2013.

On November 7, Speaker Boehner confirmed that the Republican House Majority is ready to work with the President to implement major changes to entitlement programs, along with a cleaner, fairer tax code. He also mentioned that Republicans are willing to accept additional revenues via tax reform—but not higher tax rates—by broadening the tax base and eliminating or reducing certain credits and deductions. However, the Speaker also declared that the President must be willing to reduce spending within entitlement programs. Republicans will accept new revenue increases, as long

as they come from growth and reform. Even absent a requirement to tie increases in the debt ceiling to deficit reduction, President Obama and House Republicans are likely to pursue a deficit reduction deal, or “grand bargain,” at some point before the 2014 midterm elections.

a. Bowles-Simpson Framework

One possible scenario, which has been increasingly discussed in Democratic circles, would involve the President endorsing the deficit reduction plan offered in 2010 by the President’s Commission on Fiscal Responsibility and Reform (known as “Bowles-Simpson”). Freed from the constraints of re-election, President Obama could be more open to endorsing Bowles-Simpson and using the plan as a general framework for a major deficit reduction package. Nevertheless, despite the President’s support for Bowles-Simpson, it is unclear whether Senate Democrats would support the plan, with Senator Charles Schumer (D-NY) recently dismissing the Bowles-Simpson tax proposals as a “trap” for the middle class. Additionally, House Majority Leader Eric Cantor (R-VA) confirmed that while Bowles-Simpson included many elements that Republicans could support, the plan should not serve as a framework for long-term deficit reduction, since the plan did not include a “premium support” option that provides structural reforms to the traditional Medicare fee-for-service (FFS) benefit, but did include federal revenue increases.

b. Previous Obama Administration Budget Proposals

Three additional documents include provisions that could serve as an initial framework for a major budget deal that includes Medicare savings: (1) the President’s Fiscal Year (FY) 2012 Budget proposal; (2) the President’s “Plan for Deficit Reduction and Economic Growth” that was released in September 2011; and (3) the President’s FY 2013 Budget proposal. The Medicare/Medicaid savings in the three documents overlap in many places. The single largest Medicare savings provision in these documents involves requiring that pharmaceutical manufacturers pay Medicaid-comparable rebates for brand-name and generic drugs provided to Medicare Part D’s low-income subsidy (LIS) beneficiaries (which includes Medicare/Medicaid dual-eligibles and other qualifying low-income individuals).

While the Medicaid-comparable drug rebate policy has been a non-starter for Congressional Republicans, some of the other provisions—particularly the changes to Medicare cost-sharing, limitations on supplemental coverage and the means testing provisions—could garner Republican support. In fact, House Republicans included the President’s means testing policy in December 2011 legislation, as a budgetary offset for a one-year extension to the Social Security payroll tax cut. However, Congressional Democrats remain wary of many of these changes that could impose new cost-sharing burdens on beneficiaries.

c. Tax Reform: Potential Legislative Vehicle for Medicare/Medicaid Deficit Reduction

President Obama, House Ways & Means Committee Chairman Dave Camp (R-MI) and Senate Finance Committee Chairman Max Baucus (D-MT) all have expressed a commitment to tax reform. Chairman Camp and Chairman Baucus spent considerable time in the 112th Congress laying the ground work for tax reform, and President Obama released a framework for business tax reform in February 2012. Current House Budget Committee Chairman Paul Ryan (R-WI), who will now be returning to Congress, also put forth a tax reform outline. Other tax reform proposals that are likely to be under discussion include those in Bowles-Simpson and the Domenici-Rivlin proposal from the Bipartisan Policy Center. While there are many differences between the proposals put forward to date and crucial details are lacking, the overall approach to tax reform is to achieve a reduction in tax rates through the elimination or modification of a variety of tax deductions, exemptions, and tax credits. Tax reform thus presents the potential for winners and losers, depending on the tax provisions that are modified to achieve lower rates.

For the health care sector, tax reform approaches could include limitations on, or elimination of, the income and payroll tax exclusion for employer-sponsored health coverage. Some economists believe that elimination of the exclusion could apply downward pressure on utilization (by exposing privately insured health consumers to increased costs, which may increase price sensitivity). President Obama to date has resisted full scale changes to the exclusion, instead focusing on higher income taxpayers. Other health care sector tax items could also come into play in tax reform; for example, Republicans may target some of the health care sector taxes that were “pay-fors” for health care reform. The premium tax credits could be reduced or modified as part of deficit reduction or tax reform. Another tax provision important to health care innovator companies is the research and development tax credit. All of these would be part of a complex equation within the context of tax reform and deficit reduction proposals.

Finally, in terms of Medicare and Medicaid reform, it is possible that a major tax reform package could serve as the legislative vehicle for a broader deficit reduction package (in which Medicare and Medicaid savings provisions would likely be included).

(3) Medicare Impact

a. Physician Services

While there appears to be consensus commitment among the Obama Administration, House Republicans, and Senate Democrats to enact a short-term “doc-fix,” the prospect of permanent physician payment sustainable growth rate (SGR) reform remains more uncertain due to the tremendous budgetary cost of SGR repeal. The most recent Congressional Budget Office (CBO) estimates project that the 10-year cost of repealing the SGR cost-control mechanism is roughly \$271 billion. In May 2012, Rep. Allyson Schwartz (D-PA) and Rep. Joe Heck (R-NV) introduced H.R. 5707, the Medicare Physician Payment Innovation Act of 2012, which was designed to offer a long-term approach to repealing and replacing the SGR. This proposal is widely viewed by Democrats and Republicans as, at the very least, a helpful discussion starter for a serious attempt to address the issue in a comprehensive way. Under the legislation, from 2014 – 2018, CMS would be required to aggressively test and evaluate new delivery models, as well as issue regulations (by 2016) that outline at least four alternatives to the SGR payment system. The costs of SGR repeal and a transition to the alternative models would be fully offset using savings from the reduction in military operations in Iraq and Afghanistan, something not widely supported by Republican legislators. Continued efforts by lawmakers and the Obama Administration to address long-term changes to Medicare physician payment structures likely will continue, although deficit-neutral permanent repeal of the SGR likely will remain elusive, outside a comprehensive budget and tax deal.

b. Managed Care

The ACA made changes to Medicare Advantage (MA) payment structures designed to realign regional MA rates with Medicare FFS reimbursement levels and provided incentives for MA plans that achieved four- and five-star ratings. In November 2010, CMS announced that it would replace the ACA bonus payment with a demonstration project in which bonuses would be awarded to MA plans with three stars, with increased bonuses for plans with four or more stars. The demonstration has blocked cuts to MA reimbursement that would otherwise take effect. In April 2012, the Government Accountability Office (GAO) recommended that the Obama Administration cancel the demonstration program, and Republicans who otherwise support MA have also been critical of the demonstration. Last month, House Oversight and Government Reform Committee Chairman, Darrell Issa (R-CA), subpoenaed the information regarding the demonstration programs and the rationale for the bonus payments. The demonstration is scheduled to continue through 2014, but scrutiny of the program could potentially lead to changes. As ACA implementation moves forward, MA plans are also seeking guidance on the 85 percent medical loss ratio (MLR) requirement that becomes effective in 2014. More immediately, MA organizations offering special needs plans (SNPs) are seeking SNP reauthorization, as program authority expires at the end of next year under current law.

c. Other Providers

If the sequester takes effect, Medicare provider payments will be subject to an up to two-percent across-the-board cut, estimated by CBO to save \$123 billion over nine years. This cut would be in addition to a series of recent reductions in provider payments, mandated by the ACA. Even if the sequester is delayed or eliminated, any budget deal negotiated to avoid the automatic cuts could include reductions in provider payments that could exceed two percent a year. Provider cuts could also be used as offsets to pay for a Medicare physician payment fix. Additionally, any attempts to reduce long-term deficits will almost certainly include incremental reductions to federal health care programs, including payments to providers.

The transition toward new value-based payment models likely will continue, as CMS expands the Hospital Value-Based Purchasing Program and targets both readmissions and hospital-acquired conditions in upcoming pay-for-performance programs. We also expect CMS to focus on bundled payment options and Accountable Care Organization (ACO) models to improve Medicare's affordability, efficiency and quality. Finally, providers are faced with the prospect of deeper payment reductions, emanating from the Independent Payment Advisory Board (IPAB)—which, if not repealed—can make recommendations to Congress for how to rein in Medicare spending beginning in 2014. Providers and services will likely be the main targets for finding savings. Hospitals are exempt from IPAB recommendations until 2020.

d. Prescription Drugs

Looming budget discussions put prescription drugs at risk for Medicare reimbursement cuts. Various proposals have emerged, including extending Medicaid drug rebates to the dual-eligible or low-income subsidy populations, changes to Medicare Part B reimbursement and government negotiation of prices under Part D, as well as changes to the ACA's follow-on biologics provisions.

(4) ACA Forecast

a. State Decisions on Medicaid Expansion

The June 2012 Supreme Court decision that upheld the constitutionality of the ACA also made Medicaid expansion optional for states. While CMS confirmed soon after the decision that there is no hard deadline for states to decide whether they will expand Medicaid eligibility, the agency also said that states will pay a price for delaying expansion because, under current law, the federal share of covering new Medicaid recipients declines each year starting in 2017. Another question is whether the federal government still would pay the increased share of expansion costs if a state decides to cover individuals up to 100 percent of the federal poverty level, rather than 133 percent, as required by the law, or at some level between 100 percent and 133 percent of the federal poverty level. Taking these questions into account, governors will have to decide whether it would be politically palatable in their states to forego federal money to cover more citizens and also whether their budget forecasts will permit them to bear the small—but increasing—share of the cost of coverage expansion in 2017 and beyond. It also is possible that Congress could propose to dial back the federal share of the expansion cost in order to save federal dollars, a move that would further complicate the governors' decision-making.

b. Exchange Establishment

States are now just days away from the November 16, 2012, deadline to submit a Declaration Letter for a State-based Exchange. In a November 9 letter to governors, HHS extended the deadline for more comprehensive State-Based Exchange "Blueprint" applications until December 14, 2012. The agency still plans to approve or conditionally approve

State-Based Exchanges by the statutory deadline of January 1, 2013—one year in advance of the date Exchanges are scheduled to become operational. Some states held off on taking action to form an Exchange until after the Supreme Court ruling on the ACA. Others were waiting for the election results. Now, states will need to respond or will cede responsibility for this function to the federal government.

A federally facilitated Exchange will be established in states that choose not to run their own Exchanges. Controversy has emerged over the availability of tax credits to offset premiums for plans purchased through federally facilitated Exchanges, on the basis that the ACA provision authorizing the subsidies refers only to Exchanges established by states. Oklahoma Attorney General Scott Pruitt has filed a suit arguing that the Internal Revenue Service (IRS) rule that would allow subsidies under federally facilitated Exchanges is unconstitutional. Republican members of Congress including Rep. Michele Bachmann (R-MN) and Sen. Jim DeMint (R-SC) have advanced this theory as a means of hampering Exchange implementation. Legal and political challenges around this provision are likely to continue, particularly given the fact that repealing the ACA in its entirety is now off the table as a result of President Obama's reelection.

With deficit reduction efforts likely to dominate the Congressional agenda in the near term, Republicans may push to delay implementation of the Exchanges and the expensive subsidies that go along with them as part of any compromise on budget issues. CBO has recently indicated that repeal of ACA provisions that expand health insurance coverage (while leaving other provisions unchanged) would decrease spending for major health care programs by nearly 15 percent in 2020 and would reduce the deficit by roughly \$150 billion in that year. Democratic lawmakers have long believed, however, that the key to improving the ACA's public standing is the start of the provisions that permit individuals to access tax credits through the Exchanges. Facing a difficult political environment in 2014 as the party in power with a second-term President, these Democrats will strongly resist such efforts to delay implementation further. When faced with the choice of exposing Medicare beneficiaries to greater cost-sharing, along with legitimate questions about whether the infrastructure—federal and state Exchanges—will be ready in time, though, it is possible they could acquiesce.

c. Essential Health Benefit (EHB) Rules

Non-grandfathered plans in the individual and small group markets both inside and outside of Exchanges, along with certain other types of plans, will be required to cover “essential health benefits” beginning in 2014. The Center for Consumer Information and Insurance Oversight (CCIIO) released a Bulletin describing its approach to rulemaking on EHB almost a year ago, on December 16, 2011, as well as a frequently asked questions document providing additional guidance on February 17, 2012. CCIIO has also released information on benchmark plan options. Nonetheless, states and other stakeholders have been clamoring for additional details, which had not been released prior to the elections. As of November 8, a Proposed Rule on “Exchanges Part II – Standards Related to Essential Health Benefits; Health Insurance Issuer and Exchange Responsibilities with Respect to Actuarial Value, Quality, and Accreditation” is at the Office of Management and Budget (OMB) for final review. Key issues include how EHB will be updated, how states will supplement a benchmark plan that is missing coverage in one or more of the 10 statutory categories, and rules for actuarially equivalent substitution of benefits within the 10 categories of benefits.

Plans and insurance issuers are also looking ahead to implementation of the second major round of insurance reforms enacted as part of the ACA. These include the prohibition against preexisting condition exclusions or other discrimination based on health status, rating rules, guaranteed issue, and guaranteed renewability of coverage. Despite the major impact these requirements will have on the insurance industry and for consumers, CCIIO had not issued proposed rules or guidance prior to the elections; however, we expect the agency to release them before the end of the year. HHS sent a Proposed Rule on ACA “Health Insurance Market Rules” to OMB for review on November 8, 2012.

d. Center for Medicare and Medicaid Innovation (CMMI) Update

The ACA appropriated \$10 billion for CMMI over 10 years to test, evaluate, and expand different payment structures and methodologies to reduce program expenditures while maintaining or improving quality of care. In its first two years of operation, CMMI sought and received feedback from a wide variety of stakeholders about the most promising ways to improve care and lower costs, and it developed a “menu” of criteria for payment models it wants to test. It initiated a number of demonstration projects in the areas of primary care transformation, bundled payments for care improvement, ACOs, beneficiaries who are dually-eligible for Medicare and Medicaid, and a more general “Health Care Innovation Challenge.” Some have criticized CMMI for doing too much too soon, but it is unlikely that its pace will slow down in the coming year. The State Innovation Models Initiative, a competitive grant program for states to design and test multi-payer payment and delivery models, will commence in 2013, with the first round of funding being awarded and a potential second round being announced. CMMI also will be moving forward with its bundled payment initiative, scheduled to go live on January 1, 2013 (although it has scaled this initiative back somewhat from its original design). A new round of Advance Payment Model ACOs will also come on line at that time.

e. Independent Payment Advisory Board (IPAB)

IPAB, created by the ACA, will continue to be controversial with Republicans vowing to repeal IPAB and President Obama vowing to veto any repeal effort. The 15-member IPAB—charged with making recommendations to Congress to reduce the growth in Medicare spending, if Medicare exceeds a certain growth rate—will begin making recommendations in 2014. The IPAB is restricted from making recommendations that would raise revenue or premiums paid by beneficiaries, limit benefits, change eligibility or “ration” health care. Thus, providers and services are likely to be the main targets for finding savings when the board starts making recommendations. Hospitals are exempt from IPAB recommendations until 2020. In a letter to colleagues outlining a possible agenda in light of Governor Mitt Romney's loss, House Majority Leader Eric Cantor (R-VA) renewed his call to repeal IPAB. According to the CBO, repealing IPAB would add \$3.1 billion to the deficit over 10 years. To date, there have been no implementation activities to establish the IPAB.

f. Medicaid Issues

Regardless of which states decide to expand Medicaid eligibility under the ACA, a number of other changes are on the horizon for the federal-state partnership program in the near term. In 2013 and 2014, certain primary care providers will receive increased reimbursement for certain primary care services furnished to Medicaid recipients under a provision of the ACA designed to entice more primary care providers into the program. States are continuing to adopt policies to expand Medicaid managed care agreements, and in 2013, it is estimated that more than two-thirds of states will have at least some Medicaid recipients enrolled with managed care entities. Additionally, half of all states have signaled their intention to participate in CMS's demonstration project for those dually-eligible for Medicare and Medicaid, and most of those will use a capitated model. States participating in the demonstration project may start participating either on January 1, 2013 or in 2014.

g. ACA Taxes and Fees**i. Regulatory Outlook**

The ACA includes billions of dollars in new taxes and fees, most of which are imposed on health care. Despite imminent effective dates for some of these provisions, guidance was lacking as the elections approached. Now that President Obama has been re-elected, further guidance is expected soon. The major taxes and fees that will be effective in 2013 and beyond, or for which guidance is expected soon, are as follows:

- Fee on Branded Prescription Drugs. Effective for calendar years beginning with 2011, proposed and temporary regulations have been issued by the Treasury Department. A hearing was held on the proposed regulations on November 9, 2012, and final regulations are expected to follow.
- Medical Device Excise Tax. The lack of final regulations this late in the year may make compliance difficult by the January 1, 2013, effective date. Proposed regulations were issued in February of this year, and further guidance is expected soon.
- \$500,000 Limit on Compensation Deduction for Health Insurance Issuers. Limited initial guidance has been issued, but many questions as to how the limit will be applied are still unanswered as the January 1, 2013, effective date approaches.
- \$2,500 Cap on Salary Reduction Contributions to Health Flexible Spending Accounts. Initial guidance on effective date questions was issued earlier this year, in advance of the January 1, 2013, effective date. Further guidance is expected to have some welcome news in the form of relaxation of the “use it or lose it” rule.
- Fee on Health Insurance Issuers. Effective starting in 2014, this fee imposes an aggregate amount on the health insurance industry, divided up by market share. The aggregate amount for 2014 is \$8 billion. No guidance has been issued.
- Reinsurance Contribution. Effective for 2014, 2015, and 2016, a reinsurance contribution requirement is imposed on health insurance issuers and third party administrations on behalf of self-funded plans. The aggregate amount to be collected over the three-year period is \$25 billion, \$20 billion of which is to fund the temporary reinsurance program and \$5 billion of which is for general revenues. Final regulations on the reinsurance program provide that the amount of the fee will be imposed on a per capita basis. The U.S. Department of Health and Human Services was scheduled to set forth the amount of the fee this fall but guidance has not yet been issued; informal estimates indicate that the range of the fee may be between \$60 and \$100 per plan enrollee.
- Pay or Play Penalties for Employers and the Individual Mandate. These provisions are effective starting in 2014. Some preliminary guidance has been issued (e.g., regarding whether a worker is a part-time or full-time employee) but many questions remain.
- Cadillac Plan Tax. This tax is scheduled to go into effect in 2018, and no guidance has yet been issued.
- Other. Other revenue raisers that go into effect in 2013 (and for which guidance has not been issued) include a change in the deduction rules for employers receiving Part D premium subsidies; a 0.9 percent increase in the employee share of the hospital insurance tax for wages and self-employment income in excess of \$250,000 for married couples filing a joint return and \$200,000 for single taxpayers; and a 3.8 percent tax on net investment earnings in excess of \$250,000 for married couples filing a joint return and \$200,000 for single taxpayers.

ii. Legislative Outlook

As Congress looks to address the fiscal cliff, deficit reduction, and tax reform, a number of the ACA tax provisions may come under consideration. For example, a delay, reduction or phase-in of the premium tax subsidies that are scheduled to go into effect in 2014 when the Exchanges become effective may be considered as part of deficit reduction. Despite the enactment in the ACA of the Cadillac plan tax, additional limitations on the exclusion for employer provided health coverage continue to be proposed in the context of deficit reduction and tax reform. A bill to repeal the medical device tax (H.R. 436) passed the House last year, and a House bill to repeal the health insurer’s fee garnered enough co-sponsors

to pass the House (H.R. 1370). These issues may be raised in the context of tax reform, however, repeal of these, and other ACA taxes, may be difficult to accomplish without offsetting provisions due to budget constraints.

(5) Food and Drug Issues

With the re-election of President Obama, the U.S. Food and Drug Administration (FDA) is likely to continue its current high level of regulatory oversight and enforcement. Current levels of appropriations also provide the agency with necessary resources to implement the five-year agenda contained in the recently enacted prescription drug user fee bill (the Food and Drug Administration Safety and Innovation Act). It is possible this appropriation could be reduced, under sequestration, which calls for an 8.2 percent across-the-board reduction (about \$320 million), but this seems unlikely. New FDA regulations, which were delayed or stalled before the election, will likely be published in proposed or final form, potentially provoking a Congressional response, along with the potential expansion of existing authorities. The recent fungal meningitis outbreak associated with bulk pharmacy compounded products may also drive additional FDA reform legislation in the next Congress.

a. Food Drug Administration Safety and Innovation Act (FDASIA)

FDA will continue implementation of FDASIA (also called PDUFA V) by moving forward with a variety of pending rules, most notably for the newly established generic drug user fee program. Other key regulatory implementation initiatives will include finalizing rules for unique device identifiers; promulgating regulations for the registration of commercial drug importers; establishing purchasing controls, or similar requirements, as a part of current good manufacturing practices (CGMPs) for drug products; and defining key terms such as “life-supporting” and “life-sustaining” under FDA’s drug shortage authority. Because FDASIA enjoyed strong bipartisan and agency support, it will likely remain the core of the Commissioner’s agenda for the next five years, until a sixth reauthorization of agency user fees is required in 2017.

In addition, recent quality concerns with the New England Compounding Center (NECC) will lead to even more aggressive agency enforcement, including use of FDA’s drug supply chain authorities under FDASIA. For example, FDA is likely to be even more aggressive in surveillance to determine whether compounders are operating as drug manufacturers subject to FDA CGMP and quality system requirements, which would require establishment of standards for oversight and controls of raw material and component suppliers.

b. Drug Compounding Authority – Congressional Activity

In response to the NECC fungal meningitis outbreak, Representative Edward Markey (D-MA) introduced legislation to expand FDA’s authority over prescription drug compounders. The issue frequently pits drug manufacturers and consumer advocates against pharmacies, state pharmacy boards and attorney generals. The Senate Health, Education, Labor & Pensions Committee, as well as the House Energy & Commerce Committee, will hold hearings on the NECC matter and the underlying division of responsibilities between FDA and state pharmacy boards. The role played by tough FDA enforcement of CGMP interpretations to close down generic injectable drug manufacturers may be examined. FDA also might request an expansion of its record inspection authority under Section 704 of the Food, Drug and Cosmetic Act, in order to determine if compounding pharmacies are operating as drug manufacturers. Committee Chairman Tom Harkin (D-IA) and Ranking Member Michael Enzi (R-WY) have indicated they are preparing to introduce a bipartisan compounding bill after gathering more information. Compounding legislation could serve as a vehicle for other FDA-related reform efforts for which consensus was not reached in the “must-pass” FDASIA legislation (e.g., electronic drug pedigrees).

c. ACA Implementation

FDA is working to implement the physician payment disclosure, drug sample-reporting and menu-labeling authorities of the ACA.

- Sunshine Act. This ACA provision requires manufacturers to disclose certain information regarding payments to physicians (including to physician groups or practices) and teaching hospitals. Earlier this year, CMS released an update on Sunshine Act implementation, noting that no data collection will be required before January 1, 2013 (earlier CMS had said that a “partial collection” might have been required for 2012). As such, payments made throughout 2012 are not required for disclosure. However, when CMS issues a final rule, we expect that 2013 payments will be subject to disclosure and the law requires reporting of payment information for the previous calendar year by the 90th day of the following calendar year (e.g., by the end of March 2014 for 2013 data). The December 2011 proposed rule received numerous comments from a widespread industry base of manufacturers, providers and institutions. Among manufacturer concerns regarding the proposed rule are the definition of “applicable manufacturers” and proposal to extend application of the rule to certain entities under common ownership with drug and medical device manufacturers.
- Drug Sample Reporting. The ACA requires drug manufacturers and authorized distributors to submit the following drug sample information to FDA annually: (1) the identity and quantity of drug samples requested; (2) the identity and quantity of drug samples distributed; (3) the name, address, professional designation and signature of any person who makes or signs for the request; and (4) any other category of information determined appropriate by the Secretary. To date, FDA has not begun enforcement of these requirements. It continues to review industry comments on its draft guidance. We expect that FDA will finalize its guidance, reporting system, and enforcement approach in 2013.

d. “Track and Trace” Requirements

Although Congress tackled a variety of drug issues as part of FDA user fee legislation in July 2012, the final version of FDASIA did not include pharmaceutical supply chain integrity requirements. During consideration of the user fee legislation, policymakers could not reach agreement on “track and trace” language, including whether the pharmaceutical supply should be tracked at the unit or lot level. With the user fee legislation moving forward without “track and trace” requirements—and with state-level requirements in California set to take effect in the coming years—Congress is expected to return to this issue in the near future.

On October 24, 2012, a bipartisan, bicameral working group unveiled a “Draft Proposal to Improve Drug Distribution Security.” This discussion draft reflects the ongoing effort to develop consensus policy on drug distribution security, including track and trace requirements. The draft legislation would initially establish a lot-level tracing system with a pedigree requirement. Under this system, manufacturers would be required to affix a product identifier to each saleable unit. The legislation also sets the groundwork for a unit-level tracing system that would be put in place in later years through rulemaking, following a series of pilot programs and public meetings. Congressional staff is currently reviewing input from members of Congress and stakeholders on the draft and are working to develop consensus.

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