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Federal Health Policy Report for CalPERS
October 2017

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

A. Senate Hearing on Drug Affordability. On October 17th, the Senate HELP Committee held the second of three planned hearings on the prescription drug delivery system and its effect on pricing. The witnesses represented the supply chain of pharmaceuticals—pharmaceutical manufacturers, generic and biosimilar drug manufacturers, pharmacy benefit managers (PBMs), pharmacies, and pharmaceutical distributors. Senators questioned which parties were responsible for the high cost of drugs while highlighting cases of price increases from the last year that incited public outcry (such as the Mylan/Epi-Pen episode). The witnesses representing drug makers and PBMs were the primary targets of questioning and spent much of their answers blaming each other for high prices. (The manufacturers blamed the PBMs for rebates that they claimed were not being passed onto purchasers; the PBMs pointed out that the manufacturers set the prices and make up the vast majority of overall prescription drug costs). Perhaps not surprisingly, there was consensus amongst these private sector witnesses that the best way to deal with medication costs was greater competition – not greater regulation.

B. House Mark-Up of Repeal of Independent Payment Advisory Board (IPAB)—PhRMA's Highest Legislative Priority. On October 4th, the House Ways and Means Committee passed out a bill to repeal IPAB. This Advisory Board was established by the ACA to empower the executive branch to constrain health care costs if they grew above certain targets and Congress failed to act. For easy to understand reasons, virtually all health care providers, plans and manufacturers oppose the existence of IPAB, but its repeal is the highest priority for PhRMA. The Association fears the implementation of IPAB could ultimately lead to drug pricing limitations. The non-partisan CBO projected a cost of $17.5 billion over ten years to repeal IPAB and, though the Congress generally has to pay for policies that increase costs, the Republicans on the Committee passed it out without an offset. Whether this repeal makes it through the legislative process is unclear, but it illustrates the power of the pharmaceutical industry, even at a time when it is receiving such critical public scrutiny.

C. FDA Issues Draft Guidances Aimed at Promoting Generic Drug Competition. The FDA issued six draft guidances and one final guidance in October in an effort to help encourage makers of generic complex drugs to enter markets and increase competition. Complex drugs are those drugs that include one or more features that make generic versions difficult to manufacture and to be approved; examples include asthma treatments and injectable treatments for diseases like multiple sclerosis. The guidances clarified rules and FDA practices regarding a generic drug approval application process and also offer opportunities for makers to meet with FDA to discuss the development and application process. FDA Commissioner Scott Gottlieb noted that complex branded

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drugs face little generic. This is the latest step in the Commissioner's Drug Competition Action Plan which has made increasing competition a top FDA priority.

D. **Allergan-St. Mohawk Tribe Patent Deal Nullified.** On October 16th, a federal judge invalidated Allergan's patents protecting its $1.5 billion blockbuster drug, Restasis from competition. In September Allergan tried to protect its product from competition by paying a Native-American tribe, which enjoys sovereign immunity, $13.5 million upfront in addition to $15 million in annual payments to hold the six patents. The judge's decision criticized the commercialization of the tribe's sovereign immunity and noted its troubling ramifications for future abuses of the patent system. Allergan has appealed the decision but has stated it will not seek sovereign immunity in the district court proceedings.

E. **Democratic Senators Call for Price-Gouging Penalties.** On October 27th, 13 Democratic Senators, including Senator Kamala Harris (D-CA), called on the Trump administration to move forward with a rule allowing the Department of Health and Human Services to issue penalties to drug companies that intentionally overcharge entities receiving drugs through the 340B program. The 340B program requires manufacturers participating in Medicaid to provide outpatient drugs at discounted rates to entities serving the poor such as children's hospitals, federally-qualified health centers, and rural care centers. The rule was set to begin this year; however, the Trump administration has delayed implementing the rule four times.

F. **Maryland's Price-Gouging Law Takes Effect.** A U.S. District judge denied an injunction against the state's new price gouging law, allowing the law to take effect October 1st. Under the statute Maryland can investigate complaints of "unconscionable" price increases for off-patent or generic drugs that call for fines of up to $10,000. The Maryland attorney general can also require justifications for the price hikes from manufacturers and distributors. The suit against the law, brought by the generic drug lobby, was allowed to continue.

G. **Massachusetts Seeks to Curb Prescription Drug Costs in Medicaid.** In their September 1115 Medicaid waiver submission, Massachusetts asked CMS to allow the state's Medicaid program to opt out of the requirement to cover every drug in the federal Medicaid rebate program. The move is designed to improve the program's position in negotiations with drug manufacturers by creating a closed formulary that has at least one covered drug per therapeutic class. The waiver also asks to allow exclusions for those drugs with limited evidence of efficacy and gives the Medicaid program the flexibility to set up selective specialty pharmacy networks.

CalPERS Implications: There has been some legislation and executive actions to remove some barriers for increased competition. As indicated above, the FDA Commissioner has continued to push for greater market competition through new FDA guidance and policies that encourage generic drug makers to enter into the market. CalPERS has

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strongly supported these and other actions. CalPERS was heartened by the strong commitment by the President and the Congress to aggressively tackle the issue of rising pharmaceutical costs. 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 who are considering or have advanced policies that increases price transparency, curbs price increases, and/or punishes egregious pricing practices. 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 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, such as the National Coalition on Health Care, the Pacific Business Group on Health and the Public Sector HealthCare Roundtable 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.

II. CADILLAC TAX

A. Lack of Repeal/Replace Legislation Results in No Movement on Cadillac Tax: In the American Health Care Act passed by the House on May 4th, the Cadillac tax would be delayed from 2020 to 2025. With the failure of the repeal/replace effort in the Senate (see description below), there has been no consideration of further delay of the Cadillac tax.

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.

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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 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. In addition, and simultaneously, CalPERS should begin working 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. CMS Issues Reports on ACO. On October 13th, CMS posted the 2016 results for a group of ACO models: Next Generation, Comprehensive End Stage Renal Disease (ESRD) Care, Pioneer, and Medicare Shared Savings Program (MSSP). Only the MSSP showed a net loss ($39 million) while the remaining three models showing net savings totaling $118 million. The overall success of these models seems largely driven by the increased participation in Medicare ACO programs. While the previous administration would widely distribute achievements in the ACO programs, the release of this year's results was notably muted.

B. CMS Issues Preliminary Report on CJR Model. CMS also posted early results for 2016 for the Comprehensive Care for Joint Replacement (CJR) Model on October 13th. The model requires the 800 non-exempt hospitals in 67 metropolitan statistical areas (MSAs) to test retrospective bundles Medicare payments for hip and knee replacements. In the model, participating hospitals that earn positive quality scores and spend below a target price in achieving results are eligible for reconciliations payments. In 2016, almost half of these hospitals were eligible for reconciliation payments. Under former HHS Secretary Tom Price, CMS proposed a rule that would scale back mandatory participation in this program and other compulsory bundled payment programs, arguing the agency lacked the authority to force hospitals to participate in these models. Stakeholders, such as the American Hospital Association, supported the scaling back by arguing that forced participation would lead unprepared or ill-equipped hospitals to suffer financial hardship. Supporters of the demonstration models responded saying that voluntary participation would slow down the movement to adopt value-based care practices and limit the amount of data used to evaluate their performance.

C. House Continues to Consider CHRONIC Care Act. The House continues to consider the CHRONIC Care Act after the bill was passed in the Senate in late September. The bipartisan bill expands and extends models designed to allow seniors with chronic conditions live at home, gives Medicare Advantage more flexibility to offer supplemental

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benefits and use value-based purchasing, improves access to telehealth, and ensured more financial security in the ACO program for those with chronic conditions.

The Ways and Means Committee and Energy and Commerce Committee in the House, which have jurisdiction over the bill, hope to agree on a version of the bill parallel to the Senate package. The prevailing opinion of healthcare experts is that the House will not modify the Senate version drastically and will likely package CHRONIC Care Act provisions with another priority bill such as the Children's Health Insurance Program re-authorization or must-pass Medicare extenders at the end of the year.

D. **CMS To Issue 2018 MACRA Final Rule.** CMS must issue its 2018 MACRA Final Rule before November 1st, 2017. In its proposed rule, CMS moved to exempt physicians making less than $90,000 in Medicare revenue or seeing fewer than 200 Medicare patients per year from the MIPS system starting in 2018. This is estimated to exclude 134,000 more providers from the new Quality Payment Program instituted under the 2015 Medicare and CHIP Reauthorization Act (MACRA). The move drew strong criticism from stakeholders interested in more aggressively moving towards new value-based payment models. Supporters of the proposed rule cited concerns that providers and hospitals are still not prepared to meet the burden of the new reporting and payment system.

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 to new opportunities to highlight successes 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, CalPERS staff, in conjunction with its consultants, are drafting a letter 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. "Graham-Cassidy" ACA Repeal and Replace Effort Fails Before Deadline, Pushing Likely Future Efforts to Next Year. Senators' Graham, Cassidy, Heller and Johnson proposed to effectively eliminate the Affordable Care Act's (ACA) individual and employer mandate, impose a per capita cap limitation on Medicaid, and redistribute the money from the ACA's Medicaid expansion and tax credits for premiums via large block grant to states, among numerous other changes. The redistribution of the funds would have cut and diverted billions of dollars away from California. Perhaps not surprisingly, the state and its health plan, provider and consumer stakeholders strongly opposed. This was the final attempt to repeal and replace the ACA before the October 1st deadline to use the budget reconciliation rules, (which provide a pathway for a 51-vote in the Senate). With the budget reconciliation rules expired, legislation must once again garner 60 votes to break a filibuster in the Senate. As such, there is little expectation of a new attempt to repeal the ACA until next year, when there may be a new set of budget reconciliation protections that provide another vehicle to pass such legislation with a simple majority vote.

B. Trump Administration Actions on Health Care.

i. **Executive Orders Issued on Specialty Health Insurance Plans.** After the failure by Congress to repeal the ACA, President Trump signed an executive order on October 12th that direct federal agencies to explore expanding access to association health plans (AHPs) and broadening the definition of short-term limited duration health plans (STLDs) from three months to 364 days. These plans are exempt from ACA mandates and are generally cheaper and skimpier than exchange plans. Supporters of these plans, including some small business associations, believe they offer much needed additional choice of and access to less costly plan options. Opponents, including consumer groups and insurance commissioners, have notable concerns about the impact of such new options on insurance pools, believing they could lead to more risk selection and higher premiums for those who wish to continue to purchase plan options in the ACA exchange. The ultimate outcome of the review and recommendations by the Departments of Labor and Health and Human Services is unclear, but how they are constructed and how many people have access to them could notably impact markets, including California.

ii. **Discontinuation of Cost-Sharing Reduction (CSR) Payments.** The Trump Administration discontinued the ACA's CSR reimbursements given to health plans to offset the costs of the law's required cost-sharing protections for certain lower income Americans. Fearing that President Trump would make this decision, most states – including California – permitted insurers to raise their premiums by 10-20

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percent to offset this loss of revenues. With this in mind, the non-partisan Congressional Budget Office (CBO) estimates the premium increases – and associated premium subsidies -- driven by the elimination of the CSR payments will add $194 billion to the federal deficit over the next ten years.

iii. **Attorneys-General File Suit to Prevent ACA Cost-Sharing Cutoffs.** The attorneys-general from California, seventeen other states, and D.C. joined in filing a temporary restraining order to force the Trump administration to continue making CSR payments. A federal judge in the Northern District of California denied the preliminary injunction on October 25th, citing states' planning for the discontinuation as evidence that states were given fair warning and would not require emergency relief via an injunction.

iv. **ACA Waiver Authority to Provide Flexibility and Resources for States.** The Trump administration has exercised its authority over so-called 1332 state innovation waivers to varied effects. The ACA allows for alternative state approaches, but there are clear rules preventing states from undermining benefit protections, reducing coverage, or increasing the deficit. As such, of those who applied, most states requested and a number received federal financial credit to establish reinsurance programs that reduce the costs of high-cost/high need populations in exchanges. States and many sympathetic Republicans desire more flexibility to provide lower cost benefits with less valuable coverage. However, there is limited flexibility available under the law in this area, which is why Republicans are pursuing legislation on Capitol Hill that would provide more leeway.

C. **Bipartisan Market Stabilization Bill and Response.** Senate HELP Committee Chairman Lamar Alexander (R-TN) and Ranking Democrat Patty Murray (D-WA) reached a compromise deal on October 17th on a bill that would stabilize the insurance exchange markets. The bill would fully fund the CSR payments through 2019, restore cuts to marketplace outreach efforts, make it easier for states to submit and receive approval for 1332 waivers, and expand catastrophic coverage options under the ACA. The Senators subsequently announced that the bill had 24 co-sponsors, 12 Republicans and 12 Democrats. Democrats signaled that the majority of their caucus would vote for the bill, while key Republican members have either not voiced their opinion or declared opposition. Notably, Senator Orrin Hatch (R-UT), the Chairman of the Senate Finance Committee which shares jurisdiction over health insurance markets, announced he would not support the bill and instead proposed his own measure with House member and Chairman of the House Ways and Means Committee Kevin Brady (R-TX). Senate Majority Leader Mitch McConnell suggested he would bring a bill to the floor for a vote if the President supported it. The President has given multiple conflicting signals about his position on the legislation, but of late has opposed the bipartisan compromise.

D. **Budget Resolution and Tax Cut Impact on Health Care Debate.** The 2018 budget resolution passed by the Senate and House in late October includes assumptions for

over $1 trillion in Medicaid cuts and hundreds of billions of dollars in Medicare cuts. This non-binding budget resolution also provides for important reconciliation

protections for a $1.5 trillion increase in the federal deficit in the context of the tax cut/reform legislation advocated by the President and the Republican leadership. Advocates believe a tax cut will spur economic growth and increased revenue. Opponents, citing independent analyses, argue that such projections are without foundation or precedent. More important to health care purchasers on all of these legislative developments is the potential impact of cost-shifting from major cuts to Medicare and Medicaid as well as increases in uncompensated care shifts from projected increases in the uninsured (should subsequent legislation be passed and enacted). In any case, it is worth noting that Finance Chairman Hatch, who is the lead actor on tax reform, has indicated that he has no intention of repealing ACA taxes, including the Cadillac tax, in the context of the tax reform bill.

CalPERS/California Implications: In the near term, 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. Market stabilization legislation has real potential to alleviate some of these challenges. However, as of this writing, the President and Congressional Republican Leadership have largely moved on to focus on tax reform. 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.

Recommended Positioning and Actions for CalPERS: Along with other private and public purchasers, CalPERS would be well advised to encourage bipartisanship and progress on market stabilization. Similarly, CalPERS should closely monitor and take the opportunity to formally convey comments on executive actions out of the Department of Labor on Association Health Plans that have any intentional or unintentional negative (or positive) impact on CalPERS interests. Finally, CalPERS should continue to monitor the tax cut/reform debate to ensure that they are not impacted by significant cost-shifting related to any spending cuts being contemplated.