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Health Policy Briefing

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Congress Returns from Recess: What's Next?

Even though Congress has officially returned from the August recess, the Congressional schedule is still up in the air. What is clear is that there's a lot to be done and little time to do it. Between now and October 1 (when the current appropriations expire), the House has only eight legislative days, the Senate has twelve, and both chambers will be focused on the upcoming Papal visit. Given that timeframe, there is talk of a continuing resolution (CR) to provide additional funding until the full appropriation package is ready. During the August recess, staff negotiations continued to help define the basic terms of the agreement, but at least two key elements are still left for member-level decisions. First, the duration of the CR could be four weeks, until October 29 to coincide with the expiration of the highway and mass transit programs, or much longer, extending perhaps until December 11. Second, the number of policy riders remains undecided (i.e., how "clean" of a CR), especially as it relates to Planned Parenthood. Given issues with the overall votes and logistical challenges with completing the CR, Republican leaders are currently testing conservative sentiment on alternative votes addressing the Planned Parenthood situation outside the CR package.

One key rationale for Republicans to push for the longer CR duration (until December 11) is to provide both chambers with the opportunity to move forward on reconciliation. The budget-conference agreement included a specific provision related to the Affordable Care Act (ACA). Specifically, it noted that that "[t]he conference agreement affirms the use of reconciliation for the sole purpose of repealing the President's job-killing health care law." Due to the Byrd rule, all provisions within a reconciliation bill must have direct spending implications. Thus, Republicans have noted that two key targets – the individual mandate and the employer mandate – would be significant provisions with budget implications, which could be part of a reconciliation package. Such a package has only a small chance of becoming law, due to President

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Obama's inevitable veto of any legislation so dramatically affecting the ACA. However, many view the need to provide such an opportunity for Republican members to voice their concerns with the ACA, given that many new Republicans (especially those in the Senate) have not had a chance to go on the record in opposition to the ACA.

Of course, despite what may happen with respect to reconciliation, once the CR is in place, Congress will still need to provide the full appropriations for fiscal year (FY) 2016. Given the backdrop of the Presidential campaigns, already there is talk of an omnibus, long-term CR (through September 30, 2016), or a "cromnibus" – a combination of an omnibus and long-term CR. If an omnibus is part of this larger discussion, then one key element will be dealing with the Ryan Murray Budget Control Act (BCA) discretionary budget caps, given that President Obama's FY16 budget assumed that the BCA caps were not in effect and those caps have made for difficult funding decisions.

Beyond the appropriations/CR process, Congress also has several other "must pass" legislation before the end of the calendar year, including increases to the debt limit (which must occur in November or December), addressing expiring tax breaks, extending beyond October 29 key funding to States for highway and transit programs, and the reauthorization of key programs (including the National Defense Authorization and programs related to child nutrition, aviation, pipeline safety, and student loans).

To kick off additional conversation related to the debt limit, the House Ways and Means Committee held a markup of H.R. 692, the "Debt Prevention Act" and H.R. 3442, "Debt Management and Fiscal Responsibility Act of 2015" on September 10. H.R. 692 would require the Department of the Treasury to continue to borrow to pay the principal and interest on certain obligations if the debt of the United States exceeds the statutory limit for certain obligations (i.e., payment of the principal and interest on debt held by the public or the Social Security trust funds), as well as report to Congress regarding those obligations. H.R. 3442 would require certain reporting obligations for the Department of Treasury when the debt limit is approached. Both bills were reported out of the Committee on a party-line vote (22-14) potentially foreshadowing future discussions on the topic.

While the House has focused on the debt ceiling processes, the Senate has been focused on the tax extenders. On July 21, 2015, the Senate Finance Committee passed a tax extenders bill (original bill of S. 1946). Generally, the bill would extend over 50 expiring provisions for two years—retroactively from January 1, 2015, through December 31, 2016. In content, the bill is substantially similar to legislation enacted in December 2014 that extended the expiring provisions through December 31, 2014. The House Ways and Means Committee has not yet acted on legislation that would extend beyond 2014 the full package of "tax extenders." However, the House has already passed legislation to make a number of expiring provisions permanent law. For example, the House in May 2015 passed a bill that would make the research credit permanent. Therefore, as in similar years, Congress will be pressed to deal with the tax extenders prior to the end of this calendar year.

Public Health & FDA Update

FDA Finally Decides the Issue of Nomenclature of Biosimilars …Sort Of

In one of the most anticipated Food and Drug Administration (FDA) guidances of the year, the agency announced its position on the nonproprietary naming of non-interchangeable biosimilars. With regard to biosimilars that meet the higher standard of interchangeability, however, the FDA has not made a decision and requests public input.

The guidance, "Nonproprietary Naming of Biological Products: Guidance for Industry," was released in August and will be open for comment until October 27, 2015. Whether a biosimilar should share an International Nonproprietary Name (INN) with its brand counterpart has been hotly debated. Small-molecule generics do share an INN with their reference products, but many stakeholders believe this paradigm is inappropriate for large-molecule biologics, which are far more complex and impossible to replicate exactly. The recent guidance indicates that FDA agrees, at least partly.

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Per the draft guidance, the FDA will designate a unique suffix composed of four lowercase letters to all biological products. This will distinguish the brand product from related products and any biosimilars and, as the agency notes, is intended to help prevent inadvertent substitution. While this sounds straightforward enough, the agency did pose one question for public comment: should a biosimilar that the agency deems interchangeable pursuant to the higher statutory standard share a suffix with the reference product?

In addition to the draft guidance, the FDA also issued a proposed rule to rename previously designated biologics using the process outlined in the draft guidance. Comments to the proposed rule are due by November 12, 2015.

Meanwhile, Senator Bill Cassidy (R-LA) will chair a Senate Health Education Labor and Pensions Subcommittee on Primary Health and Retirement Security hearing on Thursday September 17 entitled "Biosimilar Implementation: A Progress Report from FDA." Since the only witness is Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research, expect a lot of questions related to the recent guidance and the agency's thinking on the naming of interchangeable biosimilars.

Medicare and Medicaid News

New Season of MedPAC Begins

The Medicare Payment Advisory Commission (MedPAC) kicked off its 2015-2016 season September 10-11, 2015, with its new chairman, Dr. Francis J. Crosson, MD. Chairman Crosson previously served on MedPAC from 2004-2010, including as vice chair from 2009 – 2010.

As part of his opening remarks, the Chairman reiterated MedPAC's longstanding concerns regarding Medicare payments to physicians, specifically the imbalance between primary and specialty care payments, rising drug costs and its impact on the trust fund and Medicare beneficiaries, and Medicare payments for graduate medical education (GME). He further noted that hospitals can expect to face significant changes over the next decade.

Following his comments, commissioners tackled a robust agenda, which included staff presentations, analysis and discussions on a unified payment system for post-acute care, Medicare Advantage encounter data for Part B services, Medicare Advantage star ratings, Medicare drug spending, emergency department services at stand-alone facilities, and the Centers for Medicare and Medicaid Services (CMS) open payments program.

MedPAC will continue its conversation on these and other topics at its next meeting, set for October 8-9, 2015, in Washington DC.

Medicare Premiums on the Rise…For Some

The 2015 Medicare Trustees Report provides an outlook for Medicare Part B premiums in 2016. The current Part B standard monthly premium is $104.90, but some beneficiaries could see their monthly premiums rise and fall dramatically over the next two years. According to estimates from the latest trustees report, about 70 percent of Medicare enrollees can expect to pay the same amount for their Medicare Part B coverage in 2016 due to a "hold harmless" provision in law that prevents their premiums from increasing when their Social Security benefits are not increased (a cost-of-living adjustment is not expected in 2016 because of low inflation).

But the remaining 30 percent of enrollees could face a dramatic increase in their Medicare Part B premiums because Medicare premiums, in aggregate, cover 25% of total Part B costs. The Trustees Report suggests that the 2016 Part B premiums could be as high as $159.30/month, a 52 percent increase. Beneficiaries impacted could include new Medicare

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enrollees and beneficiaries not receiving a Social Security check, but also those enrolled in Medicaid or a Medicare Savings Program that have their premiums paid by their state. Also impacted are higher-income beneficiaries ($85,000 for individuals and $170,000 for couples) who already have their premiums income adjusted.|

The opposite impact is likely in 2017 when the Social Security benefits are expected to rise by about 3 percent, resulting in 70 percent of beneficiaries (protected by the hold harmless provision in 2016) seeing increased premiums and the remaining 30 percent seeing a substantial decline.

The Centers for Medicare and Medicaid Services (CMS) will announce the actual premium amounts in October. In the meantime, some senior advocates are urging Congress to pass a one-time fix, at an estimated $10 billion cost, that would hold off the wild premium swings for everyone.

Lawmakers Examine Medicaid Eligibility

On Friday, September 11 the Energy and Commerce Subcommittee on Health examined ongoing issues related to Medicaid program integrity. Witnesses included officials from the Department of Health and Human Services (HHS) Office of the Inspector General (OIG), a state-based health authority, and the Executive Director of the Medicaid and CHIP Payment and Access Commission (MACPAC). The Committee examined six pieces of legislation that seek to close loopholes in the Medicaid program. Democrats expressed concerns that some of the bills were attempts to scale back eligibility for deserving beneficiaries. The Congressional Budget Office (CBO) reports that Federal Medicaid spending is projected to increase by almost 70% in the next decade alone. Subcommittee chairman, Joe Pitts (R-Pa.) expressed his hope that committee members "can work together on a bipartisan basis to boost Medicaid program integrity, while making the program more sustainable, accountable, and transparent." The Subcommittee scheduled another Medicaid hearing for Friday titled "Improving the Medicaid Program for Beneficiaries."

Affordable Care Act Updates

House of Representatives Obtains Procedural Win in ACA Lawsuit Against Obama Administration

This week, a District Judge issued a procedural ruling in House of Representatives v. Burwell, clearing the way for the suit to proceed to a hearing on the merits. Per the ruling, the U.S. House of Representatives has legal standing to bring a lawsuit against the Administration for violating the spending limitation set by Article I: "No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law."

At issue are funds that the Treasury Department paid to insurance companies to provide cost-sharing assistance for low-income individuals, as required by the Affordable Care Act (ACA). The House alleges that this spending required annual appropriation by Congress. The Administration has countered that the ACA allows the Treasury Department to pay the subsidies without seeking separate congressional approval.

As Judge Collyer stresses in her opinion, this ruling is merely procedural and "the merits of this lawsuit await another day." When that day might be is unclear: the Administration has stated that it plans to immediately appeal the procedural ruling, which may delay a substantive ruling in the case.

Cadillac Tax: Cost Shifting to Patients? How Soon Will it Impact You

Recent press reports have highlighted the potentially detrimental effect of the "Cadillac tax" on Health Savings Accounts (HSAs) and the health benefits negotiated by various unions. However, often overlooked is the potential detrimental effect the "Cadillac tax" could have on overall premiums and result in major cost-shifting, especially as it relates to specialty pharmacy.

Under the Affordable Care Act (ACA), employers could be subject to a 40 percent tax on the amounts by which the costs of their sponsored plans exceed government-set thresholds. Cost of coverage includes the total contributions paid by both the employer and employees, but not cost-sharing amounts such as deductibles, coinsurance and copays when care is received. For planning purposes, the thresholds for high-cost plans are currently $10,200 for individual coverage, and $27,500 for family coverage. Those thresholds are very close to the average costs of premiums in 2014, which were annual premiums of $6,025 for single coverage and $16,834 for family coverage. This further highlights why a recent study from the nonpartisan Kaiser Family Foundation (KFF) estimated that 26 percent of all employers would face the tax in at least one of their plans during its first year, 2018. Nearly half of larger companies would face the consequences of the tax that same year, because they tend to offer better benefits. The KFF analysis further estimates that the share of employers potentially affected by the tax could grow significantly over time -- to 30 percent in 2023 and 42 percent in 2028 -- if their plans remain unchanged and health benefit costs increase at expected rates. Thus, to reduce the cost of coverage to avoid the Cadillac tax, health plans are shifting more costs to patients through increased out of pocket costs.

In addition to paying specific premiums for insurance coverage, individuals are also responsible for their specified cost sharing. The ACA sets maximum out-of-pocket (OOP) spending limits, but otherwise does not specify the combination of deductibles, copayments, and coinsurance that plans must use to meet the actuarial value requirements (more about actuarial value below). For example, one insurer may choose to have a relatively high deductible but low copayments for office visits and other services, while another may choose a lower deductible but higher copayments or coinsurance for each service. In general, the out-of-pocket maximum may be no more than $6,600 for an individual and $13,200 for two or more people in 2015.

Given the relative flexibility in designing the benefit structure, one key focus of cost containment has been specialty pharmacy. These drugs, typically used to treat chronic, serious, or life-threatening conditions, such as cancer, rheumatoid arthritis, growth hormone deficiency, primary immunodeficiencies, and multiple sclerosis, are often priced much higher than traditional drugs. Expenses for specialty pharmaceuticals, which can cost up to $10,000 for a month of treatment, are on the radar. Traditional pharmacy spending is expected to grow 3.9 percent in 2016, but specialty pharmaceuticals by 22.3 percent, says the National Business Group on Health, citing a report by Express Scripts, a pharmaceutical benefits management firm.

To help reduce the overall expenditures for specialty pharmaceuticals, health plans have instituted three key management strategies: (1) substantial cost sharing for specialty drugs; (2) required diagnostic testing as a condition of coverage; and (3) managing the site of service. All of these cost saving policies can have a direct and detrimental impact on those needing the key medications. Thus, while the overall goal of the ACA was to provide basic health care coverage for everyone, those with severe chronic conditions may be left out in the cold.

Members of Congress have introduced legislation to repeal the tax, but successful repeal likely will need to include mechanisms to offset the projected $80 billion price tag. The Obama Administration has said it is willing to work with lawmakers to improve the ACA, but opposes repealing the tax.

Pope Franics to Visit Washington DC

Pope Francis will visit Washington, DC Tuesday, September 22 through Thursday, September 24, including visits with President Obama and Congress. This will be the pope's first stop during his three city visit to the United States. On Wednesday morning, September 23, Pope Francis will arrive at the White House for a State Arrival Ceremony. He will be the third pope to have ever visited the White House. There will be a short parade route between the Ellipse and a portion of the National Mall for the public to see the pope (11:00-11:30 a.m.) before he continues on to St. Matthew's Cathedral to meet with the U.S. bishops. Pope Francis will canonize Blessed Junipero Serra, a Spanish Franciscan friar who founded a mission in Baja, California during a Mass at the National Shrine of the Immaculate Conception in Northeast DC. Coverage of the various events will be video broadcast live for public viewing on the grounds of the Washington Monument. On Thursday, September 24, Pope Francis will address a Joint Session of Congress, visit St. Patrick's Cathedral in Northwest DC, and visit several Catholic charities associated with the Archdiocese of Washington. Note that all events, except the parade, are ticketed events and will require passing through security. During this time, the Federal Government is encouraging agencies to utilize flexible workplace options like telework, flex schedules, and leave.

Upcoming Congressional Meetings and Hearings

Senate Homeland Security and Governmental Affairs Committee: field hearing titled: "All Hands on Deck: Working Together to End the Trafficking and Abuse of Prescription Opioids, Heroin, and Fentanyl;" 2:00 p.m., New Hampshire Institute of Politics, Saint Anselm College, 100 Saint Anselm Drive, Manchester, N.H.; Sept 14

Senate Health, Education, Labor and Pensions (HELP) Committee: hearing titled "Achieving the Promise of Health Information Technology: Improving Care Through Patient Access to Their Records;" 10:00 a.m., 430 Dirksen Bldg.; Sept 16

Senate Veterans' Affairs Committee: hearing on pending veterans issues, including: S. 563 - A bill to establish the Physician Ambassadors Helping Veterans program to seek to employ physicians at the Department of Veterans Affairs on a without compensation basis in practice areas and specialties with staffing shortages and long appointment waiting times; S. 1450 - A bill to allow the Secretary of Veterans Affairs to modify the hours of employment of physicians and physician assistants employed on a full-time basis by the Department of Veterans Affairs; S. 1693 - A bill to expand eligibility for reimbursement for emergency medical treatment to certain veterans that were unable to receive care from the Department of Veterans Affairs in the 24-month period preceding the furnishing of such emergency treatment, and for other purposes; S. 1856 - A bill to provide for suspension and removal of employees of the Department of Veterans Affairs for performance or misconduct that is a threat to public health or safety and to improve accountability of employees of the Department, and for other purposes. 2:30 p.m., 418 Russell Bldg.; Sept 16

Senate Health, Education, Labor and Pensions Subcommittee on Primary Health and Retirement Security: hearing titled "Biosimilar Implementation: A Progress Report from FDA;" 10:00 a.m., 430 Dirksen Bldg.; Sept 17 (The only witness will be Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research.)

House Energy and Commerce Health Subcommittee: hearing titled "Improving the Medicaid Program for Beneficiaries;" 9:00 a.m.; 2123 Rayburn Bldg.; Sept 18

House Homeland Security Oversight and Management Efficiency Subcommittee: hearing titled "Making DHS More Efficient: Industry Recommendations to Improve Homeland Security;" 10:00 a.m., 311 Cannon Bldg.; Sept 18

House Veterans' Affairs Committee: hearing titled "A Call for System-Wide Change: Evaluating the Independent Assessment of the Veterans Health Administration;" 10:30 a.m., 334 Cannon Bldg.; Sept 30

Health Legislation Recently Introduced

H.R. 3443 (introduced by Rep. Ellmers): A bill to prohibit the provision of funds under title X of the Public Health Service Act to Planned Parenthood Federation of America, Inc., or its affiliates, subsidiaries, successors, or clinics during a period of review by the Government Accountability Office; to the Committee on Energy and Commerce. (Sept 8)

H.R. 3444 (introduced by Rep. Pitts): A bill to amend title XI of the Social Security Act to reduce Medicaid and CHIP fraud in the territories of the United States, and for other purposes; to the Committee on Energy and Commerce. (Sept 8)

H.R. 3463 (introduced by Rep. Griffith for himself and Rep. DeGette): A bill to amend title XXVII of the Public Health Service Act to clarify the treatment of pediatric dental coverage in the individual and group markets outside of Exchanges established under the Patient Protection and Affordable Care Act, and for other purposes; to the Committee on Energy and Commerce. (Sept 9)

H.R. 3466 (introduced by Rep. Pocan for himself, Rep. Schakowsky, Rep. Welch, Rep. Cartwright, Rep. Hastings, Rep. Higgins, Rep. DeFazio, Rep. Grijalva, and Rep. Honda): A bill to demonstrate a commitment to our Nation's scientists by increasing opportunities for the development of our next generation of researchers; to the Committee on Energy and Commerce. (Sept 9)

H.R. 3467 (introduced by Rep. Velazquez for herself and Rep. Waters): A bill to establish a pilot program to train public housing residents as home health aides and in home-based health services to enable such residents to provide covered home-based health services to residents of public housing and residents of federally-assisted rental housing, who are elderly and disabled, and for other purposes; to the Committee on Financial Services. (Sept 9)

S. 2014 (introduced by Sen. Baldwin for herself and Sen. Collins): A bill to demonstrate a commitment to our Nation's scientists by increasing opportunities for the development of our next generation of researchers; to the Committee on Health, Education, Labor, and Pensions. (Sept 9)

S. 2019 (introduced by Sen. Klobuchar for herself and Sen. Grassley): A bill to prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market; to the Committee on the Judiciary. (Sept 9)

S. 2023 (introduced by Sen. Sanders for himself and Sen. Franken): A bill to ensure greater affordability of prescription drugs; to the Committee on Finance. (Sept 10)

S. 2027 (introduced by Sen. Ayotte): A bill to increase the penalties for fentanyl trafficking; to the Committee on the Judiciary. (Sept 10)