I. DELIVERY REFORM DEVELOPMENTS:
   A. CMS Continues Move Toward Value Purchasing: Last month, Secretary Burwell met with representatives from the Hill and health systems to discuss progress toward the goal announced in January of tying 85 percent of traditional Medicare to value or quality by 2018. At this meeting, it was announced that HHS will award $685 million to 29 medical group practices and regional healthcare systems as well as 10 national organizations and professional organizations. One of the awardees was the Children’s Hospital of Orange County. Overall, these grants will help provide 140,000 clinicians with information and technology tools to improve communication/coordination and improve training to help insure improve medical outcomes.
   B. ACOs for End Stage Renal Disease: On October 8th, CMS announced the first group of ACOs specifically aimed at treatment of end-stage renal disease (ESRD). There are currently more than 600,000 people in the US with ESRD and treatments for the disease account for over $8.5 billion in annual costs and nearly 6 percent of all Medicare spending. The 13 organizations called ESRD Seamless Care Organizations (ESCOs) will begin this month to share financial risks of treating Medicare patients with kidney failure. One of these organizations is located in San Diego. The plan has attracted some criticism from providers about the application process and the metrics selected; some feel that the models should target patients in earlier stages of the disease to slow progression and associated costs.
   C. CalPERS Implications: The above-mentioned Medicare delivery reform/value purchasing initiatives are designed to improve care and reduce costs, a long-time goal and commitment of CalPERS.
   D. CalPERS Next Steps: We are working 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.

II. ACA/Cadillac Tax Updates
   A. Ongoing Debate on the Cadillac Tax: The debate over the Cadillac tax continues with approximately 60 percent of Americans supporting the elimination of the tax according to a Kaiser Family Foundation poll released recently. Economists however, continue to stand behind and strongly support the policy as a constructive incentive to constrain health care cost growth. On October 1st, a bipartisan group of 101 economists wrote a letter to the Senate Committee on Finance and the House Ways and Means Committee in support of
the tax. Moreover, a number of Republicans and moderate Democrats believe there should be some limits to tax subsidies for health coverage. Notwithstanding their support (and that of many editorial boards and the President) several bills, (some bipartisan and some partisan), repealing the Cadillac tax have been introduced in the House and Senate. None appear to be gaining significant traction and Congressional action seems unlikely for a number of reasons including:

(1) The President has indicated that he would veto such legislation (and there appear to be insufficient support for an override);
(2) Conservative Republicans wanting the Cadillac tax repealed want it done in context of repealing the entire Affordable Care Act; and
(3) Most Democrats who support repeal of the Cadillac tax are taking the position that the associated lost revenue/savings ($91 billion over ten years) should be paid for without increasing the deficit (AND there is insufficient support for offsets that would add up to that amount).

Having said that, because of the bipartisan opposition to the Cadillac tax policy, the fact that virtually all Presidential candidates of both parties are directly or indirectly advocating for its repeal or substantial modification and the fact that the 2018 implementation is coming closer to reality and business and labor representatives are strongly opposed to it, Congress will engage in this issue in some fashion (either through a serious debate and/or the policy’s delay, modification or its repeal) sometime in 2017.

i. CalPERS Letter on Cadillac Tax: CalPERS staff, in consultation with federal health representatives, submitted a letter on October 1st to the IRS for the second round comments on implementation of the Cadillac Tax. The letter focused on the recommendation that would effectively moderate the impact of the tax on CalPERS members and plans (WITHOUT IN ANY WAY SUGGESTING OR IMPLYING THAT CalPERS SUPPORTS THE UNDERLYING POLICY).

ii. CalPERS Implications: It appears increasingly likely that the Cadillac tax will not be repealed during this Congress or Administration, despite efforts from broad groups of unusual and bipartisan allies (for reasons stated above). The outstanding questions remaining are exactly how the law will be implemented by the IRS AND whether the law will be delayed, amended or repealed prior to the 2018 effective date by the next Administration and Congress. It is clear that, over time, a substantial number of plans and members will be impacted over time because of the underlying policy’s tight indexing formula as well as the law’s omission of a geographical adjustment, which means high cost plans in places like San Francisco will be disproportionately affected.

iii. CalPERS Next Steps: CalPERS is actively providing technical support to its members about how the Cadillac tax could impact them as well as finding new and
compelling ways to illustrate the importance of a thoughtful implementation of the law to the Administration if the law is ultimately implemented on schedule in 2018. In addition, the Board will be presented additional background information on this subject as well as options for taking a formal position on the Cadillac tax.

III. MISCELLANOUS DEVELOPMENTS OF RELEVANCE TO CALPERS:

A. Two Year Budget Deal: Republican leadership in the House and the White House reached an agreement on a two-year budget deal that will raise the debt ceiling and avert default through March 2017 and makes several changes to health programs discussed below. The budget deal passed the House 266-167 and the Senate 63-35. It will quickly be signed by the President, as Treasury estimates that the deadline for raising the debt ceiling is November 3rd. Notable provisions include:

i. Part B: As was discussed in the previous update, several consumer groups raised concerns about the potential for a 50 percent (or higher for some higher income seniors) premium increase (from a base rate of $104.90 to $159.30) for Medicare Part B. This increase would have impacted approximately 30 percent of Medicare beneficiaries due to a hold-harmless provision for many beneficiaries when low inflation precludes a Social Security cost-of-living adjustment. The budget deal, while not entirely eliminating the increase, reduces it to 14 percent – a $120 per month plus a $3 surcharge to repay to loan from the Supplemental Medical Insurance Trust fund used to pay for the reduction. This provision would apply again in 2017 if there is no COLA increase again.

ii. Medicaid rebate: This applies a provision that single source and innovator drugs must pay a rebate if their price increases faster than inflation to generic drugs as well – a trend that had been increasing recently. Not surprisingly, this provision was strongly opposed by the Generic Pharmaceutical Association.

iii. Reimbursement changes for acquired physician practices: The budget deal prospectively does not allow physician practices purchased by health systems farther than 250 yards from the main campus of a hospital to receive the higher reimbursement rates given under CMS’ Outpatient Prospective Payment Section, but instead places them in either the lower reimbursement rates from Ambulatory Surgical Center or the Medicare Physician Fee Schedule. This section is aimed at reducing rising costs from higher reimbursement rates seen when physician practices are purchased by hospitals. The American Hospital Association vigorously opposed this provision; they argued that it endangers patient access to care at hospital outpatient departments. The Federation of American Hospitals, which represents for-profit hospitals, did not oppose the overall deal.

iv. Repeal of automatic enrollment: This repeals the ACA provision that large employers, those with more than 200 employees, must automatically enroll new full-time equivalents into a qualifying health plan if offered by the employer. This
provision proved difficult to implement without excessive disruption and its repeal was not opposed by the Administration or Democrats.

v. **Medicare payment cuts extended:** Under the sequester, Medicare payments were cut 2 percent; this deal explicitly extends these cuts for the length of the deal. Despite this, AARP issued a strong endorsement of the budget deal – mostly because they were pleased about the moderation of the Part B premium increase.

vi. **CalPERS Implications:** Assuming the deal passes and is enacted into law (as it is expected to do), the bipartisan compromise alleviates concerns over a default on the federal debt that would have had significant fiscal implications for the country as a whole. Furthermore, it relieves much of the increase in part B premiums that would have affected some CalPERS members. Moreover, some of the reforms – site of care payment and generic drug inflation increase limitations may be something CalPERS and its contracting purchasers can mirror and benefit from.

vii. **CalPERS Next Steps:** CalPERS staff will be reviewing how CMS implements the policies outlined above to determine more specific impact implications for CalPERS as a whole.

B. **Biosimilars:**

i. **Medicare Reimbursement:** CMS finalized their proposed policy on Medicare reimbursement for biosimilar drugs. While they did not adopt the policy advocated by the National Coalition on Health Care (NCHC) of putting all biosimilars in the same reimbursement code as the reference product, they will blend non-interchangeable biosimilars with each other and is reserving the right to blend interchangeable biologics with the reference product when they are better understood.

ii. **NCHC Letter to FDA:** On October 27th, the National Coalition on Health Care wrote a letter to Acting FDA Commissioner Stephen Ostroff opposing the unique naming provisions for biosimilars that FDA has issued in draft guidance. They state that using unique names for biosimilars is unprecedented, will undermine acceptance and uptake of biosimilars, and are unnecessary for patient safety and pharmacovigilance. They add that the naming provision may in fact harm patient safety by interfering with safety alert systems that pharmacists currently use. They further state that if the FDA does decide to still implement this draft guidance that they should keep the same naming conventions for brand biologics, biosimilars and interchangeables and that adding a suffix only to generic biologics would differentiate them from the original products and chemical generics, casting doubt on safety and efficacy, that originator products and biosimilars should retain the same core name and any distinguishing feature should follow rather than proceed the core name, and finally, that the names for interchangeable biologics should be completely identical to the reference product.
iii. **CalPERS Implications**: Both the final Medicare reimbursement policy and the position on the proposed naming regulation will help to ensure a thriving biosimilars marketplace with the proper incentives for physicians to prescribe the lowest cost drug.

iv. **CalPERS Next Steps**: CalPERS staff and consultants will continue to track the FDA’s position on the naming regulation. We will look for additional opportunities to ensure that incentives for innovation are balanced with affordability and that there is a broad understanding amongst policy makers of the impact of drug costs on payers like CalPERS.

C. **Exchange Enrollment Projections**: HHS announced on October 15th that they expected relatively low enrollment growth for the upcoming enrollment period, aiming for 10 million people to be covered at the end of 2016, a small increase over the more than 9 million projected to be enrolled at the end of 2015. CBO previously estimated that 21 million would be signed up through the exchanges in 2016, though many argue that at least some of the difference has to do with fewer people dropping employer sponsored coverage than expected and that uninsured rates are still at historic lows. Also some suggest that HHS is lowering expectation so they can surpass them later this year.

i. **CalPERS Implications**: Enrollment numbers in CA are generally better than in other states. However, over time, the question will be whether affordability of these plans’ premiums AND ongoing enrollment in them by those who have been enrolled can be retained. To the extent that they cannot and that new enrollees cannot be secured (AND to the extent that some have hoped that the lessening numbers of uninsured will reduce cost shifting), this could be a disappointing development. Having said that, it is also clear that there has been very low dropping of Americans in employer-sponsored plans into the exchanges – as some (including the Congressional Budget Office) had suggested. That seems to be the case for CalPERS members as well.

ii. **CalPERS Next Steps**: None necessary.

D. **Republican Presidential Candidates’ Broad-Based Health Reform**:

i. **Jeb Bush**: Governor Bush would replace the ACA with a more state-centric model. He said that he planned to give states greater flexibility in benefit design, eliminating the required benefits covered under the ACA and stressing the importance of the availability of catastrophic coverage and tax credits for such plans. He also advocates capping federal funding to states through a block grant-like system for Medicaid. In addition, he would alter the Cadillac tax and instead cap the tax exemption for employer-based health plans at $12,000 for individual plans and $30,000 for families. Finally, under his plan he would increase the
maximum amount that individuals are able to contribute to their health savings accounts from $3,350 to $6,650.

ii. **Ben Carson**: Although his exact position is somewhat murky, Dr. Carson recently proposed to replace or, at minimum, provide an alternative to Medicare and Medicaid with savings accounts. He has proposed a “cradle to grave” $2,000 per year tax-free government contribution to an individual account with a third of the money designated for insurance to cover severe medical incidents. Additional funds could be contributed by individuals and employers and accounts could be shared among family members, which he says makes each family its own insurance company. The plan would cost an estimated $630 billion annually according to his back of the envelope calculation.

iii. **Health Republican Debate**: During the Republican debate on October 28th, candidates offered their fixes and changes they would make to Medicare. Most echoed common Republican ideas for Medicare. Jeb Bush touted his health savings accounts, and Ben Carson talked about the benefits of his savings account plan and also said that he felt that the private sector could get more out of the current money being spent on government plans. Marco Rubio said that any changes he would make would not impact current beneficiaries. Rand Paul advocated for raising the eligibility age. Mike Huckabee emphasized his belief that the country should focus on cures for costly chronic disease particularly Alzheimers, diabetes, heart disease and cancer.

iv. **CalPERS Implications**: Significant changes to Medicare proposed by many Republican candidates could have far-reaching implications for CalPERS and members, including changes in how members obtain coverage, how plans offer coverage, costs, and a number of other potential impacts.

v. **CalPERS Next Steps**: CalPERS federal representatives will continue to monitor health care proposals from candidates and comment on their potential implications for CalPERS. For now, though, it is ill advised to spend too much time on evolving proposals until the field narrows, policy positions solidify and the election is engaged at the general election level.

E. **Campaigns Continue to Address Prescription Drug Costs and Consolidation**:

i. **Letters to FDA and FTC from Secretary Clinton**: On October 19th, Hillary Clinton wrote letters to both the Acting Commissioner of the FDA and the Chairwoman of the FTC about Turing Pharmaceuticals recent 5,000 percent increase of its drug Daraprim. In the letters, she asked the FTC to investigate whether the company’s distribution program is anti-competitive behavior in violation of the FTC Act as well as the broader trend of dramatic price increases in the pharmaceutical industry. On the FDA side, she asked the FDA to expedite any pending applications and encourage applications for alternatives to the drug. She further asked the FDA to
consider temporary importation of drugs from other countries such as Canada and the UK as well as to address the generic backlog at FDA to increase competition across the board.

ii. **Rubio Joins in Criticism of Drug Companies:** On October 16th, Republican Presidential candidate Senator Marco Rubio also criticized drug companies for profiteering and arbitrarily raising prices, becoming the first Republican candidate to speak out strongly against the industry. While he did not lay out any specific proposals, he said that he favors reducing obstacles for approval of generic drugs, cutting time and cost of bringing competition to the market, and incentives for physicians to prescribe less expensive drugs that are equally as effective.

iii. **Hillary Clinton Addresses Health Care Consolidation:** On October 21st, Hillary Clinton said that she had “serious concerns” about mergers between Anthem and Cigna, and Aetna and Humana. She said that the mergers should be scrutinized for undue concentration and potential negative impacts of the mergers. She also said that she would strengthen antitrust enforcement at the Justice Department and FTC. These mergers add to an increasing trend of consolidation in all areas of health care, including recently announced mergers between Rite-Aid and Walgreens, and Pfizer and Allergan.

iv. **CalPERS Implications:** As polls have repeatedly shown, consumers are increasingly concerned about rising drug prices. As such, we can expect candidates to continue to speak out on this issue and make it a priority in their platforms to provide relief either through market-based or government intervention. Interventions proposed by the candidates could have significant and positive impacts on bending the prescription drug cost curve. CalPERS should also continue to monitor the increasing number of mergers in the health care sector for impacts on pricing and costs.

v. **CalPERS Next Steps:** CalPERS staff and federal health representatives will continue to explore and recommend ways for CalPERS to speak out on and present the negative impacts of rising costs in health care, particularly related to drug costs.