JPS
Jennings Policy Strategies Inc.
1301 Pennsylvania Avenue NW
Suite 500 Washington, D.C. 20004

Federal Health Policy Report for CalPERS January 2016

I. **DELIVERY REFORM DEVELOPMENTS:**

- A. New Accountable Care Model: On January 5, the Centers for Medicare and Medicaid Services (CMS) announced a new Accountable Health Communities (AHC) model. According to CMS, the goal of the model will be to identify and address the health-related social needs of beneficiaries in areas related to housing instability and quality, food insecurity, utility needs, interpersonal violence, and transportation needs (beyond medical transportation) and thereby narrowing the gap between clinical care and community services. This is the first alternative delivery/payment model announced by CMS that focuses beyond health care services directly on coverage for health-related social needs.
- B. Growth in Accountable Care Organizations: On January 11, CMS announced 121 new participants in Medicare Accountable Care Organization (ACO) initiatives designed to improve the care patients receive in the health care system and lower costs. CMS also announced that providers and hospitals have signed up to join new types of ACOs, which in addition to being paid for positive patient outcomes will also receive penalties for negative ones. With new participants in the Shared Savings Program (SSP), the Next Generation ACO Model, Pioneer ACO Model, and the Comprehensive ESRD Care Model, there will now be:
 - Nearly 8.9 million beneficiaries served
 - A total of 477 ACOs across SSP, Pioneer ACO Model, Next Generation ACO Model, and Comprehensive ESRD Care Model
 - 64 ACOs are in a risk-bearing track including SSP, Pioneer ACO Model, Next Generation ACO Model, and Comprehensive ESRD Care Model
 - i. CalPERS Implications: ACOs, a critical part of the Administration's efforts to encourage value-based care, are delivering better care and they continue to show promising results on cost savings. In 2014, they had a combined total net program savings of \$411 million for 333 Medicare Shared Savings Program (Shared Savings Program) ACOs and 20 Pioneer ACOs. Shared Savings Program ACOs also outperformed group practices reporting quality on 18 out of 22 measures. These Medicare delivery reform/value purchasing initiatives are similar to policies already being implemented by CalPERS and are moving Medicare in a similar direction.
 - ii. CalPERS Next Steps: We continue to work with CalPERS staff to monitor and ensure that these and other announced federal delivery reform programs to ensure they do not inadvertently undermine system reforms that we are proposing and implementing. If they are not aligned, CalPERS staff will document challenges/problems and we will work with the HHS/CMS to modify accordingly.
- C. Improvements Sought in Health Information Technology: On January 20, Senators Alexander and Murray released a bipartisan Senate Health, Education, Labor and Pensions

JPS
Jennings Policy Strategies Inc.
1301 Pennsylvania Avenue NW
Suite 500

Committee staff draft of legislation to help improve health information technology, including electronic health records, for doctors and patients.

- i. CalPERS Implications: Improvements in interoperability and electronic health records are critical to advancing initiatives designed to improve care and reduce costs, a long-time goal and commitment of CalPERS.
- ii. CalPERS Next Steps: To continue to advocate for and execute on initiatives that advance the goal of achieving reforms that ensure high quality care at much more affordable costs. CalPERS staff and consultants will follow this effort in the Senate to ensure it is helpful in achieving these goals.

II. **Cadillac Tax Update**

- A. Update Provided at Off-Site Meeting: On January 20, CalPERS staff and consultants provided the Board with an update on the Cadillac tax. This update included analysis of current plans and alterations in plan design that could possibly mitigate or address the tax. Staff and consultants also provided a summary of recent Congressional action, the current state of play, the possible implications of the election on the Cadillac tax, and a proposed path forward including further analysis and vigilant engagement with stakeholders, Congressional interests and the Administration.
 - i. CalPERS Implications: While there is no legislative imperative for CalPERS to take a position immediately because of the recently enacted two-year delay, continued education of relevant stakeholders about the implications of the tax on CalPERS employers and employees is essential. Having said, despite the delay, the issue is not going away and will continue to be considered by the Treasury Department and the transition team of whomever is elected President at the end of this year.
 - ii. CalPERS Next Steps: Staff and consultants will continue to brief the Board and others about developments and implications surrounding the Cadillac tax and will actively seek opportunities to engage in Washington to influence this issue, including ensuring that any actions by the Obama Administration further clarifying how the law will be implemented are responsive to CalPERS' comments and priorities. Moreover, this will be an issue at beginning of next Administration and new Congress in 2017 and policy to delay, amend or repeal the underlying policy will most certainly be taken up. As we get closer to that date, consultants will seek further direction from CalPERS Board Members and senior staff.

MISCELLANOUS DEVELOPMENTS OF RELEVANCE TO CalPERS: III.

A. Employer Reporting Requirement Delayed: The Administration delayed the Affordable Care Act (ACA) reporting requirement giving insurers, self-insuring employers, and applicable large employers an extra two months to report what kind of health coverage they provide. The Treasury Department said it decided to offer the extra two months after getting feedback from the business community. Employers had previously faced a February 1 deadline for giving employees reports on the sort of coverage they offered and

JPS
Jennings Policy Strategies Inc.
1301 Pennsylvania Avenue NW
Suite 500

Washington, D.C. 20004

provided, the first time they have been required under the ACA to offer that information. Employers will also get another three months to give that information to the IRS, after previously facing a February 29 deadline for paper reports and a March 31 deadline for electronic reporting.

- i. CalPERS Implications: The information that employers will provide is to help the IRS keep track of the ACA's requirement that people have health coverage. However, employers have complained that the reporting requirements are highly burdensome and may have been of concern to many of CalPERS' employers.
- ii. CalPERS Next Steps: There is a bipartisan group of Senators working on legislation that they hope to introduce shortly to streamline and simplify the requirements. Staff and consultants will continue to follow this legislation to ensure it is helpful for CalPERS' employers.
- B. ACA Enrollment: On December 30, HHS Secretary Sylvia Mathews Burwell announced that more than 8.5 million people had signed up for plans on HealthCare.gov through December 26. The figures mark a sharp drop off over the Christmas holiday and after the December 17 deadline to sign up for coverage starting at the beginning of 2016. About 4.1 million people chose plans between December 13 and December 19. The data does not include enrollments from exchanges in 12 states and the District of Columbia. These numbers reflect the fact that 60 percent of HealthCare.gov consumers returned to the website to update their information or select a new plan this year. That is up from about 50 percent last year, about half of whom switched plans. Customers who change to a different plan at the same coverage level could save over \$600 a year. As of January, it appears that nationwide enrollment should exceed the 11 million net number that was initially projected by Secretary Burwell. The Congressional Budget Office now projects it will be closer to 13 million.
 - i. CalPERS Implications: Informational only.
 - ii. CalPERS Next Steps: None necessary.

C. Prescription Drug Pricing:

- i. Congressional Investigation on Sovaldi: An 18 month Congressional investigation into Gilead's pricing strategy used for its hepatitis C treatment, Sovaldi, showed that Gilead focused almost entirely on maximizing revenue of the drug. Senators Grassley and Wyden spearheaded the inquiry and said that their report raised several questions including the role of "value" in the pricing debate. On January 21, as a follow-up to this report, Senators Grassley and Wyden sent a letter to the health care and patient community requesting responses to the policy questions raised in their report.
- ii. Congressional Hearings on Sudden Drug Price Increases: On January 28, the Senate Health, Education, Labor and Pensions Committee will hold a hearing to discuss the reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA) which is designed to speed access to safe and effective generic drugs to the public and reduce costs to industry. The law requires industry to pay user fees

JPS
Jennings Policy Strategies Inc.
1301 Pennsylvania Avenue NW
Suite 500 Washington, D.C. 20004

to supplement the costs of reviewing generic drug applications and inspecting facilities. The additional resources enables the Agency to reduce the backlog of pending applications, cut the average time required to review generic drug applications for safety, and increase risk-based inspections. The current legislative authority for GDUFA expires at the end of September 2017. At that time, new legislation will be required for FDA to continue to collect generic drug user fees for future fiscal years. This hearing, at which Janet Woodcock of the FDA will be the sole witness, is the initial step in the reauthorization process which will involve extensive negotiations between Congress and the Administration. A second panel of purchasers was scheduled for February 2 but has been delayed indefinitely due to the government shutdown pursuant to the weather. It is possible that CalPERS board member Priya Mathur may be invited to be one of the panelists for this discussion.

On February 4, the Committee on Oversight and Government Reform will hold a hearing to review drug pricing. The purpose will be to discuss methods and reasoning behind recent drug price increases, the role of pharmacy benefit managers in negotiating drug prices, and address concerns about the lack of transparency in pricing contracts, and impediments to a timely review and approval of generic drug applications, and how the government can improve the efficiency and competitiveness in the market. Witnesses will include executives from Valeant Pharmaceuticals, Turing Pharmaceuticals, U.S. Food and Drug Administration and Pharmaceutical Care Management Association.

iii. 21st Century Cures Update: On January 9, the Senate Health, Education, Labor and Pensions committee unveiled its next steps for the upper chamber's pending counterpart to the House-passed 21st Century Cures bill, outlining a plan for three executive sessions on numerous bipartisan bills, the first of which will be held on Tuesday, February 9. The additional meetings will take place in March and April. Bills to be considered by the committee include measures to streamline FDA's regulation of combination products, establish a priority review program for breakthrough medical devices, allow sponsors of new drugs to use information from previously approved therapies, establish a program at the National Institutes of Health (NIH) to provide opportunities for new researchers and legislation on electronic health records, among other items.

The announcement was not issued jointly with Ranking Democrat Patty Murray (WA). A Democratic aide stated that the Feb. 9 markup is representative of a good faith, bipartisan effort, but notes the rest of the agenda outlined in the release is Alexander's schedule and does not include input from Democrats. The discussions were stalled in recent weeks as Democrats pushed for provisions related to drug pricing and mandatory funding for the NIH. Questions also continue to loom about

JPS
Jennings Policy Strategies Inc.
1301 Pennsylvania Avenue NW
Suite 500 Washington, D.C. 20004

the political viability of an FDA reform bill in an election year, and sources outside of Capitol Hill indicated that Senate Majority Leader Mitch McConnell (KY) is hesitant to introduce such a bill on the full Senate floor as it could force Republicans facing difficult reelections to vote on contentious issues like drug pricing.

- iv. Further Congressional Interest: On January 11, Rep. Lloyd Doggett (D-TX) and over 50 other lawmakers issued a letter urging the Department of Health and Human Services to use its statutory authority to help mitigate the rising cost of prescription drugs. The letter calls on the agency to develop guidelines for excising so-called march-in rights, with which the government can invalidate intellectual property claims that are based on federally funded research if the benefits of the patented products aren't "available to the public on reasonable terms."
- v. CalPERS Implications: It is encouraging that there is enhanced and increasingly visible bipartisan Congressional interest in reigning prescription drug costs. However, it is important to point out that there does not appear to be any viable legislative solutions on the immediate horizon. Nonetheless, it is also worth noting that CalPERS is one of the few purchasing (public or private) entities that Congressional Committees is requesting to serve as a data and policy resource.
- vi. CalPERS Next Steps: Continue working to document CalPERS' Rx drug expenditures, cost trends and implications for public, media and aligned stakeholder consumption. Staff and consultants will continue to look for opportunities for CalPERS to engage in this issue.
- vii. Donald Trump Embraces Medicare Direct Negotiation: Republican Presidential candidate Donald Trump stated on January 26th that he is in favor or allowing Medicare to directly negotiate prices on prescription drugs. This is a position generally only seen from Democrats such as Hillary Clinton and Bernie Sanders. Advocates for this policy argue that, as the largest purchaser in the nation, Medicare should have access to much better prices. Detractors say that it would jeopardize access to some drugs and point to low cost savings projected by CBO. Both PhRMA and AHIP have attacked the policy, aligning two powerful and unlikely allies. As of this writing, no other Republican candidates have expressed support for this policy.

D. Updates from the Campaign Trail

i. Wide Range of Health Policy Positions: Nearly all sides of the health care debate are currently represented in the Presidential campaign and the topic continues to be a high profile issue. Most of the Republican candidates continue to express a desire to repeal and replace the Affordable Care Act, but with relatively modest specificity. On the Democratic side, Hillary Clinton and Martin O'Malley have laid out plans to improve the ACA by increasing coverage and cutting out of pocket costs. Bernie Sanders has embraced a single payer policy, dubbed "Medicare for All." Vigorous debate continues on the Democratic side over the political feasibility

JPS
Jennings Policy Strategies Inc.
1301 Pennsylvania Avenue NW
Suite 500 Washington, D.C. 20004

of a single payer system and the associated significant tax but also insurance coverage increases compared with the practicality of building on the Affordable Care Act.

- ii. CalPERS Implications: Significant when the likely winner of the Presidency becomes clear and more detailed policy is unveiled
- iii. CalPERS Next Steps: Closely follow campaigns' policy pronouncements and progress.