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Federal Health Policy Report for CalPERS
July 2017

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

A. New Food and Drug Administration (FDA) Drug Policy: On June 27, the FDA posted a list of branded drugs that have no patents or exclusivities and for which the agency has yet to approve a generic drug application. The agency announced that it intends to expedite the review of any generic drug application for products on this list to ensure that they come to market as expeditiously as possible. The FDA will continue to refine and update the list.

The FDA also announced a change to its policy on how the agency prioritizes its review of generic drug applications. The FDA will expedite the review of generic drug applications until there are three approved generics for a given drug product. The agency is revising the policy based on data that indicate that consumers see significant price reductions when there are multiple FDA-approved generics available. According to the FDA, these steps will increase competition in the market for prescription drugs and facilitate entry of lower-cost alternatives.

These actions are among the first taken under the agency's Drug Competition Action Plan, announced by FDA Commissioner Scott Gottlieb in late May. These actions follow closely the FDA's announcement of a public meeting held on July 18, 2017, to solicit input on places where the FDA's rules – including the standards and procedures related to generic drug approvals – are being used in ways that may create obstacles to generic access, instead of ensuring the vigorous competition Congress intended.

B. Study Released on Need for Increased Generic Competition. On July 3, a study in the Annals of Internal Medicine found that generic drug prices may keep rising unless more is done to spur competition, especially in cases when manufacturers have few financial incentives. The authors said that addressing competition alone might not be enough to curb the problem. Manufacturers do not always have an incentive to make a compound, or may be unable to obtain raw materials at competitive prices. The study was based on data from January 2008 to June 2013 that contained 1.08 billion prescription drug claims for 53.7 million patients. The authors used Department of Justice criteria to track how competitive a particular market for a drug was over the time period.

C. FDA Reauthorization Act Passed By House: On July 13, the House passed the FDA Reauthorization Act of 2017 (H.R. 2430) by voice vote. Lawmakers added a new section to the FDA Reauthorization Act of 2017 that calls on the HHS Secretary to work with Congress to take administrative and legislative steps to lower the cost of prescription drugs for consumers and taxpayers. Lawmakers said such action should balance the

need to encourage innovation with the need to improve affordability. President Trump has proposed that FDA receive more than $2 billion in medical product industry fees in fiscal year 2018. This would allow the government to cut FDA's taxpayer financing, but still receive the same amount of money overall. But lawmakers and the industries opted not to change the fee amounts negotiated by the Obama administration, which would impose an additional cost on the drug and device industries. Timing for eventual passage of the user fee bill in the Senate is unclear as leadership from both parties have been focused entirely on ACA repeal/replace dynamics. This legislation must be passed by the end of September or cuts that will delay drug approvals will occur. As of this writing, the Majority and Democratic Leaders of the Senate are attempting to reach a time agreement to bring up the bill for a vote. Since most believe the debate around a comprehensive ACA repeal is effectively over, there is increasing expectation that the user fee bill will pass the Congress prior to the August recess or certainly in September.

CalPERS Implications: Public polling and private purchaser publc complaints continue to validate CalPERS focus on prescription drug pricing as an issue worthy of attention and to drive lawmakers to look into pricing practices to determine root causes and develop fixes. While the FDA seems interested in using administrative authority to put into place helpful policies, it is questionable whether any "game-changing" legislative fixes are possible in the near term. It is also unclear how much these administrative actions or the voluntary actions taken by some manufacturers will ultimately bring down prices for consumers and purchasers such as CalPERS.

Recommended Positioning and Actions for CalPERS: CalPERS should continue 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, participate in hearing testimony, and in authorizing op-eds that clearly convey and promote progress in this area. Finally, CalPERS should collect and release data of relevance on prescription 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. **Senate Passes Amendment to Repeal Cadillac Tax:** Amongst the votes taken in the Senate during the consideration of the repeal/replace of the Affordable Care Act (see detail below), there was an amendment offered by Senator Heller (R-Nevada) to repeal

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the Cadillac tax which was agreed to by a vote of 52-48. Given the ultimate disposition of the repeal/replace effort in the Senate, despite the delay of the Cadillac tax in the American Health Care Act (AHCA) passed by the House, the Cadillac tax currently remains unchanged and will take effect in 2020 under current law.

CalPERS Implications: With the passage of the AHCA in the House and the vote to repeal the Cadillac tax in the Senate are positive developments. However, given the apparent failure of the repeal process in the Senate, it is unclear what legislative vehicle would be available for a Cadillac tax repeal or reform. Rep. Kevin Brady indicated on July 28 that the ACA's taxes would not be addressed in the GOP's forthcoming tax reform efforts, however that could always change. The Cadillac tax could be a prime candidate for inclusion in any bipartisan ACA fix given the support on both sides of the aisle for reforming or repealing it. However, it is worth noting that in the so-called "Problem Solvers Caucus" unveiling (detailed below) no such provision was included. They chose instead to eliminate the employer mandate provision, which also costs significant revenue relative to current law.

Recommended Positioning and Actions for CalPERS: 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 whether it be in tax or health reform. This position has been and will continue to be conveyed individually or collectively through labor/business coalitions as well as other creative communication mechanisms such as op-eds or hearing testimony. Should additional legislation be unveiled that includes a delay, reform, or repeal of the Cadillac tax, CalPERS will have to weigh the benefit of such policy against any potential negative effects of other potentially problematic provisions that may be included..

III. DELIVERY REFORM DEVELOPMENTS:

A. **End Stage Renal Disease (ESRD) Proposed Rule Advances Quality Incentives**: On July 5th, CMS issued a proposed rule that would make changes to the ESRD prospective payment system (PPS) for 2017. Under the ESRD PPS, all renal dialysis services provided to Medicare beneficiaries in an outpatient setting are reimbursed according to a bundled payment rate. CMS anticipates that under the proposed rule, payments to providers would slightly increase with the hope and expectation that over time there would be a better return on investment.

B. **Hospital Outpatient Rule Proposes Drug Payment Changes:** On July 13, CMS issued a proposed rule for the CY 2018 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System. The proposed rule updates Medicare payment policies and rates for hospital outpatient departments, ASCs, and partial hospitalization services furnished by community mental health providers. The provision that received the most attention was a payment reform in the way that 340B,

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a program for providing drugs for low-income individuals, drug prices are reimbursed. Under the proposed rule CMS would pay hospitals the average sales price minus 22.5 percent, which is the current estimate of the average minimum discounts hospitals currently receive. The current reimbursement rate for 340B is average sales price plus six percent. CMS asserts that this would help save seniors $180 million per year and reduce their out of pocket costs. Hospitals have asserted that this would hurt many essential access hospitals that provide most drugs under the 340B program and are often already financially strapped. CMS will accept comments until September 11, 2017.

C. **Physician Fee Schedule (PFS) Rule Proposes Changes in Delivery System Reforms:** On July 13, CMS issued a proposed rule that would update the PFS and other Medicare Part B payment policies for CY 2018. Health care payment reform advocates particularly noted changes to accountable care organization rules and financing. In particular there was a good deal of interest in beneficiary assignment for certain ACOs, increasing payments for office based behavioral health services payments, simplifying certain telehealth claims, and delaying the expansion of the Diabetes Prevention Program from January 1, 2018 to April 1, 2018. CMS will accept comments on the proposed rule until September 11, 2017.

CalPERS Implications: The Trump Administration continues to pursue more targeted and voluntary delivery system reforms. Notwithstanding this fact, the ACO reforms appear to be initially well received. 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.

Recommended Positioning and Actions for CalPERS: Because of CalPERS ongoing leadership and interest in delivery reforms that accelerate the movement away from fee for service to "value purchasing," it is advisable for the System to promote continued progress. To that end, CalPERS should ensure that the latest regulations and any further actions taken by the Administration, are consistent with the system's desired delivery system goals. 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 where possible and when aligned with CalPERS' position. To further encourage progress, CalPERS should 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.

IV. ADDITIONAL UPDATES

A. **Updates Around Affordable Care Act (ACA) Changes/Repeal/Replace:** On July 25, the Senate voted 51-50, with Vice President Mike Pence breaking a tie vote, to begin debate

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on multiple pieces of legislation that would repeal portions of the ACA. The Senate considered, but failed to pass, the following pieces of legislation:

- On July 25, the Senate voted 43 to 57 against an updated version of the Better Care Reconciliation Act, the Senate's bill to repeal and replace portions of the ACA.
- On July 26, the Senate voted 45-55 against the Obamacare Repeal Reconciliation Act, the Senate's bill to repeal significant portions of the ACA without replacement.
- On July 28, the Senate voted 49-51 against the Health Care Freedom Act (also known as the "skinny" bill) to repeal limited portions of the ACA without replacement. This "skinny bill" was seen as the most likely to pass the bill failed in dramatic late night fashion with Senator John McCain (R-AZ) surprising many, including the Republican leadership by joining Senators Murkowski (R-AK) and Collins (R-ME) and voting against the bill.
- No further votes on ACA repeal are currently scheduled, as the majority assesses whether to work across the aisle for future reform efforts. Following the failure of this vote, President Trump called for the process to continue and the Senate not to move on to other business until passing health care legislation.
- To respond to President Trump's challenge, some from the conservative House Freedom Caucus have been discussing Senators Graham, Cassidy, and Heller's legislation which would block grant ACA funding to the states. With Senator McConnell seeming to be ready to move on to other priorities and given the unexpected failure of even the skinny bill, it's unclear whether they will be able put together enough of a coalition to convince leadership to bring their legislation up.
- In addition, he threatened to withdraw the cost sharing reduction payments to insurers, which would further destabilize the individual market and increase premiums.
- In an attempt to address the uncertainties around cost sharing payments a new bipartisan group of over 40 members who call themselves the Problem Solvers Caucus unveiled a broad outline of a set of policies to stabilize the insurance market, to provide funding for an insurance market stabilization fund, eliminate the employer mandate, and provide for other narrowly crafted state flexibility reforms. This is the first initiative that Republicans have embraced as an alternative to repeal of the ACA and instead takes steps towards addressing some of its shortcomings. While the policy is vague, and likely not to be enacted, it is notable that a number of the Republican sponsors serve on committees of jurisdiction. This development may signal the beginning of a new direction on the ACA debate, but most experts believe there is a lot of work to be done to achieve consensus around specific policy objectives.

B. **Medicare Trustees Issue Report:** On July 13, in their latest report, the Medicare Trustees projected that the Medicare Part A trust fund will be depleted in 2029, a year later than what trustees predicted last year. The improved financial health of the trust fund is a result of continued and unexpected constrained health care cost growth. This is of course encouraging news in terms of the financial health of the Medicare program, but it also

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means that the controversial Independent Payment Advisory Board (IPAB) will not be triggered into action to recommend further proposals to cut Medicare spending.

CalPERS Implications: The ongoing discussion over ACA repeal/replace bill continues to offer opportunities and challenges for CalPERS. Although the legislation appears to be stalled for now, it is a rapidly evolving dynamic that could quickly change (as illustrated by the July 31st unveiling of the Problem Solvers Caucus policy outline). Furthermore, the Trump administration is still likely to take administrative action in making changes to the law.

Recommended Positioning and Actions for CalPERS: CalPERS has already urged, in comments to Chairman of the Senate Finance Committee, that any health care reform be bipartisan. Given the current disposition of the repeal/replace effort, CalPERS should work through direct advocacy and strategic individual or coalition letters/communications to urge a commitment to bipartisanship and to focus on the changes, both legislative and administrative, to the underlying law that could directly impact the System. The situation will continue to rapidly evolve and, as such, consultants and CalPERS staff should and will continue to monitor developments and possible positioning around any changes.