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Federal Health Policy Report for CalPERS
November 2017

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

A. FDA Reports on Mylan EpiPen Failures. On November 2nd, based on accounts by patients and physicians, the FDA reported that failure of EpiPens to deploy correctly have been cited in seven deaths this year through mid-September. The FDA has received 228 reports of EpiPen failures so far this year — up from 105 last year, up from just four in 2012. In addition to the deaths, 35 people were hospitalized, according to the reports. At the same time the price of the EpiPen has soared, so have reports of malfunctions. Mylan controls about 70 percent of the market for emergency allergy treatments. The EpiPen design has changed recently; Mylan said the advancements are crucial to the pen's safety and functionality, but the changes also protect it from competition by generic device makers until 2025.

B. Allergan Patent Deal Under Scrutiny. On November 7th, a group of Democratic Senators sent a letter to Allergan Chief Executive Officer which was critical of Allergan's deal with New York's Saint Regis Mohawk Tribe, saying it is difficult to conceive of Allergan's transaction as anything other than a sham to subvert the existing intellectual property system (as background, the contract with the tribe was designed to extend market exclusivity and thus block competition). In the letter, the senators said they were concerned that tribes could reach similar deals with other manufacturers of brand-name prescription drugs. They asked Allergan to disclose the terms of its agreement with the tribe and explain whether it has plans for similar patent transactions. A bipartisan group of representatives from the House Oversight and Government Committee made a similar request for documents from Allergan in October.

C. Hospitals Sue Over 340b Cut. On November 13th, the American Hospital Association, Association of American Medical Colleges, America's Essential Hospitals, and other plaintiffs sued to block HHS from implementing payment reductions for 340b prescription drugs established in the 2018 Hospital Outpatient Prospective Payment System final rule. The rule lowers Medicare reimbursement for drugs purchased through the 340b Drug Pricing Program by nearly 28 percent compared to current policy, totaling a $1.6 billion reduction in payments for next year. Representatives David McKinley (R-WV) and Mike Thompson (D-CA) introduced bipartisan legislation on November 14th to block the payment reductions, which will otherwise take effect January 1, 2018.
Much of the concern from the hospitals might be the result of where many of the drug companies' most expensive new drugs are — cancer treatments delivered in hospitals. Cancer drugs are roughly a quarter of new drugs in development and roughly half of hospitals today are eligible for discounts under the 340b program. Hospital trade groups say the drug companies are creating a diversion from their own pricing issues. PhRMA questions if the $6 billion in discounts that hospitals and clinics serving low income

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patients receive for certain drugs are helping patients or are padding the books of hospitals.

D. **CMS Proposed Additional Regulatory Changes in Medicare that Effect Drug Prices.** In the 2018 final Medicare physician fee regulation, CMS made a change to the Obama Administration's proposal on treatment of biosimilar drugs. Under the previous rule, biosimilar drugs are grouped into the same payment calculation creating an incentive for physicians to prescribe the least costly drug in a therapeutic class. Beginning in 2018, CMS will use separate codes to pay for biosimilar biological products under Part B. This change eliminates the financial incentive to prescribe the least costly drug in a therapeutic class and rewards those biosimilar manufacturers with sales forces who can market directly to the provider. As such, this has been widely interpreted by purchasers as setting a bad precedent that will increase costs by increasing the utilization of higher priced pharmaceutical products.

   CMS also issued a proposed rule with technical changes to Medicare Advantage and Part D. In that regulation, CMS seeks comment on a proposal to force manufacturers and pharmacy benefit managers (PBMs) to pass through rebates and pharmacy incentives to the patient and to limit the profit earned by the pharmacy and the PBM. This is viewed as a large change that would make it harder for pharmaceutical manufacturers to use rebates to manipulate the market to capture market share or justify excessive prices to other purchasers.

   CalPERS Implications: In recent months, there has been some legislation and executive actions to remove some barriers for increased competition both at FDA and at CMS. CalPERS has strongly supported these and other actions. However, the fact is that neither the President nor the Congress has displayed sustained interest or notable success on this issue. The lack of meaningful progress by both the Administration and Congress has ceded much of the action to states. This suggests that public and private purchasers have to be even more aggressive in their advocacy for federal intervention over time.

   Recommended Positioning and Actions for CalPERS: CalPERS should continue to engage with Congress and the Administration both individually and with other consumer, payer and provider stakeholders to advance policies that improve competition and lower costs in the pharmaceutical drug market. The System can also further its interests by continuing to actively participate with our coalition partners in direct advocacy in support of priority policies. This can be accomplished and supplemented through stand-alone or group letters, oral or written testimony, Op-Eds or other such communication strategies. CalPERS should also continue to leverage its data in a way that highlights prescription drug costs, identifies cost drivers, and gives substantive analysis on the impact of policy prescriptions that impact drug costs, price transparency, and their effects on care quality.

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II. CADILLAC TAX

A. Republican Tax Bill Does Not Repeal, Reform Or Delay Cadillac Tax: At the time of this submission , there were no changes to the Cadillac tax as part of the Republican tax reform proposal considered by the Congress. There may be amendments to repeal or delay the tax, but they are not expected to prevail on this legislative vehicle. However, an attempt to delay this tax may be considered in end-of-year legislative vehicles that may or may not include delays in the health insurance and medical device taxes that were included in the Affordable Care Act.

CalPERS Implications: While further delay of the Cadillac tax is still under consideration as part of a year-end package, it is not a certainty that will occur. In addition, there is a good deal of skepticism in this Administration about regulatory work done by the previous Administration and little sense of responsibility for keeping the ACA moving on track. In addition, tax reform, which is a priority of this Administration, is occupying a good deal of staff time and any cuts that Congress passes will take precedence in terms of implementation. As a result, the staff working on Cadillac tax implementation are having difficulty getting the attention of the necessary officials at Treasury/IRS to move regulations forward. It appears unlikely that the next issuance from Treasury and IRS will be a proposed regulation but rather another notice floating ideas and soliciting comments.

Recommended Positioning and Actions for CalPERS: CalPERS has consistently and strongly objected to the enactment and implementation of the Cadillac tax. 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 has been and should 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. In addition, and simultaneously, CalPERS should reengage our work with employer groups who also need regulatory guidance out to get the necessary attention to this issue and send the message that failure to get these regulations published will mean trouble for businesses.

III. DELIVERY REFORM DEVELOPMENTS:

A. Additional Funding Tied to Alternative Payment Models. On November 1st, a new Health Care Payment Learning & Action Network (LAN) report found that 29 percent of U.S. healthcare payments were connected to alternative payment models (APMs) in 2016. That was an increase from 23 percent the previous year. LAN, a public-private partnership that HHS created in 2015 to promote APMs, said the results were close to its goal of having 30 percent of healthcare payments tied to APMs by 2016. The group hopes that number will increase to 50 percent by next year. There remains concern that while the private sector continues to advance value-based purchasing, Medicare's delivery system reform movement has slowed.

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B. CMS Issues Final Rule to Implement Changes to the Quality Payment Program (QPP). Under QPP, overall payment rates for services under the Physician Fee Schedule will remain at 2019 levels through 2025, but beginning in 2019, the amounts paid to eligible providers will be adjusted according to the provider's participation in one of two QPP tracks: the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs). The final rule, issued on November 2nd, will continue to implement the QPP, but would increase the number of providers that are exempt from MIPS, ease reporting requirements, and extend transition timelines for providers, especially those in small and rural practices. Provisions of the rule include, but are not limited to:

- Low-Volume Threshold Increase - CMS finalized its proposal to exempt providers with less than $90,000 in Part B charges or less than 200 Part B beneficiaries from participating in MIPS in 2018.
- Technology and Information Exchange Exemptions - MIPS providers will be allowed to continue to use the 2014 Edition of Certified Electronic Health Record Technology.
- Eligible Advanced APM Models - For 2018, the following models will count as Advanced APMs: Next Generation Accountable Care Organizations (ACOs), Comprehensive Primary Care Plus Models, Comprehensive ESRD Care Models (Two-Sided Risk Arrangement), the Vermont All-Payer ACO Model, Comprehensive Care for Joint Replacement Model (CEHRT Track), Oncology Care Model (Two-Sided Risk Arrangement), ACO Track 1+ Model, and Medicare Shared Savings Program (Tracks 2 and 3).
- All-Payer Combination Option - Beginning in 2021, providers will be eligible to receive Advanced APM incentive payments based on their 2019 participation in both a Medicare Advanced APM and one or more Other Payer Advanced APMs.

C. CMS Issues Final Medicare Provider Payment Regulations. In November, CMS issued final payment regulations for physicians, hospital outpatient departments, ambulatory surgical centers, home health providers, and end stage renal disease facilities. The most relevant provisions for CalPERS include:

- Medicare Shared Savings Program (MSSP) - CMS is finalizing revisions to the assignment methodology for certain MSSP ACOs, easing the application process, and adding to the services defined as primary care.
- Telehealth Services Update - CMS is finalizing its proposal to eliminate requirements to include telehealth modifiers on applicable claims, and is separately finalizing the addition of several telehealth service codes. These include codes for health risk assessments, chronic care management, and crisis psychotherapy. Responding to comments, CMS is also establishing a code to allow providers to bill for certain remote patient monitoring services.
- Diabetes Prevention Program (DPP) - CMS will expand the Medicare DPP nationally beginning January 1, 2018, after determining the model met Center for Medicare and Medicaid Innovation criteria for expansion. The agency had proposed delaying the expansion until April 1, 2018. CMS is also finalizing additional supplier enrollment and compliance requirements.

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- Payment for 340B Drugs - The final rule lowers CY 2018 payment rates for separately payable, non-pass-through drugs and biologicals, other than vaccines, purchased through the 340B Drug Pricing Program. Payment will be based on average sales price (ASP) minus 22.5 percent instead of ASP plus 6 percent, which CMS expects to reduce spending by $1.6 billion in CY 2018. Rural Sole Community Hospitals, PPS-exempt Cancer Hospitals, and Children's Hospitals are exempt from this change in 2018. The rule will result in an offsetting increase to the OPPS conversion factor, adjusting payment rates for other services.
- The rule also finalizes changes to the ESRD Quality Incentive Program (QIP), which reduces payments by up to 2 percent for ESRD facilities that do not meeting specific quality performance standards. CMS will ease Extraordinary Circumstances Policy for facilities that are unable to meet data submission requirements in 2018 and replace several ESRD QIP measures for 2021.

D. CMS Issues Proposed Changes to Medicare Part C and D. On November 16th, CMS issued a rule that proposes significant regulatory changes for Medicare Advantage (MA) and the prescription drug benefit (Part D) plans, beginning in contract year 2019. CMS estimates that the changes would result in approximately $195 million in net savings between 2019 and 2023. Provisions of the rule include, but are not limited to:

- Establishing a new MA open enrollment period, which will occur between January 1st through March 31st annually;
- Reducing Medical Loss Ratio (MLR) reporting requirements, while allowing fraud detection activities to be included in the MLR numerator;
- Updating MA and Part D Star Rating measures and the methodology for calculating those measures;
- Eliminating the "meaningful difference" requirement and easing plan uniformity requirements, which would allow more variety in benefit packages;
- Creating more flexibility to increase maximum out-of-pocket and cost-sharing limits;

CalPERS Implications: While the above demonstrates that there continue to be some encouraging developments on successes with the ongoing transition from volume to value purchasing in health care, it is troubling to note actions or non-actions from HHS that signal a slowing of activities in and commitment to this value-purchasing agenda. To the extent that this trend continues, we may see actions by providers and manufacturers to take advantage of a negative pivot in this area, possibly contributing to higher prices and overall costs than any purchaser would like to see.

Recommended Positioning and Actions for CalPERS: As a leader in innovations in value purchasing, CalPERS may wish to consider new opportunities to highlight successes or positive or negative lessons learned in this area. Greater exposure to successes might encourage other public and private sector purchasers to adopt and scale up efforts in this area. This would help move a much greater percentage of the nation's health care system to adopt approaches that will improve or maintain quality as it secures greater affordability – something that benefits all purchasers, including CalPERS. To contribute to this outcome,

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CalPERS' coalition partners submitted comments to provide input to the Administration on potential advancements for the Centers for Medicare and Medicaid Innovation to pursue. We will also look for additional opportunities for CalPERS to use its platform to promote its agenda, including, of course, our offering up opportunities for (1) meetings with federal officials in the executive and congressional branch, (2) discussions with major health care stakeholders and opinion leaders, (3) oral and written messaging through Op-Eds and testimony, etc.

IV. Additional Updates

A. Health Care Implications of Tax Reform. The Senate Finance Committee passed a version of the Senate's tax reform legislation that would reduce the ACA's individual mandate penalty to zero beginning in 2019. The tax reform bill retained the longstanding healthcare deduction for high out-of-pocket costs (unlike the House bill). However, it did not delay or repeal the Cadillac tax or the health insurance tax—two problematic provisions retained in the Affordable Care Act law. The Congressional Budget Office (CBO) estimates the repeal of the individual mandate penalty will increase the number of uninsured by 13 million over the next ten years and cause premiums to rise 10 percent above the current baseline. CBO also stated that both Republican tax-cut proposals would trigger $25 billion in automatic Medicare spending cuts in 2018. Sixty votes in the Senate would be required to override the automatic spending reductions. America's Health Insurance Plans (AHIP), the American Academy of Family Physicians, the American Hospital Association, the American Medical Association, the Blue Cross Blue Shield Association, and the Federation of American Hospitals sent a letter to congressional leaders, voicing their opposition to a repeal of the ACA individual mandate in the GOP's tax reform legislation.

The American Academy of Actuaries also sent a letter to Majority Leader McConnell and Democratic Leader Schumer, cautioning against repealing the Affordable Care Act's (ACA) individual mandate as part of tax reform legislation. The actuaries indicated this would result in increased premiums and insurers leaving the marketplace. According to an analysis by The Commonwealth Fund, some people's tax cuts under the GOP Senate bill would be canceled out by the increased premiums they would face due to the repeal of the ACA's individual mandate. And, for those roughly 7 million people who buy insurance on their own but don't get premium subsidies, high health care costs would endure even after the bill's tax cuts expire.

A swing vote that may determine whether the tax reform passes may come from Republican Senator Susan Collins (R-ME). President Trump and the Senate Republican leadership has implied that if she votes for the tax bill there will a commitment to pass separate bipartisan legislation to mitigate the impacts of the mandate repeal through policies that are designed to stabilize the insurance marketplace. The independent Congressonal Budget Office, health

insurers and consumer advocates have indicated that any such set of policies (specifically provisions to mitigate the associated risk selection that would result from the mandate repeal) would be insufficient to address resulting from repeal of the mandate.

In addition, Senator Collins's Democratic colleagues who have worked with her on this issue – Senator Patty Murray (D-WA) and Senator Bill Nelson (D-FL) have underscored that the policy Senator Collins appears to be relying on to address the mandate repeal is far from adequate and, as such, they are strongly urging her to vote against this tax package. As of this writing it is unclear which way the Senator from Maine will vote and/or whether any type of subsequent legislation to address the impact of such repeal is at all viable.

B. **Employer Mandate Being Enforced.** The Internal Revenue Service (IRS) posted the draft Form 1095-C which will be sent to employees of Applicable Large Employer subject to the employer shared responsibility provision in the ACA. The Form 1095-C includes information about the health insurance coverage offered to employees and their employees by their employer. The IRS also released the 8-page form letter 226J that they will use in notifying an employer of its liability for not offering coverage and showing how the amount was calculated.

C. **New Health and Human Services Secretary Nominated.** President Trump nominated Alex Azar to be the next Secretary of Health and Human Services (HHS). Azar served for nearly 10 years at the Indiana-based U.S. arm of Eli Lilly and Co. and worked with then-Governor Mike Pence. He held multiple positions at HHS during the President George W. Bush Administration, including as General Counsel and Deputy Secretary. The Senate Finance and Health, Education, Labor and Pensions (HELP) Committees are holding hearings on Azar's nomination, but only the Finance Committee will vote on whether to advance it to the full Senate. Azar's HELP Committee hearing is scheduled for November 29th and Senate Finance Committee hearing on December 5th. While he has and will receive a great deal of scrutiny about his ability and commitment to contain prescription drug prices, Mr. Azar is expected to be confirmed barring something unexpected emerging from the confirmation process.

CalPERS/California Implications: The tax reform debate is particularly noteworthy to CalPERS as it will likely NOT provide for Cadillac Tax "relief" but will include a $1.5 trillion deficit increase. Such an increase in the deficit will increase pressure to cut federal health programs and lead to cost-shifting to CalPERS and other purchasers by increasing the numbers of uninsured/uncompensated care. Moreover, the ACA insurance markets will continue to face legislative and administrative challenges and opportunities. The status quo will likely be a relatively unstable marketplace, though there will be exceptions, including most likely Covered California. Even in California, though, individuals earning over 400 percent of income ($48,000 for a single person) who are not subsidized (and not eligible for premium tax credits) – a disproportionate number of whom live in the state—face increasing difficulty affording coverage.

Recommended Positioning and Actions for CalPERS: Along with other private and public purchasers, CalPERS should continue to monitor the tax cut/reform debate to ensure that

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they are not impacted by significant cost-shifting related to any spending cuts being contemplated.