

10.16.17 – 10.20.17 Health Wrap Up

Please find below a summary of the latest major health policy developments in Washington this week. Please let us know if you have any questions.

Scheduling note: The House was on recess this week.

ACA STABILIZATION

Senators Alexander (R-TN) and Murray (D-WA) formally introduced their stabilization bill yesterday with 24 cosponsors evenly split between Democrats and Republicans. With 12 Republican cosponsors, if all Democrats voted for the legislation, it would have enough votes to meet the key 60 vote threshold. Included among the list of Republican cosponsors are some key players – Murkowski (R-AK), Collins (R-ME), McCain (R-AZ), Graham (R-SC), and Cassidy (R-LA). Bill text and a section-by-section summary are attached.

Unlike the repeal and replace bills that have been in the mix all year, the bill does not make changes to Medicaid, undermine protections for individuals with preexisting conditions or eliminate the Essential Health Benefit (EHB) requirements.

The bill restores the cost sharing subsidies, allows broader access to catastrophic coverage plans and gives states some additional flexibility for section 1332 waivers; that flexibility includes:

- Allowing governors to approve a waiver instead of the state legislature
- Reducing the HHS review period to 90 days
- Allowing expedited review for “me too” waivers and emergency waivers
- Permitting state waiver applications to have “comparable affordability” (the ACA required waivers to be “as affordable”)

While the bill was introduced with broad support, hurdles remain: leadership has not promised a vote, despite cosponsoring the legislation, Senators Graham (R-SC) and Cassidy (R-LA) say they are working with Sen. Johnson (R-WI) to try to move the bill to the right to make it more palatable to the House and the White House has been inconsistent in its messaging.

At this point, it is anticipated the bill might be wrapped into an end of year “Christmas tree” package - perhaps with CHIP reauthorization and the FY 18 spending bills. As you know, the Continuing Resolution (CR) keeping the federal government open expires on December 8th.

BUDGET AND APPROPRIATIONS

FY18 Budget Resolution

Last night, the Senate adopted a fiscal 2018 budget resolution on a 51-49 vote after a significantly shortened vote-a-rama. All Democrats opposed the measure, as did Senator Rand Paul (R-KY). During the voting session, known as a vote-a-rama, lawmakers rejected amendments from Rand Paul (R-KY) and Mike Lee (R-UT) that aimed to repeal Obamacare, as well as another amendment offered by Paul that would slash discretionary spending by \$43 billion.

Republicans, eager to speed up the timeline on tax reform, worked out a compromise that would likely eliminate the need for a conference committee. An amendment by Budget Chairman Michael Enzi (R-WY) was adopted 52-48 that would modify the House-passed budget resolution, discarding reconciliation instructions aimed at getting \$203 billion in mandatory spending cuts and replacing the House directive for a deficit-neutral tax cut with one that could add up to \$1.5 trillion to the deficit over 10 years, similar to the Senate's. Another key change allows for higher defense spending without offsets. Under the amendment, the Pentagon's FY18 budget could be increased to \$640 billion — without offsets — if lawmakers reach a deal to raise the current spending caps.

The House and Senate need to pass identical budgets in order to allow Republicans to use reconciliation, the fast-tracking procedure that sidesteps the Senate's typical 60-vote threshold for passage. The House could take up the legislation and adopt it when it returns next week, triggering the next stage in the reconciliation process when the House Ways and Means Committee would draft a tax overhaul with the goal of passing it and sending it to the Senate. Already, leaders of the House Freedom Caucus consisting of the chamber's most conservative members have indicated reluctant support for the Senate-passed budget, which clears what would otherwise be one of the most difficult hurdles.

Facilities and Administrative Costs Hearing

On Tuesday, the House Labor HHS Subcommittee will hold a hearing on the role of facilities and administrative costs in supporting NIH-funded research. Witnesses include:

- Dr. Kelvin Droegemeier, Vice President for Research, University of Oklahoma
- Dr. Gary Gilliland, President and Director, Fred Hutchinson Cancer Research Center
- Dr. Bruce T. Liang, MD, FACC, Dean, University of Connecticut School of Medicine
- Dr. Keith Yamamoto, Vice Chancellor for Science Policy and Strategy, University of California - San Francisco

CHILDREN'S HEALTH INSURANCE PROGRAM AND OTHER HEALTH PROGRAM EXTENSIONS

Two weeks after committees in both chambers approved separate bills, lawmakers are still fighting over how to pay for funding for the Children's Health Insurance Program. On Monday, House Energy and Commerce Chairman Greg Walden (R-OR) said he had not yet received a counter-offer from Democrats and again called on them to offer suggestions for offsets so the House could pass its committee-approved CHIP bill and a separate bill to fund community health centers and other public health programs. As previously reported, House Republicans' proposals to pay for the funding include changes to Medicare premium increases for people with income over \$500,000 a year and benefits for lottery winners who qualify for Medicaid. Democrats also oppose the offsets in the community health centers bill including one that would cut \$6.35 billion from the Prevention and Public Health Fund over 10 years. Both Walden and Pallone last week said that they were discussing offsets and Walden initially said he had hoped to come to an agreement by last Friday. In the Senate, questions on offsets still remain. Finance Chairman Orrin Hatch (R-UT) and Ranking Member Ron Wyden (D-OR) have been reportedly been discussing the issue, but the committee has yet to release any information on their plan for offsets.

DRUG PRICING

On Tuesday the Senate Health, Education, Labor and Pensions Committee held a hearing entitled, The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay, Part II. This was the second hearing in a series of hearings on prescription drug costs. During his opening statement, Chairman Alexander (R-TN) noted that this hearing was delayed because the last hearing went off track with a discussion on ACA repeal efforts. A webcast of the hearing and opening statements can be found [here](#).

Witnesses included:

- Lori M. Reilly, Executive Vice President, Policy, Research & Membership, Pharmaceutical Research and Manufacturers of America
- Chester “Chip” Davis, Jr., President and Chief Executive Officer, Association for Accessible Medicines
- Elizabeth A. Gallenagh, Senior Vice President Government Affairs and General Counsel, Healthcare Distribution Alliance
- Mark Merritt, President and Chief Executive Officer, Pharmaceutical Care Management Association
- Thomas E. Menighan, BSPHarm, MBA, ScD(Hon.), FAPhA, Executive Director and Chief Executive Officer, American Pharmacists Association

During the hearing, Senators questioned witnesses about the lack of price transparency, drug importation from other countries and pharmaceutical patents. The hearing at times was contentious, especially when Senator Warren questioned how drug companies are able to hold on to patents for so long, which means a longer wait for generics that cost less.

Over the course of the hearing, Senators repeatedly returned to the issue of transparency in drug pricing. In relation to this, many members commented on rebates or discounts or other pricing differences and the lack of transparency. Senator Lisa Murkowski (R-AK) said the general public is frustrated by being unable to understand why drug prices are so high. She noted that drug manufacturers set list prices that almost no one pays and then pharmacy benefit managers negotiate different prices often resulting in one hospital charging something different than a hospital across the street.

Senator Al Franken (D-MN) questioned why drug prices in the U.S. tend to be so much higher than in other industrialized countries. He referenced a 2015 Bloomberg report that said that Advair costs about \$310 in the U.S., compared with under \$75 in Canada and around \$35 in France. He wanted to know why prices are so much higher in the United States for a drug produced in the United States. He also noted that much of the basic research used by the drug industry is funded by taxpayers through the National Institutes of Health. Ms. Reilly said that the U.S. does have a different system than other countries - providing compensation to companies for their research and development. She also argued that drug prices in European countries are artificially depressed.

Next month, the committee will hear testimony about a National Academy of Sciences report on access to affordable drug therapies.

SUBSTANCE USE AND MENTAL HEALTH

White House Opioids Commission Meeting

On October 20th, the President's Commission on Opioids held its fourth meeting with testimony from insurers (agenda with witness list is attached).

The Commission will hold its fifth and final meeting on November 1st to accompany the release of their report. Commission Chair Christie said witnesses at the final meeting will include patients and family members. Christie also told the health plans present that the report would incorporate the recommendations included in their statements, but that they should also anticipate a report that “will place new demands on you.”

There was no mention from the Administration officials who spoke at the meeting about a formal emergency declaration. On Monday, in an impromptu press conference the President said the declaration would be made next week. However, his announcement apparently caught Administration officials off guard and staff had indicated to us this week that we should not count on an announcement following in short order.

In his remarks, White House staffer Reed Cordish said that the Administration is moving “aggressively” to combat the epidemic and cited the examples of the Food and Drug Administration’s (FDA) work on changing clinician prescribing behavior, reviewing if naloxone’s status should be changed to over the counter and asking for Opana to be removed from the market.

Department of Labor Secretary Acosta said that the opioid misuse and overdose epidemic is the “number one issue for labor force participation.” He also noted that his Agency is responsible for enforcement of the Mental Health Parity and Addiction Equity Act (MHPAEA) but said their authority is weakened because they have to enforce the law “employer by employer” instead of going to the insurers directly. He also claimed there are no civil penalties for non-compliance (note: the IRS has the power to levy fines).

Much of the witness testimony at the Commission meeting included summaries from the witnesses of the actions their health plans have taken to address the opioid misuse and overdose epidemic. A summary of key issues raised by the witnesses is attached.

Energy and Commerce Committee Hearing

Next week, the House Energy and Commerce Committee will hold a hearing on the opioid misuse and overdose epidemic. Witnesses will include:

- Scott Gottlieb, MD, Commissioner, Food and Drug Administration (FDA)
- Elinore McCance-Katz, MD, PhD, Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration (SAMHSA)
- Anne Schuchat, MD (RADM, USPHS), Principal Deputy Director, Centers for Disease Control and Prevention (CDC)
- Nora Volkow, MD, Director, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH)
- Neil Doherty, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration

EMPLOYER-BASED WELLNESS PROGRAMS

On Thursday, the Senate Health, Education, Labor, and Pensions Committee (HELP) held a hearing titled “Examining How Healthy Choices Can Improve Health Outcomes and Reduce Costs.” It focused primarily on how employers can incentivize wellness among employees. The witnesses include:

- Steve Burd: CEO of Burd Health and former CEO of Safeway
- Dr. Michael Roizen: Chief Wellness Officer at the Cleveland Clinic
- Dr. David Asch: Exec. Director of Center for Health Care Innovation at the Univ. of Pennsylvania
- Jennifer Mathis: Director of Legal Advocacy at Bazon Center for Mental Health Law

The hearing examined the value of workforce wellness programs in driving down healthcare costs and reducing instances of chronic disease. It also examined the implications of an August federal district court ruling which threatens the legal standing of wellness programs in years to come based upon the voluntary nature of employee participation. This hearing laid the foundation for possible legislation which would aim to define the voluntary nature of participation without threatening the medical privacy of

participants. Both Senators Alexander and Murray viewed this issue as an opportunity to address major healthcare drivers outside the marketplace stabilization legislation described at the beginning of this Wrap Up.

CONGRESSIONAL RETIREMENTS

On Thursday, Rep. Pat Tiberi (R-OH) announced he will not seek re-election. Tiberi's retirement opens up the chairmanship of the House Ways and Means Committee Health Subcommittee and marks the 7th retirement of 24 Republicans on the key healthcare and tax Committee.

TRUMP ADMINISTRATION

HHS Secretary

It was reported on Tuesday that President Trump is leaning towards nominating Alex Azar, a former pharmaceutical industry executive and George W. Bush administration official, to serve as HHS secretary. Trump has allegedly signed off on Azar, but the pick wouldn't be final until the White House makes a formal announcement. Azar served as HHS general counsel and deputy secretary during the Bush administration. Azar joined Eli Lilly and Company in June 2007 as a senior vice president of corporate affairs and communications right after leaving the Bush administration

ONDCP Director

On Tuesday, it was announced Rep. Tom Marino (R-PA) had recused himself from his nomination to be Director of the White House Office of National Drug Control Policy (ONDCP). The announcement followed a story on 60 Minutes about legislation enacted last year that undercut the DEA's authority to stop distributors from sending prescription drugs to doctors' offices and pharmacies. Marino previously withdrew from consideration for the position last spring, citing a serious illness in his family.

CMS Payment Model Pilot Update

This week, CMS unveiled long-awaited information about its new Merit-based Incentive Payment System pilot program authorized in MACRA. The pilot program which has been in development for two years will track cost data for certain key medical procedures and reward or penalize a provider based upon performance and cost. It will compare the new results against previously collected data from 17,000 practices nationwide last year. This week, CMS announced the procedures which will constitute the benchmarks are: percutaneous coronary intervention, knee arthroplasty, cataract removal, lower limb revascularization, colonoscopy, intracranial hemorrhage, and pneumonia. MIPS will likely play a key role in future CMS payment reform proposals.

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