AVENUE SOLUTIONS

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Federal Health Policy Report for CalPERS
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I. DELIVERY REFORM DEVELOPMENTS:

A. Knee and Hip Replacement Bundling: The House Budget Chairman, Representative Tom Price (R-GA), is currently circulating a September draft letter asking the Center on Medicare and Medicaid Services (CMS) to delay the January 2016 start-up date for a new bundling reimbursement model tying hip and knee replacements to quality and value measures. (This effort is part of CMS's push toward linking payments to value based incentives). The Price letter reportedly argues that health care providers need more time to prepare for system and payment changes such as this. As of this writing, at least 30 members, including Republicans and Democrats have signed the letter.

B. Potential Issues with Hospital Readmissions:

i. A September report from JAMA said that hospital readmissions, which are penalized under the ACA, are largely driven by patient characteristics such as income and education, rather than the quality of care that they receive. The report indicated 22 characteristics that are associated with higher probabilities of readmission, but are not taken into account by CMS. The Medicare Payment Advisory Commission and the American Hospital Association have recommended, for several years, broadening the factors used for determining penalties for readmission. In response, the National Quality Forum is working with Medicare officials to develop a two-year trial with risk adjustments for socio-economic and demographic characteristics.

ii. Additionally, an August report in Health Affairs alleged that hospitals are cheating to avoid the readmissions penalties. Rather than actually reducing the number of readmissions happening, the report states that hospitals have been labeling readmissions as "observation stays," and/or have treated emergency rooms (both of which are not considered readmissions). If true, this would cast into doubt the effectiveness of the program, which has been a focus of the delivery system reform efforts within the Administration, and the drop in readmission rates from 19 percent in 2011 to 17.5 percent in 2013. The American Hospital Association responded on August 27th saying that this report overstates the impact of these practices and that other studies have not found the same result.

C. Mixed Results from ACOs: In August, CMS released data showing that nearly 350 ACOs saved Medicare $411 million in 2014, down slightly from $417 million in 2013. However, according to a Kaiser Health News report, after paying bonuses, the program actually lost nearly $3 million. Many blame this on a combination of a lack of desire by many ACOs to take on financial risk at this point, as well as implementation difficulties in shifting to this

new model quickly. Clif Gaus, President of the National Association of ACOs, has said that Medicare should be making it easier for ACOs to earn bonuses early on in the process and that no start-up makes profits in the early years. Others have stated that consumers need a greater incentive to stay in the ACO's delivery system.

D. Merit-Based Incentive Payment System (MIPS): The Medicare Access and CHIP Reauthorization Act, which repeals the Medicare Sustainable Growth Rate, consolidates several Medicare value-based payment schemes, including the meaningful use EHR incentive program, into the new Merit-Based Incentive Payment System (MIPS). Under MIPS, scheduled to start in 2019, physicians would receive boosts or cuts in Medicare payments depending on how they perform on a series of measures. Doctors who have enough of their Medicare payments tied to alternative payment models rather than fee for service will get a 5 percent bonus and be exempt from MIPS. CMS is asking for feedback on how it should implement MIPS, soliciting thoughts specifically on whether or not doctors should be given partial credit for meeting some, but not all, of meaningful use measures. Comments are due to CMS on October 30.

E. CalPERS Implications: CalPERS has been a national leader in demonstrating how bundled payment and delivery reforms (reference pricing) for hip and knee replacements can achieve notable savings without undermining quality. In implementing this and other reforms, CalPERS has inspired public and private purchasers to accelerate efforts to incentivize more efficient provision of care. However, recent developments in D.C. outlined above well illustrate that health care providers consistently work to highlight quality and process concerns to support their contention that delivery reforms should be delayed.

F. Next Steps: CalPERS may wish to consider more actively supporting CMS efforts to further accelerate bundling payment reforms by producing creative information about the positive patient, physician, plan and payer experience with the reference pricing initiative. Moreover, the CalPERS may wish to review the implications of the finding that that some hospitals may be re-directing patients to settings that do not count against the re-admission penalties/disincentives and, as such, are defeating the objectives of the policy. Conversely, CalPERS may wish to work with the National Quality Forum and others to help determine and address legitimate concerns about linkages between income and education and their impact on readmissions. Finally, CalPERS may consider providing feedback to CMS on their MIPS effort to ensure policies are supportive, rather than detrimental, to CalPERS ongoing value-based initiatives.

II. PRESCRIPTION DRUG COSTS:

A. Biosimilar Reimbursement:

i. **CMS Regulation:** In August, a bipartisan group of 33 House lawmakers urged CMS to drop its proposal to create single billing codes for biosimilars that reference the

same brand biologics. (The CMS proposal is designed to help facilitate the use of biosimilar product alternatives to originator and very expensive biotech products). The proposed 2016 Physician Fee Schedule calls for calculating the pay for billing codes based on the average sales price of all biosimilars that reference a common biologics license application. The law and CMS' interpretation of it would lower reimbursement for all similar products within this category and incentivize the use of less expensive medications.

Consistent with the argument taken by BIO (the biotech trade association), the August Congressional letter argues that biosimilars are more complex than traditional generic drugs, so they should not be treated as though they are generics. Senator Wyden, however, who is the Ranking Democrat on the Senate Finance Committee, sent a letter in support of the CMS policy. In addition, AARP, the National Coalition on Health Care (NCHC), MedPAC and possibly other purchasers supported the CMS position or urged that CMS go further and put all biosimilars in the same reimbursement code with the reference biologic. This would even further incentivize movement away from reference biologics towards the lowest cost biosimilar.

ii. **FDA Regulation:** FDA released a proposed rule and draft guidance outlining how it plans to name biosimilars. Under the proposal, every product will get a unique FDA-designated suffix composed of four lowercase letters. The agency also requests input on other naming proposals, such as having the suffixes derive from the name of the company making the drug. FDA delayed making a decision on how it will name interchangeable biological products. Most advocates of the use of biosimilars, such as AARP and the National Coalition on Health Care (NCHC), have raised concerns about the FDA suffix proposal because they believe it will lead to confusion and hesitancy amongst physicians and their patients to use less expensive biosimilars. Comments on the draft guidance are due Oct. 25. Comments on the proposed rule are due Nov. 11.

iii. **CalPERS Implications:** Should BIO and its allies win the day at both CMS and FDA, there is little doubt that an opportunity to moderate prescription drug costs will be undermined.

iv. **Next Steps:** CalPERS may wish to submit (or join others in submitting) comments to address what most purchasers have concluded is a flawed proposed FDA guidance and rule. Consistent with this, CalPERS should continue to work with allies to ensure CMS, at minimum, does not backtrack on its current proposal and, even better, seriously considers putting all biosimilars and their originator product in the same reimbursement code.

B. Legislation to Limit Prescription Drug Spending: In response to rising prescription drug costs and projections of greater problems in the futures, state legislatures from Ohio to

Pennsylvania to Massachusetts are considering bills to set limits on drug prices. In California a ballot initiative is circulating for signatures that would cap prices at the rates paid by the Department of Veterans Affairs, which are generally lower than those paid by other purchasers. Conversely, however, many states are also considering an array of policies to undermine barriers to effected prescription drug cost management programs.

C. **Presidential Campaigns on Prescription Drug Costs:** As surveys have shown increasing concern from consumers about high prescription drug prices, both Hillary Clinton and Bernie Sanders have released plans in September to combat rising costs for prescription drugs.

   i. Secretary Clinton would (1) eliminate tax write off subsidies for direct to consumer advertising and establish a more aggressive review procedure for FDA for direct-to-consumer ads to ensure that they are clear and understandable; (2) require drug companies to invest a set amount of revenue into R&D or pay into a fund to support research; (3) cap covered out-of-pocket drug costs at $250 per month (this is modeled after a California exchange policy that has already been implemented); (4) eliminate a backlog of generic approvals at FDA; (5) incentivize greater competition for biotech products by lowering the length of market exclusivity for biotech innovators; (5) prohibit "pay for delay" agreements between innovators and generics that delay market competition; (6) allow reimportation of drugs; (7) invest in comparative effectiveness research; and (8) authorize Medicare to directly negotiate on prescription drugs where there is little competition.

   ii. Senator Sanders' plan would also allow direct negotiation for Medicare, permit reimportation, and prohibit pay-for-delay agreements. He also wants to close the Medicare Part D donut hole, or coverage gap where seniors are required to pay out of pocket costs for their prescription, by 2017, or three years earlier than under current law. He would also move prescription drug coverage for low income seniors to Medicaid from Medicare part D, where higher prices are paid for prescription drugs. He is particularly harsh with any sort of fraud. Whether the company settles or is convicted, any company found at fault in civil or criminal violations would terminate exclusivity for that product. He would also require companies to publically report price information and the amount spent on research and development both in the US and abroad.

   iii. Republican candidates for President, to-date, largely have not released specific details for their approach to managing prescription drug costs. Most have focused their health policy comments around their commitment to repeal the Affordable Care Act. There is little question that most of the policy outlined above by the Democratic candidates would be opposed by the Republican candidates and framed as excessively regulatory. Republicans running for the White House are more likely to focus on system-wide capitated payment reforms rather than directly target prescription drug coverage and cost policy.

D. **Another High Cost Treatment Approved:** In August, the FDA approved Amgen's Repatha, a new cholesterol lowering treatment. This biologic will annually cost up to $14,000 a patient and is designed to treat patients with rare genetic conditions that do not fare well with traditional statin treatments. While it is approved by FDA for a small subset of patients, physicians are free to prescribe this to a broader segment (potentially millions) of patients. This combined with the open-ended use of this drug for chronic, long-term purposes has raised understandable concerns amongst payers about another large increase in prescription drug costs. This concern comes on the heels of the late September release of a Steven Brill piece on Johnson and Johnson's aggressive (and subsequently successfully challenged) techniques to market a schizophrenia drug **off-label** to physicians to improve sales. With some recent largely "green-light" court rulings (and the clear utilization objectives of the manufacturers in mind), increased **off-label** marketing practices (and their implications) is starting to get closer scrutiny by the purchasers.

E. **CalPERS Implications:** For years, CalPERS has been amongst the most aggressive at signaling the negative cost implications of the beginning of the "generic cliff" where there will be insufficient competition and choice to apply against new "single-source" medications, particularly specialty products, for which purchasers cannot leverage discounts. According to private health plans and the Medicare actuary, overall health premiums are being significantly driven by prescription drug prices and utilization. If off-label marketing accelerates this trend, CalPERS could witness (and be forced to underwrite) even greater cost burdens.

F. **Next steps:** CalPERS staff is working aggressively to not only manage these drug costs with its contractors and plans, but is also developing data that helps inform both "best-practice" plan administration AND the public and policymakers about the implications of these drugs costs trends. In addition, CalPERS continues to support a range of policy interventions that would help ameliorate some of these unsustainable prescription drug cost trends, including amongst other policies, greater competition and choice by (1) eliminating barriers to larger numbers of high quality generics and biosimilars; (2) opposing efforts by the pharmaceutical industry to block consumer access to those products (either through their efforts to expand market exclusivity protections or other drug management restrictions), and (3) permitting Medicare the authority to directly negotiate for excessively priced prescriptions that face little or no competition.

III. CADILLAC TAX

A. **Many Employers Offer Plans that Would be Impacted by Cadillac Tax:** A late August analysis by the Kaiser Family Foundation found that roughly a quarter of employers offer workers at least one health plan that is likely to trigger the ACA "Cadillac tax" in 2018. Employers are widely expected to reduce costs to avoid triggering the tax.

B. **Treasury Department Continues to Request Options for Implementation of the Law in Second Round of Comments from Stakeholders Due October 1st:** Business, public

purchasers, plans, labor unions and others continue to urge the Treasury Department to use all tools at its disposal to moderate the impact of the implementation of the so-called Cadillac tax on businesses and other entities having to administer it. CalPERS will be submitting their own comments to further clarify System concerns and suggested implementation approaches (without in any way suggesting support for the underlying law). [More information on this is outlined below in "CalPERS Actions" section].

C. **Legislation to Repeal Cadillac Tax:** On September 24th, Senators Brown (D-OH) and Sanders (I-VT) introduced a bill with 5 other Democrats, including future Democratic Leader Schumer, to repeal the Cadillac Tax. The bill includes a sense of the Senate that the associated cost should be totally offset. Senators Heller (R-NV) and Heinrich (D-NM), introduced their version of repeal on September 17th. Additional legislation from the House Ways and Means Committee proposes repealing the Cadillac tax along with significant components of the ACA including the individual and employer mandates, the medical device excise tax, and the Independent Payment Advisory Board. Each of these bills have little chance of passing or sustaining an almost inevitable veto from President Obama, but they do show increasingly organized pressure on both Democrats and Republicans to repeal the Cadillac Tax. Groups such as the "Alliance to Fight the 40" composed largely of purchasers, businesses, and unions will likely support many of these and other efforts aimed at repealing the tax.

   Presidential Candidate Positions on Repeal of Cadillac Tax: Notably, Hillary Clinton (because of her serious concerns about underlying flaws of the Cadillac Tax including the lack of well-defined geographic adjustment, an unrealistically low indexing mechanism, as well as issues with the perceived impact of the law on counterproductive cost sharing increases) announced at the end of September that she would support a full repeal of the tax. As such, when combined with Senator Sanders' position, the current leading Democratic contenders for President are embracing the notion that the total elimination of the Cadillac tax is desirous – something that many Republicans seem to be embracing as well. However, the White House has not yet signaled whether they would support these efforts, and indeed there is every indication that the President would strongly oppose a full repeal of the tax. Furthermore, there is no consensus on an offset to pay for the approximately $90 billion cost of repeal, nor is there a certain legislative vehicle to accomplish repeal.

D. **CalPERS Implications:** As we have reported previously, a number of current CalPERS health plan offerings are already projected to be subject to the Cadillac tax unless modified prior to 2018. And, over time, more plans will find themselves in this situation unless the current ACA policy is modified, impacted CalPERS plans are restructured or there are new successes at constraining the costs of current plan structures. While the ACA policy is based on economic principles supported by both Republican and Democratic health economists, its current indexing structure is unrealistically tight.

E. CalPERS Actions and Next Steps: CalPERS staff in consultation with the federal advisors already submitted a first round of comments to the Treasury Department's Internal Revenue Service regarding preferred approaches in implementing the current law provisions of the Cadillac tax. A second round of comments are being submitted as well prior to the October 1st filing date. In general, the comments are focused around approaches that will limit the impact of the law on CalPERS members and plans. For example, CalPERS requests that the Treasury Department and the IRS consider allowing the plan sponsor and ASO Organization to agree by contract which entity will be responsible for the Excise Tax, thereby removing a potential ambiguity. In addition, the CalPERS Board may wish to weigh in (to support) bipartisan legislation to repeal the Cadillac Tax; the outstanding question would be whether that support would apply to an offset necessary to pay for the cost of repeal (some $90 billion over next ten years).

IV. MISCELLANOUS DEVELOPMENTS OF RELEVANCE TO CalPERS:

A. Large Medicare Part B Premium Increase: Without federal action, Medicare Part B premiums will increase by 50 percent (or more in some cases for higher income seniors) for approximately 30 percent of Medicare beneficiaries due to a "hold-harmless" provision triggered when low inflation precludes a Social Security cost-of-living adjustment (COLA) and protects all other seniors from a Part B premium increase. For those impacted, Part B premiums will increase by at least 50 percent (an increase from $104.90 to $159.30). This will include (1) seniors who were public employees and some teachers who never paid Social Security but are paying for separately for Medicare (4.4 million or 8 percent of beneficiaries), (2) low income seniors who are eligible for both Medicare and Medicaid (dual eligibles) and whose home state Medicaid program pays their premiums (9 million or 17 percent of beneficiaries), and (3) seniors who have annual earned incomes in excess of $85,000 for singles and $170,000 for couples (about 3 million or 6% of beneficiaries). Depending on their income, seniors' Part B premiums will increase anywhere from $223 to $510 per month, depending on size of income and family status.

Without question, the one-year premium hike will be substantial for impacted parties, though it is important to note that much of the impact of this hike will likely be smoothed out by 2017 (when premiums reset back to a base dollar amount when Social Security COLAs are granted and the Part B premium costs is spread amongst all beneficiaries). Recognizing that the Administration can only blunt this impact modestly via executive action, AARP and the states are raising concerns to the Congress and the Administration and seeking a one-time fix to address. The challenge is that a provision to hold the 30 percent of the impacted population harmless costs an estimated $10 billion and offsets will be extremely difficult to come by.

i. **CalPERS Implications:** CalPERS staff and their federal consultants are gauging the extent to which CalPERS enrollees will be impacted by the 2016 premium hike.

Clearly, there will be a number of CalPERS members who will be effected, particularly those never paid into Social Security and pay a separate Medicare premium or those who are in the income brackets referenced above.

ii. **Next Steps:** As CalPERS makes a determination about scope of impact of the Part B premium hike on its members, the Board may wish to weigh in on whether CalPERS should explicitly support federal intervention and, if so, whether it will need to engage on the federal offset question.

B. **Competition and Mergers in Health Care:** In September, both the House Judiciary Committee's Antitrust Subcommittee and Senate Judiciary Subcommittee on Anti-Trust, Competition Policy and Consumer Rights held hearings on the state of competition among hospitals, doctors and insurance companies since the ACA's passage. Predictably, the groups disagreed on the impact of the mergers between Anthem-Cigna and Humana-Aetna, with the insurers stating that the mergers would help cut costs and remove redundant systems and the hospitals and providers saying that the loss of competition would result in agreements between large insurers and reduce the negotiating power of providers. The insurers concluded by saying that, after divestitures in specific areas of limited competition, they expected the Justice Department to approve the mergers. Consumer representatives are generally opposed to the plan consolidation, arguing even if there are increased efficiencies, they are skeptical savings will be passed through to

i. **CalPERS Implications:** The state of California already has a fairly consolidated network of insurers and, as such, the California Insurance Commissioners has raised initial concerns about the merger. Amongst other things, he rightly says that the Commissioner's office does not have rate review authority, which 35 other states enjoy, for their individual (non-group) insurance market.

ii. **Next Steps:** Rarely does the Congress legislate anti-trust changes or direct actions the Justice Department or the Federal Trade Commission should take on a pending merger proposal. However, we will be talking to CalPERS staff leadership teams to determine if this is an area CalPERS and/or the Board should consider engaging.