

Federal Health Policy Report for CalPERS April 2017

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

- A. **FDA Approves Fifth Biosimilar:** The Food and Drug Administration (FDA) announced on April 21, 2017 that it has approved a biosimilar product for Johnson & Johnson's Remicade, an arthritis and psoriasis drug. This is the second biosimilar approved for Remicade. While the price of this recently approved drug is not yet known, biosimilars offer the potential to create competition and lower the costs of some of the most expensive biologic drugs.

- B. **FDA User Fee Draft Legislation Released:** On April 14, 2017, the Senate Health, Education, Labor and Pensions (HELP) and House Energy and Commerce committees released a discussion draft of the Food and Drug Administration (FDA) user fee reauthorization bill which provides funding for drug approvals. Legislative authority for FDA's current user fee programs expires September 30. Without a timely reauthorization, the agency would be forced to lay off hundreds of staff and could mean that prescription drug manufacturers that have medications with little or no competition will continue to be able to excessively price and inflate their products. Although some were hopeful that the user fee bill would become a vehicle for addressing drug pricing – and there will likely be amendments urging the consideration of potential policies – bipartisan leadership on both committees are working hard to keep the bill free from additional provisions and instead largely making it an extension.

- C. **FDA Commissioner Confirmation Reported out of Committee.** On April 27, 2017, Dr. Scott Gottlieb, the Trump Administration's FDA Commissioner Nominee was reported out of the Senate Health, Education, Labor and Pensions Committee by a bipartisan 14-9 vote, (with 2 Democratic votes). The Committee's Ranking Democrat, Senator Patty Murray, voted against the nominee, citing potential financial conflicts with the pharmaceutical industry and questions about his ability to stand up to political pressure from the Trump White House. The vote, nonetheless, set the stage for the eventual likely final confirmation vote in the Senate in upcoming days/weeks. Prior to the vote at his confirmation hearing, Dr. Gottlieb testified that, to curb the rising price of drugs, FDA should modify its process for proving interchangeability, making it easier for generic drugs to enter the market. He declined to say if he supports drug pricing negotiations, saying the issue is outside of FDA's jurisdiction. He also didn't say whether he would support allowing importation of cheaper drugs from overseas. Instead, Gottlieb told the Senate HELP Committee he wants to pursue ways to boost competition for more complex generic products, such as the EpiPen, right away. He said some of these

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complex products have long had monopolies because FDA doesn't have a scientific process to approve would-be copycats after their patents have expired.

D. Public Citizen Report Secures Limited Rx Drug Pricing Constraint Commitments:

According to new survey results from Public Citizen released on April 12, 2017, three of the 28 largest global pharmaceutical companies will go along with Allergan's pledge to raise prices by no more than 10 percent annually. While only three companies explicitly agreed to the pledge, others argued that when rebates and discounts are taken into consideration, their price increases have been in the single digits. When asked by Public Citizen, AbbVie, Novo Nordisk and Valeant pledged to follow Allergan's lead and keep price increases to the single digits. Public Citizen surveyed 28 companies, but only 13 responded within three attempts at contact, and the group could not glean a company's pricing strategy for 10 of the 28 companies.

- E. Medicare Drug Pricing:** On April 4, 2017, the Medicare Payment Advisory Commission (MedPAC) a congressional Medicare advisory panel, unanimously supported recommendations that would restructure how the program pays for physician-administered drugs, ending more than two years of discussion on the topic. Medicare Part B now reimburses doctors for these drugs based on a formula — average sales price plus 6 percent — that critics say incentivizes doctors to prescribe high-cost treatments. MedPAC agreed that drug companies should pay a rebate when the average sales price of their products increases faster than an inflation benchmark. MedPAC also supported a new “drug value program,” which would create a negotiation system for physician-administered drugs, similar to what is used in Medicare Part D for pharmacy prescriptions. The group suggested creating a voluntary program that would be phased in by 2022 at the earliest. To encourage participation, however, they suggest gradually reducing the ASP add-on percentage. MedPAC also said HHS should use the same billing code for a reference biologic and biosimilar, which would incentivize doctors to use the cheaper copycats of branded biologics. The panel estimated its package of recommendations would save between \$1 billion and \$5 billion over five years.

CalPERS Implications: President Trump and his staff continue to tell stakeholders that the Administration is planning to take actions to address drug prices. While legislative action on drug pricing seems less likely at this point, meaningful administrative policies could yield helpful outcomes for CalPERS in constraining drug costs. It is a certainty that drug manufacturers will push back strongly against almost any significant attempts to constrain costs.

Recommended Positioning and Actions for CalPERS: In an environment where President Trump and an array of consumer, business, labor, health plan, and provider stakeholders are raising consistently loud, public criticisms on the pricing practices of the pharmaceutical

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industry, CalPERS is liberated to be even more aggressive than usual in publicly embracing and advocating for policies that it believes will provide positive impact and relief. This includes direct engagement with stakeholder partners as well as individual advocacy by CalPERS with the new Administration/Congress on policies that will expand competition, eliminate barriers to competition, or use the government's leverage to lower costs. In addition to direct lobbying/advocacy, CalPERS can proactively engage and advance priority positions in the various coalitions in which it is a member as well as co-sign or author coalition and/or stand-alone letters, hearing testimony, and op-eds that clearly convey and promote progress in this area. Finally, it would be of benefit for CalPERS to collect and release data of relevance on drug spending that highlight cost drivers to the system and in particular may wish to analyze the potential impact that drug reimportation or transparency initiatives would have on costs and quality for the system to determine any action in supporting or opposing any legislation.

II. CADILLAC TAX UPDATE

A. Delay of the Cadillac Tax Still in Play: The American Health Care Act (AHCA), which would repeal and replace the Affordable Care Act and included a delay of the Cadillac tax from 2020 to 2026, has made a resurgence due to changes to increased state flexibility on some provisions in the ACA. It is still not clear, however, whether it can pass the House and faces an uphill battle in the Senate.

CalPERS Implications: Unless the House Republicans can reach consensus and bring some form of the AHCA back up in a second attempt to pass their repeal/replace legislation, the current law effective date for the imposition of the Cadillac tax remains 2020.

Recommended Positioning and Actions for CalPERS: CalPERS has consistently and strongly objected to the enactment and implementation of the Cadillac tax. Recognizing that health care tax incentives will be front and center in both the ACA repeal/"repair" and tax reform debates, CalPERS should and will continue to advocate against limits on federal tax incentives for health coverage that create inordinate pressure on employers to excessively reduce benefits and/or increase cost sharing. This position can be conveyed individually or collectively through labor/business coalitions as well as other creative communication mechanisms such as op-eds or hearing testimony.

III. DELIVERY REFORM DEVELOPMENTS:

A. Medicare Inpatient Proposed Rule: On April 14, 2017, CMS released the proposed 2018 Medicare inpatient hospital [payment rule](#). The proposed increase in operating payment rates for general acute care hospitals paid that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users is approximately 1.6 percent. Other additional payment adjustments will

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include continued penalties for excess readmissions, and the worst performers by hospital acquired infection metrics, as well as continued upward and downward adjustments under the Hospital Value-Based Purchasing Program. CMS projects the rule would increase Medicare spending on inpatient hospital services by \$3.1 billion in 2018. Long-term care hospitals' Medicare payments are projected to decrease by \$173 million, or 3.75 percent, over the same period. CMS also released a Request for Information seeking "positive solutions to better achieve transparency, flexibility, program simplification and innovation".

- B. CMS Released Medicare Advantage Data:** On April 13, 2017, CMS' Office of Minority Health (OMH) released two reports that analyze [racial, ethnic](#), and [gender](#) disparities among Medicare Advantage beneficiaries between 2014 and 2015. The report on gender alone found that men and women had similar patient experience measures (such as access to care and customer service) as well as most care quality measures; however there were substantial differences in some clinical care measures, with women experiencing better care in 5 of 24 measures and men experiencing better care in 3 of 24. When racial and ethnic disparities were considered, OMH also found significant differences in patient experience including timely access to care.
- C. CMS Announced Awardees:** On April 6, 2017, CMS announced two groups of [awardees](#) for the [Accountable Health Communities \(AHC\) Model](#). (There were no California awardees.) CMS awarded 12 Assistance Track organizations and 20 Alignment Track organizations. CMS is expected to announce Awareness Track awardees this summer. The five-year model will begin on May 1, 2017. The three-track Model will allow select organizations to test approaches that address the unmet health-related social needs of Medicare and Medicaid beneficiaries:
- i. Assistance Track participants will provide community navigation services to beneficiaries;
 - ii. Alignment Track participants will provide community navigation services and promote alignment between clinical and community-based social services; and
 - iii. Awareness Track participants, which have yet to be announced, will increase beneficiary awareness of the community-based services that are available to them.

CalPERS Implications: The Trump Administration continues to pursue more targeted and voluntary delivery system reforms. However, it will be important to monitor any potential changes to the delivery system reform effort that delay physician movement to value-based payment models as well as potential Centers for Medicare and Medicaid Innovation demonstrations on fundamental Republican Medicare reform ideas such as premium support.

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Recommended Positioning and Actions for CalPERS: Because of CalPERS ongoing leadership and interest in delivery reforms that accelerate the health system's movement away from fee for service to "value purchasing," it is advisable for the System to promote continued progress. To that end, CalPERS can and should proactively engage and advance priority positions in the various coalitions in which it is a member as well as co-sign or author coalition and/or stand-alone letters, hearing testimony, and op-eds where possible and when aligned with CalPERS' position. To further encourage progress, CalPERS may also collect and release data on the successes of its more aggressive delivery reforms in an attempt to not only highlight the best practices of the System but encourage more aggressive action from the federal government.

D. ADDITIONAL UPDATES

- a. **Updates Around Affordable Care Act (ACA) Changes/Repeal/Replace.** Since the GOP's American Health Care Act (AHCA), which would have repealed and replaced the Affordable Care Act (ACA), was pulled from the floor due to lack of support, several key House Republicans have been working to find a way forward on House passage by uniting the moderate and conservative wings of their party around a proposal. The amendments currently being offered include additional \$15 billion in risk sharing funding to attempt to stabilize the market as well as allowing states to submit waivers to opt out of certain required ACA benefits and regulations that prevent underwriting of individuals medical conditions in an attempt to bring down premiums and stabilize the state's market. These amendments won the endorsement of members of the conservative House Freedom Caucus and several conservative groups such as the Heritage Foundation who were previously opposed to the AHCA. However as of this writing, it was unclear whether the bill would pass the House due to both conservative holdouts and more moderates who felt that the changes took away too many consumer protections. The Congressional Budget Office (CBO) has not officially provided a cost estimate for the amendment, however permitting states to opt out of some of the ACA's regulations, such as the continuous coverage provision, would most likely result in an increased number of uninsured from the previous CBO score of an additional 24 million uninsured, but could potentially increase cost savings. The bill, if it passes, would face a steep uphill climb in the Senate given the slim Republican majority, as several members including Senators Collins, Graham, Cruz, and Grassley have indicated concerns with the bill.

CalPERS Implications: The ongoing discuss over ACA repeal/replace bill continues to offer opportunities and challenges for CalPERS. On the positive side, it may offer a vehicle to repeal reform or delay the Cadillac tax. On the other hand, the primary challenge related to the ongoing debate relates to the issue of cost shifting to states, public/private purchasers and consumers through the imposition of a new employer tax exclusion cap, excessively deep cuts to Medicare/Medicaid and/or significant declines in the number of insured

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Americans. Although the legislation appears to be stalled for now, it is a rapidly evolving dynamic that could quickly change. Furthermore, the Trump administration is still likely to take administrative action in making changes to the law.

Recommended Positioning and Actions for CalPERS: Because the debate of issues surrounding the ACA can be so political, it is advisable for CalPERS to stay focused on the changes, both legislative and administrative, to the underlying law that could directly impact the System. To this end, it is recommended that CalPERS focus its engagement on embracing policies that could reduce the System's cost or cost exposure (such as limiting or repealing the Cadillac tax) and opposing policies with potential to shift cost burdens to CalPERS (such as Medicare, Medicaid, and coverage loss cost shifting) through direct advocacy and strategic individual or coalition letters/communications. As noted above, the situation is rapidly evolving and, as such, consultants and CalPERS staff should and will continue to monitor developments and possible positioning around any changes.