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Forward look

Top regulatory trends for 2016 in Life Sciences & Health Care

Foreword

This publication is part of the Deloitte Center for Regulatory Strategies' cross-industry series on the year's top regulatory trends. This annual series provides a forward look at some of the regulatory issues we anticipate will have a significant impact on the market and our clients' businesses in the year ahead. For 2016, we provide our regulatory perspectives on the following industries and sectors: Banking, Securities, Insurance, Investment Management, Energy and Resources, Life Sciences & Health Care.

The issues outlined in each of the six reports provide a starting point for the crucial dialogue about future regulatory challenges and opportunities to help executives stay ahead of evolving requirements and trends. We encourage you to share this report with senior executives at your company. Please feel free to contact us with questions and feedback at centerregstrategies@deloitte.com.

Best regards,

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Introduction

The life sciences and health care sectors face a year full of activity in 2016, with the prospects of the election year spotlight once again being directed to the health care marketplace.

As we closed out 2015, there was some noteworthy Congressional activity. In legislation agreed to in late December, Congress included provisions that delayed and suspended some key tax provisions enacted as part of the Affordable Care Act (ACA). The legislation delays the first year of the so-called Cadillac tax on high-cost employer-sponsored coverage by two years to 2020, and suspends the health insurer fee for 2016 and the medical device excise tax for two years.

While the White House expressed support for the larger agreement that included the delays, President Obama pledged to veto legislation the Senate passed in December that would repeal major provisions of the Affordable Care Act (ACA), such as the medical device tax and the Cadillac tax. The bill also would end premium assistance tax credits to purchase coverage in the ACA's exchanges, eliminate the tax penalties associated with the employer and individual mandates, and end the ACA's Medicaid expansion. The House is expected to vote on the bill and send it to the President in January.

President Obama on Monday, November 2, 2015, signed into law the Bipartisan Budget Act of 2015, a two-year budget deal that generally cleared the decks of any must-pass legislation until after the November 2016 elections. The law suspends the federal debt limit until March 2017 and sets federal spending levels through September 2017, teeing up that date as a potential lynchpin in the health care legislative agenda for the next president and Congress.

As a result of the president's expected veto of the ACA repeal and the enactment of the budget agreement, the life sciences and health care sectors can generally shift focus in Washington, DC, to the regulatory front for 2016. The Obama Administration is entering its final year in office and will be working to complete regulations on key health care priorities. Notably, some of the Administration's major regulatory priorities—such as the Cadillac tax and the new Medicare payment law, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)—are aimed at controlling health care costs. The CMS Actuary's most recent data on national health expenditures showed that US health care spending increased by 5.3 percent in 2014, largely as a result of the ACA's major health coverage expansion under Medicaid and the ACA's insurance Exchanges. Health care spending increased by 2.9 percent in 2013, the lowest growth rate on record in the 55-year history of CMS' National Health Expenditure Survey. Health spending accounted for 17.5 percent of the US gross domestic product (GDP) in 2014, up from 17.3 percent in 2013.

Congress will continue to consider health care legislation, but election year politics could make it more difficult for major laws to be enacted in a period of divided government. The limited congressional calendar for 2016 could be another barrier to negotiating bipartisan legislation: the Senate is scheduled to be in session 31 weeks next year while the House is scheduled to be in session 28 weeks to allow time for campaigning ahead of the elections.

Notwithstanding the limited congressional calendars, health care is all but certain to remain a pivotal issue in the 2016 elections. The Affordable Care Act continues to be a central point of debate, and polls show that affordability of health care and prescription drug prices are important issues for voters on both sides of the aisle.

This report looks at six key regulatory activities in life sciences and health care for 2016:

1. ACA implementation
2. Excise tax on high-cost employer-sponsored coverage
3. Medicare payment reform
4. Medicaid managed care
5. 340B drug pricing program
6. Life sciences regulatory topics

The Administration will be issuing, and in some cases finalizing, regulations in each of these areas in 2016. It will be important for stakeholders in the life sciences and health care sectors to consider each of these issues as they evaluate their strategic priorities and regulatory compliance activities for 2016.

1. ACA implementation

Implementation of the Affordable Care Act remains a top priority for President Obama, and his Administration is working to finalize regulations on critical components of the law before leaving office.

Having just completed the third open enrollment period for the ACA's individual exchanges, qualified health plans (QHPs) sold on the exchanges have continued to draw scrutiny and spark debate over premium increases and benefit design features, such as provider networks and deductibles. Importantly, stakeholders will have to consider how any new requirements to limit cost-sharing on prescription drugs or expand plans' networks might translate to higher premiums.

Elections for Congress and the presidency are sure to feature debate over the ACA, but stakeholders also should keep an eye on state-level elections. Governors and state legislatures play a critically important role in decisions related to operation of the ACA's exchanges, as well as Medicaid expansion.

Another issue drawing attention from states is the possibility of pursuing other avenues to expand health coverage via waivers under Section 1332 of the ACA. Beginning in 2017, states could use the waivers to opt out of the individual and employer mandates and other components of the ACA. Relative to the ACA, alternative models would have to:

- Provide coverage "at least as comprehensive"
- Cover as many or more individuals
- Include equal or greater affordability standards
- Not increase the federal budget deficit

The Departments of the Treasury and of Health and Human Services in December provided guidance on the criteria the agencies will use to evaluate waiver applications. Notably, the guidance indicated that waiver proposals from states using the federally-facilitated Exchange might not be considered feasible at this time because "the Federal platform cannot accommodate different rules for different states."

Of critical importance to health plans and organizations offering health benefits to employees, January 2016 will mark the first compliance deadlines for the ACA's information reporting requirements. Employers will have to provide information returns to all full-time employees and the IRS, while health plans generally will have to provide information returns to members enrolled in fully insured products not purchased through the ACA exchanges. Implementation of the ACA will remain a critical business issue for health care stakeholders in the year ahead, raising the possibility of continued change into the future. Beyond the law's impact on the health care marketplace, 2016 will mark the first time many organizations will have to operationalize some of the law's administrative requirements for employers.

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2. Excise tax on high-cost employer-sponsored coverage

As part of a bill to fund the federal government for 2016, Congress agreed to delay the so-called "Cadillac tax" on high-cost employer sponsored coverage for two years and repealed a provision that would have made the tax non-deductible for employers and plans.

This new tax stands to upend the longstanding tax incentives for more generous employer-sponsored health benefits.

As a result of the delay, the first year the tax will apply will be 2020, rather than 2018. The delay will give stakeholders additional time to assess their exposure to the tax and plan for it, but it remains a topline strategic issue given the scope of the tax and its potential to disrupt the US model of health care coverage offered in the commercial market. The 40 percent excise tax will be a strong disincentive for any employer to offer health benefits that exceed the tax's thresholds of $10,200 for self-only coverage and $27,500 for all other coverage. This new tax stands to upend the longstanding tax incentives for more generous employer-sponsored health benefits.

The tax will apply to all employer-sponsored coverage, whether self-funded or fully insured. The excise tax applies to coverage sponsored by:

- Private businesses
- Non-profit organizations
- State and local governments
- Labor unions
- The federal government, via the Federal Employee Health Benefits Program (FEHBP)

Retiree coverage and employer-sponsored group health plans purchased through SHOP exchanges and private exchanges also are subject to the tax.

Employer-sponsored health coverage is a critical source of revenue for health plans, health care providers, and life sciences companies. As a result, any movement away from the historically generous health benefits that employers offer could ripple through the health care marketplace and have a significant effect on stakeholders' commercial revenue and strategic priorities.

Many organizations will begin making changes to their employee health benefits offerings in the coming years as they work to mitigate any liabilities under the new tax. As such, health plans, health care providers, and life sciences companies could face greater pressure in negotiations as employers drive harder to keep the value of employee health benefits below the tax's thresholds.

The Cadillac tax is an issue of strategic importance for the C-suite of all companies because it could have major implications for their strategic partnerships, tax liabilities, compliance programs, consumer engagement initiatives, vendor relations, and talent recruitment and retention strategies.

Stakeholders should keep abreast of the critical regulations that the Administration is releasing in 2016 in order to prepare and plan for compliance with the Cadillac tax when it takes effect.

3. Medicare payment reform

MACRA fundamentally changes how Medicare payments to health care professionals will be set in the future.

The law puts significant revenue at stake for hospitals and health plans that employ health care professionals, making it imperative for the C-suite to actively engage in their organizations' response to the law and adjust their business strategies going forward.

When President Obama signed MACRA into law in April 2015, it repealed the Sustainable Growth Rate (SGR) formula for physician payments and set updates to the Medicare Physician Fee Schedule for all years in the future. The law provides significant financial incentives for health care providers to participate in risk-bearing coordinated care models (eligible alternative payment models, or APMs) and move away from the fee-for-service reimbursement system. Health care professionals who opt to stay out of the new risk-bearing coordinated care models will receive lower payment updates and will be subject to significant new reporting requirements under the Merit-based Incentive Payment System (MIPS).

Importantly, after MACRA was enacted, the CMS Actuary projected that payment updates set under the law will not keep pace with the average rate of physician cost increases. This can be expected to place more pressure on the revenue streams for health care providers and health systems that employ health care professionals.

Because MACRA is expected to drive participation in APMs, the law could present strategic opportunities for organizations interested in employing or entering into other arrangements with health care professionals.

Organizations that currently participate in accountable care organizations (ACOs) and other types of APMs will need to evaluate how their ACOs or other APMs stack up against criteria that the Department of Health and Human Services is required to release by November 1, 2016.

In addition to the opportunities and risks presented by MACRA, the November 2015 budget agreement includes a provision on site-neutral payments that could affect Medicare reimbursements for hospitals and health systems that employ health care professionals. Beginning January 1, 2017, the provision would bar provider-based off-campus hospital outpatient departments (PBD HOPDs) that execute CMS provider agreements after November 2, 2015 (the date the Bipartisan Budget Agreement was enacted), from being reimbursed under the CMS Outpatient Prospective Payment System (PPS). Instead, such facilities are eligible for reimbursement under the Medicare Physician Fee Schedule (PFS) or the Ambulatory Surgical Center Prospective Payment System (ASC PPS). Reimbursements under the PFS or ASC PPS generally are lower than payments under the PPS.

Health care stakeholders would be well-advised to keep close tabs on regulations the Administration releases on MACRA next year.

MACRA repealed the Sustainable Growth Rate (SGR) formula for physician payments and set updates to the Medicare Physician Fee Schedule for all years in the future.

4. Medicaid managed care

The Administration is in the process of rolling out the first changes to Medicaid managed care regulations since 2002, a time period during which enrollment in Medicaid managed care plans has increased significantly.

The proposed rule would apply medical loss ratio (MLR) requirements to Medicaid and CHIP managed care plans for the first time.

CMS has indicated that it aims to release a final rule on Medicaid managed care by April 2016. A proposed rule was published in the June 1, 2015, Federal Register.

A key aim of the proposed rule was to align the rules governing Medicaid managed care and coverage under the Children's Health Insurance Program (CHIP) delivered in managed care with rules for other major sources of coverage, including QHPs available through Medicare Advantage (MA) and exchanges under the ACA.

Notably, the proposed rule would apply medical loss ratio (MLR) requirements to Medicaid and CHIP managed care plans for the first time. If the proposed rules are finalized as drafted, Medicaid and CHIP managed care plans beginning January 1, 2017, would be subject to an 85 percent MLR standard (i.e., at least 85 percent of premiums would have to be spent on medical costs).

In addition, the Administration could further the move toward coordinated care models if it finalizes language from the proposed rule that would require Medicaid and CHIP managed care plans to include mechanisms to promote coordinated care and delivery system reform efforts.

Given the growth of Medicaid managed care in recent years, stakeholders should keep a close eye on final regulations from the Administration that could affect significant revenue from their government programs business line.

5. 340B drug pricing program

The Administration has said it will provide final updated guidance on the requirements of the 340B drug pricing program by September 2016, after releasing long-awaited draft guidance in August 2015.

Affected providers, who remember previous proposed guidance rollouts that were never finalized, may conclude that the new 340B guidance may be a similar fire drill. However, given the current Administration's desire to finalize rulemaking in a number of important areas, this may not be the case this time. Over the past several years, Congress, the Administration, and health care stakeholders have been attempting to balance the program's goals of providing drug discounts to entities that serve lower income populations with certain parameters to limit the expansion of the program. Some of the parameters relate to the definitions of qualified drugs patients, and entities eligible to participate in the 340B program.

The draft guidance did not change the overarching purpose of the program to provide drug discounts for certain patients in qualified entities, but it did include significant proposed changes relative to which drugs the program applies to and which provider entities are eligible to claim the discounts. The changes include new restrictions on entity eligibility, drug eligibility, and patient eligibility. The changes could limit the scope of 340B and could affect the savings realized by covered entities under the program.

The proposed guidance also will have implications for health plans participating in Medicaid managed care. Managed Medicaid prescriptions filled in 340B contract pharmacies would not be eligible for the 340B program unless a covered entity provides the government a written agreement with its contract pharmacy and State Medicaid Agency or Managed Care Organization that describes a system to prevent duplicate discounts.

In addition, the Administration reiterated the requirement of routine audit and monitoring practices and indicated that a covered entity's failure to maintain adequate records demonstrating compliance could result in program termination.

If the rules eventually go into effect without significant alteration, providers will need to understand the financial impact these changes could have. Further, providers will be required to begin to assess the administrative changes that will be required to comply with the updated guidance, including requirements related to employment or contractual arrangements for prescribing health care professionals.

The changes include new restrictions on entity eligibility, drug eligibility, and patient eligibility.

6. Hot topics in life sciences

President Obama's Precision Medicine Initiative, scrutiny of drug prices, and debate over biosimilars will be some of the major issues facing the life sciences sector in 2016.

Life sciences companies will need to engage on multiple fronts in 2016 in order to take advantage of any new opportunities while mitigating exposure to emerging risks.

The White House is moving ahead with its Precision Medicine Initiative, a new biomedical research effort intended to facilitate the development of more targeted treatments based on individual differences in people's genes, environments, and lifestyles. The initiative includes the development of a new voluntary research cohort by the National Institutes of Health (NIH) that will use information from patients' electronic medical records. The initiative also includes a new regulatory approach to genomic technologies by the Food and Drug Administration and new cancer clinical trials by the National Cancer Institute at NIH.

The Obama Administration on November 20, 2015, convened a summit on "pharmaceutical innovation, access, affordability and better health." At the summit, Acting CMS Administrator Andy Slavitt highlighted the Administration's efforts to move toward value-based payments and called for more public information about the efficacy of drugs and more transparency about how drug prices are set. The summit came shortly after CMS sent letters to state Medicaid directors and five pharmaceutical firms about prices and access to Hepatitis C treatments, requesting that the companies' CEOs provide information about challenges they have encountered when entering into discount or value-based purchasing arrangements with state Medicaid programs.

Also of interest to life sciences companies, the Bipartisan Budget Act of 2015 extended the inflation-based Medicaid rebate currently paid on brand drugs to also apply to generic drugs if the price of the drug has increased faster than inflation (CPI-U). Currently, only single source and innovator multiple source drugs pay an additional rebate. Drug makers are required to pay these rebates quarterly to state Medicaid programs.

Stakeholders are anxiously awaiting final guidance from the FDA for naming biosimilar drugs. The Administration released proposed guidance in August 2015 that suggested that reference products and biosimilars have proper names that share a core drug substance name. To help identify each product, the FDA would then designate a suffix of four lower case letters to biosimilars that would have no intrinsic meaning. An industry trade group suggested that the proposed suffixes have some meaning rather than be randomly assigned.

Life sciences companies will need to engage on multiple fronts in 2016 in order to take advantage of any new opportunities while mitigating exposure to emerging risks.

Conclusion

To make the most strategic decisions, stakeholders must remember that change is the only constant in the life sciences and health care sectors. The regulatory events that lie ahead in 2016 and beyond will mark some of the most far-reaching changes to the US health care markets and delivery systems.

It will be more important than ever for stakeholders to understand the legislative and political environment in Washington, as well as changing market trends and regulatory events in order to most effectively execute on their priorities. Because many of the regulations the Administration will be focused on in 2016 will be focused on controlling the growth of health care costs, stakeholders will want to closely consider how the regulations could affect their revenue streams.
For 2016, stakeholders in the life sciences and health care sectors will want to:

Keep abreast of the debate around health care in the 2016 elections. The 2016 presidential election will result in the first time a new Administration takes charge of the implementation of the Affordable Care Act. Whether a Republican or Democrat is elected President, a new Administration could usher in a new set of priorities for the health care marketplace, whether it be greater flexibility for states to pursue alternatives to the ACA's model to expand health coverage or greater attention to drug prices and the FDA approval process.

Evaluate how changes in commercial health coverage might affect your organization. As employers reduce the generosity of their employee health benefits to stay below the Cadillac tax thresholds, stakeholders in the life sciences and health care sectors need to evaluate how those changes might affect utilization of their products and services, as well as contract terms and payment strategies among parties in all sectors. At the same time, stakeholders will want to assess their own health benefit offerings, determine when their health benefit packages will incur the Cadillac tax, and consider their employee benefits strategy going forward.

Assess your role in the new Medicare and Medicaid payment systems. The systemic changes to the Medicare payment system for health care professionals presents strategic opportunities and risks for health systems and health plans and their business relationships with health care professionals. Providers and plans will need to keep a close eye on regulations coming in 2016 to plot their strategy for the new payment system intended to decisively shift government payments away from the fee-for-service system and bend the cost curve.

Stay nimble. The scale of changes underway in the US health care system are unlike anything we have seen in recent memory. The confluence of these systemic changes could drive significant shifts in decision making by health care consumers, employers, and other health care stakeholders, and could prompt stakeholders to reassess their relationships with consumers and other players in the life sciences and health care sectors.

Moving forward

The regulatory landscape for life sciences & health care continues to evolve, making it important for stakeholders to keep a watchful eye on new and modified requirements. For updated information about the latest regulatory trends and developments, please visit the Deloitte Center for Regulatory Strategies' Reg Pulse blog.

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