10.9.17 – 10.13.17 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 Senate was on recess next week. The House will be on recess this week.

EXECUTIVE ORDER

Yesterday, President Trump signed an Executive Order (EO) directing the Federal agencies to undertake rulemaking processes to:

- Consider expanding access to Association Health Plans (AHPs)
- Consider expanding coverage through low cost short-term limited duration insurance (STLDI)
- Consider changes to Health Reimbursement Arrangements (HRAs)

A fact sheet on the EO is attached.

Because the EO directs the Agencies to undertake rulemaking processes, no immediate changes have gone into effect. Rather, the Agencies will draft rules and the process will likely provide opportunities for public comments and take months. The rulemaking process will not be complete in time to affect the 2018 plan year as open enrollment begins on November 1st.

As AHPs and SLTDI plans are not subject to the ACA's mandates such as having to cover the 10 Essential Health Benefits categories, consumer advocates have expressed concerns that expanding these plans would undermine the stability of the insurance marketplaces. If healthier consumers flock to the lower cost/less robust plans, the ACA marketplace's pool may be undermined by having sicker beneficiaries.

Similar to other actions taken by the Administration on birth control and immigration, the EO will likely be subject of legal challenges - possibly from states, insurers and/or consumer advocacy groups – but the lawsuits may not be filed until the regulations are released by the departments.

The Administration described the EO as just the first of many steps they may take to modify the health reform law.

COST SHARING REDUCTIONS

Late Thursday evening, following the President's executive order, the White House announced it would not continue to make cost sharing reduction payments to insurers participating in state exchanges. These CSR payments to insurers incentivize insurers to offer silver-level plans to cover families between 100% and 250% of the federal poverty level. This move comes after several months of signals from the Administration that CSR payments would not be made indefinitely. Nonetheless, insurers will make necessary adjustments to plans offered on state exchanges, with some experts estimating it will result in a 19% increase in silver plans this year to compensate for the lost assistance.

The cancellation raised hopes among some Democrats and centrist Republicans that the Trump administration could accept a bill that would revive the subsides while offering states more flexibility to opt out of Obamacare, but OMB Director Mick Mulvaney today said that President Trump will oppose any congressional attempts to reinstate funding for Obamacare subsidies unless he gets something in return. The comments delivered a severe blow to efforts by Senators Alexander and Murray to strike a bipartisan deal on funding the subsidies. Mulvaney did suggest, however, that the insurance payments could be a bargaining chip in a broader negotiation with Congress to either repeal the ACA or fund Trump's long-stalled border wall with Mexico.

BUDGET AND APPROPRIATIONS

A senior Senate appropriator has told VSA that Congress has every intention of passing an FY18 Omnibus appropriations bill (which they are urging members to call a "consolidated appropriations bill") by December 8th when the current CR expires. They are very reluctant to pass a continuing resolution for any of the 12 bills which would comprise an omnibus. Once the Senate passes the second disaster supplemental bill, which passed the House this week,

Appropriations staff in both chambers will have cleared the deck for preliminary discussions on the Omnibus. However, we do not expect full engagement by lawmakers until late November.

CHILDREN'S HEALTH INSURANCE PROGRAM AND OTHER HEALTH PROGRAM EXTENSIONS

As previously reported, the House Energy and Commerce Committee last week passed legislation to reauthorize the Children's Health Insurance Program (CHIP) and extend funding for community health centers and several other programs along party lines after Democrats objected to certain offsets that would raise Medicare premiums for wealthier seniors as well as make cuts to the ACA's Prevention and Public Health Fund. The funding lapse for both the Children's Health Insurance Program and Community Health Centers closes its second week with only modest prospects of an agreement in sight. Chairman Walden stated this week that the House was unlikely to take up the CHIP bill until the week of October 23 as Republicans and Democrats are still trying to negotiate a bipartisan agreement on offsets. Walden said he would give Democrats until the end of this week to negotiate a deal regarding offsets, but as of press time no deal has been announced. As a result, Walden says, Republican leadership will likely proceed with consideration of the partisan version of the Healthy Kids Act as passed by the Committee. With the House in recess next week, the waiting game on CHIP continues with no end in sight.

340B DRUG PRICING PROGRAM

On Wednesday, the House Energy and Commerce Oversight and Investigations Subcommittee held a hearing examining how covered entities utilize the 340B Drug Pricing Program. A webcast of the hearing and opening statements can be found here.

In his opening statement Vice-Chairman Morgan Griffith (R-VA) said that the 340B program is an important program, but that the dramatic growth of the program, coupled with a shortage of information about how it is used, has led to questions about whether the program has grown beyond Congress' original intent. He noted that because HRSA is not able to report how covered entities use the program, the Committee sent letters to a diverse group of entities in September about their use of the program, asking the entities to report a wide range of information, including the amount saved on drug purchases through participation in the 340B program, the level and type of charity care provided by the entities, and how patients benefit from 340B discounts. He also said that that the committee has heard from the entities they contacted, as well as many others who reached out on their own to share the work they are doing with the program dollars. He specifically noted that they had heard from rural entities that started delivery services to ensure that patients in remote areas are able to receive their medications, entities that pass savings directly to their patients using a cash card program, and entities that are using their savings to combat the opioid crisis, including by examining prescribing practices and providing behavioral health services to their communities. He indicated that the committee is concerned that not all participating entities have devoted program dollars to improving patient care, providing access to vital services, or lowering prescription drug costs for patients. He noted that the program is vital to many covered entities and their patients, but it is crucial that Congress ensure that the program dollars are used in accordance with the intent of the program and that there is accountability and transparency in the program.

Chairman Walden said that the committee has been examining the 340B Drug Pricing program for about two years. He mentioned the hearing that was held in July and noted his concern with the fact that government witnesses were unable to answer many questions about how covered entities use the 340B program due to the lack of reporting requirements in the statute. He noted that the 340B program enables covered entities to do some real good in their communities and is often the difference in keeping their doors open or closing, which could result in a loss of care to vulnerable populations. He said that it is the job of the committee to ensure that programs serve their intended purpose and operate with integrity, and that participating entities are held accountable for how they spend program dollars. He noted that the lack of transparency requirements has resulted in inconsistent data and that much of the data that they do have is self-reported by entities that measure charity care and program savings in various ways. He believes it is important that entities be able to share their work in a way that takes into account the specific needs of their communities, but noted that the inconsistencies only further demonstrate that we need better data on this program.

Vice-Chairman Griffith closed by saying that it is important for the committee to see how they can better leverage federal resources and authorities to better address the opioid crisis, as well as see how federal programs intersect. He asked what percentage of 340B drugs are prescription opioids and what steps are in place to prevent diversion and misuse of these drugs once they are dispensed to patients. Most witnesses said they had to get back to the committee with that data, but did note that the 340B program has allowed them to provide things like counseling, education about best practices for opioids, and purchase Naloxone for communities. It was noted by Dr. Paulus that free clinics are not eligible for the 340B program. Mr. Gifford also noted that the Ryan White Program cannot use 340B savings to purchase Naloxone.

A full summary of the hearing is attached.

SUBSTANCE USE AND MENTAL HEALTH

Energy and Commerce Committee

On Wednesday, the House Energy and Commerce Committee held a Members Day on the opioid misuse and overdose epidemic and heard testimony from Members of Congress on proposals to address the epidemic. A hearing notice and background memo are available here.

While no future action was formally announced at the hearing, Energy and Commerce Committee Chair Walden (R-OR) previously announced that the Committee will hold a hearing on the epidemic the week of October 23rd. We have since heard the hearing may be delayed until November.

Signifying the bipartisan interest in this issue, 55 Members spoke at the session, including House Minority Leader Pelosi (D-CA). Pelosi said it was only the second time she had testified as leader "because this issue rises to the level, as you know, of life and death." Pelosi made a plea for bipartisan work to address the epidemic, voiced her support for Medicaid expansion and said efforts to address the epidemic must include both providers and the pharmaceutical industry to reduce unnecessary prescriptions.

In his opening remarks, Health Subcommittee Chair Burgess (R-TX) noted that it does not matter where one lives, the crisis has touched every corner of American society and said, "now more than ever, we must come together and strengthen our commitment to fight this heartbreaking malady."

A full summary of the session is attached.

White House Opioids Commission

The fifth meeting of the President's Commission on Combating Drug Addiction and the Opioid Crisis will take place on Wednesday, November 1st from 1:30 pm until approximately 3:30 pm. The meeting will consist of personal stories regarding addiction and discussion of and voting on the Commission's Final Report that will be posted on ONDCP's Commission website shortly before the meeting.

TRUMP ADMINISTRATION

HHS Secretary

On Tuesday, it was announced that HHS Deputy Secretary Eric Hargan will serve as the agency's acting secretary. Don Wright, acting assistant secretary for health, had served as the agency's acting secretary since Tom Price stepped down on Sept. 29. Hargan was confirmed as deputy secretary by the Senate on a 57-38 vote last week. Hargan served in several roles at HHS between 2003 and 2007, including acting deputy secretary, before leaving government work to practice law in Chicago.

NIH/Pharmaceutical Companies Public-private Partnership

On Thursday, it was announced that NIH and a consortium of 11 pharmaceutical companies are launching a public-private partnership to find cancer biomarkers for immunotherapies. The partnership will be funded by as much as $215 million, with drug makers pitching in $55 million and the National Cancer Institute contributing up to $160 million over five years. The group intends to coordinate clinical trials to ensure biomarkers' validity for cancer immunotherapies — which enlist a patient's immune system to fight the disease — can be standardized. Currently, immunotherapies are often effective with just certain cancers or certain patients, and the partnership hopes the treatment can be expanded to new groups of patients. The partnership is "precompetitive," NIH Director Dr. Francis Collins said, and therefore intended to set aside questions of intellectual property. Data sharing will be a priority, and an organizational meeting to further define governance and other questions is set for next month.

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