

**Federal Health Policy Report for CalPERS
 November 2016**

I. PRESCRIPTION DRUG PRICE/COST DEVELOPMENTS OF RELEVANCE TO CalPERS:

- A. CMS Releases New Medicare Drug Spending Data.** New [CMS data](#) on Medicare drug spending reveals that overall Medicare spending on the 20 drugs with the highest yearly increases more than tripled from \$146 million in 2014 to \$486 million in 2015. The program's total drug spending for its more than 73 million beneficiaries in 2015 was \$57 billion. Nine of the top 10 Medicare drugs with the biggest price hikes from 2014 to 2015 are new to the Medicare transparency tool known as the drug spending dashboard. Interestingly, the prescription drug price hikes that drove this year's finding are different than those that drove last year's cost trend.
- B. Hospitals Urge Action to Address Drug Prices.** On November 30th, the American Hospital Association sent a [letter](#) to President-elect Trump urging him to adopt a comprehensive set of solutions to address escalating drug prices, including providing support for the introduction of generic alternatives, discouraging anti-competitive tactics, improving access through drug reimportation, providing mandatory rebates, and placing requirements around direct-to-consumer advertising.
- C. Fate of Medicare Part B Drug Pricing Demonstration Unclear Post-Election:** On November 18th, Democratic leaders asked the Obama Administration not to release the final regulations for the controversial Part B drug demonstration to develop alternative reimbursement approaches to constrain high cost specialty drugs. Republicans and some Democrats strongly protested the project, as they viewed it as too broad in scope. They argued it could limit patient access to some drugs and hurt independent, small and rural physician practices. The pharmaceutical lobby, doctors, and some consumer groups have fought the demo with print and TV ads. There is still a small possibility that the Administration will release the final regulation which would largely be symbolic as it can be undone with a quick vote by Congress in January or by the Trump Administration.
- D. House Passes 21st Century Cures Legislation.** On November 30th, the House passed bipartisan legislation intended to expedite the discovery, development, and delivery of new treatments and cures. The legislation provides the National Institutes of Health (NIH) with \$4.8 billion in new funding that is fully offset and will help advance the Precision Medicine Initiative to drive research into the genetic, lifestyle, and environmental variations of disease (\$1.5 billion); bolster Vice President Biden's "Cancer Moonshot" to speed research (\$1.8 billion); and invest in the BRAIN initiative to improve our understanding of diseases like Alzheimer's. The legislation is [supported](#) by the Administration as well as PhRMA and several disease advocacy groups, and opposed by the consumer advocacy group Public Citizen which claims that it "creates an overly-broad category of 'breakthrough' devices and pressures the FDA to rush approval of these devices, potentially leading to poor decisions." The conservative advocacy group Heritage Action also opposes the bill calling it a "Christmas tree, loaded with handouts for special interests" and paid for with budget gimmicks. Despite some Democratic

opposition in the Senate related to the amount and type of funding provided for NIH, it is expected to pass on December 5th and be sent to the President for signature.

- E. Food and Drug Administration Finalizes Rule on Citizens Petitions:** The FDA has finalized changes to its process for submitting citizen petitions that have been abused by the pharmaceutical industry to stop or delay drug approvals. The pharmaceutical industry and patient groups they financially support, often use these petitions to assert to the FDA that it is not possible to develop a generic or biosimilar competitor, thus forcing the FDA to delay or in some cases deny approvals of new drug products that would provide competition and lower cost. The final rule clarifies that the agency will consider a certification or verification deficient if it does not match every word of what is required under law, or if the signature is made on behalf of someone, not by the person who authored the petition or supplemental document. It also provides other provisions such as locking-in a shorter process for an FDA response to deny or approve the citizen petition.

Historically, the vast majority of these petitions have been denied as scientifically unwarranted, but the FDA resources dedicated to this process, and the delay in its conclusion, effectively blocks competition. As such, purchasers and generic and biosimilar competitors are generally quite pleased with this final FDA regulation.

- F. Potential Collusion on Diabetes Medicine Pricing:** On November 4th, Senator Sanders and Representative Cummings called on the Justice Department and Federal Trade Commission to investigate potential collusion among drug companies on the rising prices of diabetes medicines. The cost of insulin more than tripled between 2002 and 2013, the lawmakers noted in a [letter](#), even though the original insulin patent expired more than 75 years ago. The letter specifically identifies Sanofi, Novo Nordisk, Eli Lilly, and Merck. Sanofi and Novo Nordisk have reportedly taken nearly identical price hikes of their drugs within days of each other 13 times since 2009, the Democratic lawmakers say. Eli Lilly has also matched rising prices on Novo Nordisk insulin products on multiple occasions. Eli Lilly and other companies have been fined in Mexico for colluding on insulin prices. The rising prices have significant implications for government and private sector pharmaceutical spending. For example, the American Diabetes Association estimates, in 2015, Medicare spent more per beneficiary on diabetes medication than any other class of drugs, primarily due to rising prices.
- G. CalPERS Implications:** The election outcome will significantly impact the debate on drug pricing. If the stock market is any indicator, there is a strong belief that a Republican Congress and Trump Administration will be far less aggressive in addressing prescription drug prices (PhRMA stocks increased notably upon the news of his election). And, while it is true, the President-elect did make statements during the campaign indicating an interest in addressing drug prices, he has been notably more quiet on the issue since the election. Having said that, the President-elect could easily pivot back to his populist instincts and could, for example, express concerns regarding news of a high drug price perceived abuse and call for action. This could very quickly alter the current perception around these dynamics.

H. CalPERS Next Steps: Since the upward prescription drug cost trend shows no signs of abating, we will continue to work with CalPERS staff to shed light on the implications of problematic pricing practices and support policies and other interventions to moderate this trend. We will also continue to advocate for tools that empower CalPERS as a purchaser. Moreover, CalPERS staff and consultants will seek out and support efforts designed to lower overall prescription drug cost growth.

II. CADILLAC TAX UPDATE

- A. Election Outcome Makes Repeal and Replace More Likely:** Earlier this year, Congress passed, and President Obama vetoed, [H.R. 3762](#), which would have repealed several provisions of the Affordable Care Act (ACA) including the Cadillac tax. However, the Republicans have indicated their commitment to work on and pass a replacement policy that may include an alternative to the Cadillac tax. More specifically a likely blueprint for the replacement plan, released by the Speaker of the House of Representatives, Paul Ryan, in June of this year entitled [“A Better Way: Our Vision for A Confident American”](#) included such a provision. The Ryan plan repeals the ACA and replaces it with several provisions including a cap on the employer exclusion for health care coverage, which depending upon the details could be just as, or even more negative for CalPERS as the Cadillac tax.
- B. CalPERS Implications:** While Speaker Ryan’s proposal on the employer exclusion has been met with significant hostility from employer groups, it is difficult to say what their position would be in the context of a larger tax reform/infrastructure package which addresses many of their other priorities. As such, continued efforts to raise concern and urge action is advisable. Regardless, much discussion and debate will continue on this issue both in the tax and health reform context.
- C. CalPERS Next Steps:** Continue to review, develop and promote helpful regulatory and legislative reform interventions that would mitigate against any negative impact on CalPERS plans and keep the Board informed of opportunities in this regard.

III. DELIVERY REFORM DEVELOPMENTS:

- A. Final Physician Fee Rule Emphasizes Care Coordination:** The Centers for Medicare and Medicaid Services (CMS) announced changes to how Medicare pays for primary care that could result in an estimated \$140 million in additional funding in 2017 to providers. The agency says several coding and payment changes could eventually lead to as much as \$4 billion or more being funneled into care coordination and patient-centered care. The [final rule](#) expands a program developed by the YMCA which is aimed at helping people avoid diabetes. The expanded program would start in 2018 and the CMS is seeking comment on whether to launch the effort nationally or in additional select markets. The agency also finalized a proposal to publicize data that informs how Medicare Advantage costs are set. The information would be at least five years old and exclude any proprietary information. The data, they argue would show how healthcare is used in different regions and by different populations.

- B. CMS Announces Quality Measures Under Consideration (MUC):** Value-based purchasing requires quality measures to ensure that public and private purchasers are achieving improved health outcomes as they are working to achieve greater efficiency in the health care system. To help facilitate better and more outcomes-oriented, quality measures, CMS [posted](#) the final Measures under Consideration List on the CMS website and has sent them to the National Quality Forum (NQF). NQF will review and make recommendations on these measures through a multi-stakeholder review process that includes patients, clinicians, commercial payers and purchasers. This year’s MUC list contains 97 measures that have the potential to drive improvement in quality across numerous settings of care.
- C. CalPERS Implications:** It is unclear whether the new Administration will continue the focus on reforming the delivery system in the same way and using the same methods as the current Administration. For example, the implementation of MACRA is the most significant tool since the ACA for moving physicians from a volume-based to a value-based system. The new Administration could reissue MACRA regulations to increase the focus on Medicare Advantage, rather than on other partially capitated models such as Accountable Care Organizations and bundled payments. In addition, it is possible that the Center for Medicare and Medicaid Innovation (CMMI) which has conducted many of the demonstrations leading to the current delivery system reform models will not survive the Congressional repeal effort in its current form and/or will not be used in the same manner by the incoming Administration.
- D. CalPERS Next Steps:** Continue to encourage Medicare’s movement of providers towards value-based arrangements that ensure cost-effective, high-quality care.

IV. MISCELLANEOUS UPDATES

- A. Election Outcome Fundamentally Alters Health Care Landscape:** President-elect Trump has indicated that healthcare reform will be among his top three priorities and that in his first 100 days as President, he will fight to: “amend, repeal or replace” the ACA; cancel many of President Obama’s executive actions, memorandums, and orders; and issue a requirement that for every new federal regulation that is finalized, two existing regulations must be eliminated.

Major Health Care Appointments Unveiled

On November 29th, President-Elect Trump announced the nominations of Congressman Tom Price of Georgia for Health and Human Services (HHS) Secretary as well as Seema Verma, a health policy consultant from Indiana as administrator for the Centers for Medicare and Medicaid Services. Congressman Price, an orthopedic surgeon by training, has been an outspoken critic of the ACA and was an early supporter of President-Elect Trump. Verma assisted with the development of Indiana’s controversial Medicaid expansion, which is viewed by many conservatives as a model for future Medicaid reforms. These two positions will be critical as the Republican Congress works to pass and enact a repeal and if successful, a possible replacement for the ACA. As such, they

can expect to receive a great deal of scrutiny in their confirmation process, but most currently believe that they are likely to be ultimately confirmed.

Repeal Update

Senate Majority Leader Mitch McConnell signaled the Senate would move swiftly to repeal the ACA now that the GOP Congress will have a Republican President next year. House Speaker Paul Ryan also highlighted repeal plans in a celebratory press conference. Meanwhile, Republicans close to President-elect Trump, including Vice President-elect Mike Pence and Dr. Ben Carson, have suggested a more gradual approach to repealing the ACA in order to avoid chaos in the marketplace. Senator Alexander, Chairman of the Health, Education, Labor and Pension Committee, stated that he is looking forward to working with the incoming HHS Secretary, Tom Price, to “first replace, then repeal” the ACA.

An immediate repeal of the ACA, in its entirety, is unlikely, as a repeal proposal could be prevented by a Democratic filibuster in the Senate. However, Congress and President-elect Trump may repeal many of the ACA’s major provisions through a budget reconciliation bill. As mentioned earlier, [H.R. 3762](#), would have repealed several provisions of the ACA including: premium tax credits, cost-sharing reduction assistance, small business tax credits, the individual mandate, the employer mandate, Medicaid expansion, the medical device tax, the insurer fee, and the Cadillac tax. The bill did not specifically repeal the authority for the exchanges or the insurance reforms. Some of this is due to the rules of reconciliation which preclude provisions that do not have a significant budget impact while other parts are excluded due to their popularity. Because it is the only plan that has passed both the House and Senate, it is likely that this bill will serve as the blueprint for ACA repeal. Because this repeal is projected by the Congressional Budget Office to result in 22 million more uninsured and a significant disruption of the individual insurance market, Republicans will emphasize their commitment to eventually passing a replacement bill that would avert or help mitigate against these problems. In subsequent additions of this report, we will provide summaries of approaches they may take to achieve this outcome.

- B. Part B Premium and Deductible Increase:** On November 10th, CMS announced the 2017 premiums for the Medicare inpatient hospital (Part A) and physician and outpatient hospital services (Part B) programs. According to the [announcement](#), Medicare Part B beneficiaries will see their monthly premium rise more than 12 percent in 2017. The annual deductible for all Medicare Part B beneficiaries will be \$183 in 2017, compared to \$166 in 2016. For 70 percent of Medicare beneficiaries, the average 2017 Part B premium will be about \$109, compared to \$104.90 for the past four years. The Part B premium rates will be low for most seniors due to a hold harmless provision of the law that prevents premiums from increasing beyond the Social Security Cost-of-Living Adjustment (COLA). The Social Security COLA for 2017 is 0.3 percent. For the remaining

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30 percent of beneficiaries, the standard monthly premium for Medicare Part B will be \$134 for 2017, a 10 percent increase from the 2016 premium of \$121.80. Their increase is greater because the formula requires them to cover most of the increase in Medicare costs for all beneficiaries. While this increase is notable, it is much less than most policy-makers feared and as such—unlike last year—it is unlikely that Congress will intervene to moderate these premium hikes.