10.23.17 – 10.27.17 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.

SUBSTANCE USE AND MENTAL HEALTH

Emergency Declaration

Yesterday, at a White House event the President directed the Department of Health and Human Services (HHS) to declare the opioid misuse and overdose epidemic a national public health emergency. Shortly thereafter, Acting HHS Secretary Hargan made the declaration official.

Many on and off Capitol Hill called the emergency declaration a "good first step," but cited the need for more funding to fully address the epidemic as new funds or a request for new funds did not accompany the declaration. In a statement, Senator Capito (R-WV) said, "Of course, the president's action is just part of what must be a larger and broader national effort. Communities in West Virginia and across the country need more resources for recovery, treatment and enforcement, and it's essential that we do what we can to provide the support they need. As a leader on the Appropriations Committee, I have worked hard to secure funding to fight the opioid epidemic on all fronts, and I will continue pushing and advocating for much-needed resources."

As indicated by Senator Capito's statement, the announcement has spurred advocacy on Capitol Hill for funding to address the epidemic. In press reports yesterday, Administration officials indicated they might make a request to Congress for more dollars. Additionally, on Wednesday, Senators Markey (D-MA) and Casey (D-PA) introduced legislation to build on the funding in the *21st Century Cures Act* by appropriating $45 billion annually through 2027.

While no new federal funds to address the epidemic accompanied the declaration, it does allow the Agencies to loosen certain regulations.

The declaration itself did not provide specifics on next steps the Administration might take, but Trump's remarks and an accompanying fact sheet provided a sense for the Administration's priorities. In Trump's remarks some of the policies he mentioned included:

- A "massive advertising campaign" against drug abuse
- Quick approval of waivers submitted by states to waive the Institute of Mental Disease (IMD) prohibition on Medicaid reimbursement for treatment facilities with more than 16 beds
- An Food and Drug Administration (FDA) request for a high-risk opioid to be withdrawn from the market (presumably a reference to Opana)

Additionally, a White House fact sheet accompanying the declaration referenced greater use of telemedicine for medication assisted treatment (MAT) in rural areas, expedited federal hiring of specialists, Department of Labor funding for dislocated worker grants in states with high rates of opioid misuse, and re-directing funds from HIV/AIDs programs to help individuals eligible for those programs to receive substance use disorder treatment.

In closing the event, President Trump said, "the epidemic will get worse before it gets better, but get better it will. It is time to liberate our communities from this scourge of drug addiction...we can be the generation that ends the opioid epidemic."

The Presidential Commission on Combating Drug Addiction and the Opioid Crisis will release its final report on November 1st. At yesterday's White House event, President Trump announced the Administration will review and then act on certain recommendations following the report's release.

Energy and Commerce Committee Hearing

On Wednesday, the House Energy and Commerce Committee held a hearing on the opioid misuse and overdose epidemic. Witnesses included:

- 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

Full witness testimony is available here.

Overview

In his opening remarks, Chairman Walden (R-OR) noted that the hearing was the first full Committee hearing of the year, which he said points to the importance of the issue. No future action was announced, but at the end of the hearing Health Subcommittee Chair Burgess (R-TX) said the hearing was lengthy but informative and he anticipates the testimony from the federal witnesses and the 50+ Members who spoke at the Members day a couple weeks ago will inform Committee action going forward.

In statements, the witnesses acknowledged the scope of the epidemic. Dr. Schuchat from the CDC noted that this is one of the few public health problems that is getting worse, not better. Additionally, Dr. Volkow from NIDA said this is an urgent crisis that needs an all hands on deck approach to solve it. Volkow added that Medication Assisted Treatment (MAT) is vastly under-utilized and relapse rates are too high. She said more research, including partnering with industry, is needed and showed a nasal naloxone demo as an example of a successful partnership with industry.

In his statement, FDA Commissioner Gottlieb said that due to missed opportunities, the opioid misuse and overdose epidemic was allowed to spread and said, "long ago, we ran out of straightforward options" for addressing it. Gottlieb noted that some of the proposed solutions may make some people "uncomfortable." He laid out steps the FDA is taking, which include:

1. Issuing new guidance for product developers to support the development of new addiction treatments
2. Supporting access to existing treatments that work because "far too few people" are able to access Medication Assisted Treatment (MAT), partly due to insurance barriers

a. FDA is gathering data to support a label change for MAT that could indicate MAT is for all patients who have experienced an overdose. Gottlieb said the label change could increase insurance coverage.

b. He also noted that health providers and insurance companies need to understand that for many patients, the data shows that MAT must be given for long periods of time – even their entire lifetime – and the FDA will be revising product labels to reflect this data

3. Increasing efforts to promote non-addictive pain medications and abuse deterrent formulations
4. Joining efforts to break the stigma associated with MAT. Gottlieb said that stigma prevents individuals from getting into treatment and recovery. He also said that individuals on MAT should not be considered "addicted" or replacing one drug with another and said such an attitude "reveals a flawed interpretation of science"

A more detailed summary of some of the key issues covered during the hearing is attached.

BUDGET AND APPROPRIATIONS

On Thursday, the House agreed to the FY2018 Congressional Budget Resolution by a vote of 216-212. The resolution previously passed the Senate by a vote of 51-49. With both chambers having adopted identical text, Congress now has set official targets for federal spending and revenue for FY18 and beyond. To achieve their spending goals, Republicans in Congress plan to reduce domestic spending by $5.1 trillion compared to baseline projections, including $1.8 trillion in cuts to Medicare, Medicaid, and CHIP over the next ten years. Of course, because this document only reflects proposed cuts, actually implementing these cuts still requires an act of Congress. Most of these cuts are unlikely to come to fruition. More important than agreeing upon spending and revenue totals for the coming year, the FY18 budget resolution sets the process for budgetary legislation. By far the most impactful procedural tactics set forth in the budget are the reconciliation instructions. As you no doubt remember from the Affordable Care Act repeal/replace effort this year, reconciliation is the process whereby legislation may pass the Senate with 51 votes instead of the customary 60.

In the FY18 budget resolution, Congress made Tax Reform the legislation on which reconciliation will be used. Loose principles for Tax Reform have been announced in prior months. These basic tenants are: reducing individual rates, reducing corporate rates, reducing pass-through rates, and reforming tax deductions. Some estimates believe the cumulative costs of the reduced rates could be as high as $5.8 trillion in lost revenue. The aforementioned Budget Resolution adopted by Congress requires lawmakers to find offsetting revenue for most of those cuts. In the end, Congress cannot increase 10-year deficits by more than $1.5 trillion. To achieve this, Congress and the Administration have been identifying major tax expenditures. On November 1st, House Republican leadership is planning to unveil their long-awaited Tax Reform legislative text to provide Americans direct answers to which tax deductions will be retained, adjusted, or eliminated. The House Ways and Means Committee is expected to vote on the plan on November 6th and if all goes as planned the legislation will be brought to the House floor the following week. The Senate, meanwhile, has ambitious plans of its own, hoping to pass the bill by the end of November, even working through the Thanksgiving recess if necessary. Republican leaders hope to have it on the President's desk by the end of the year.

Meanwhile, with the second hurricane recovery supplemental spending bill awaiting the President's signature, the Appropriations Committees are returning to work to pass a year-end omnibus spending bill. Unresolved, however, are the

lingering spending caps in place since 2012. Both defense and non-defense programs are facing increased tension operating under the caps. One senior House appropriator has told VSA that most of the work on his portion of the bill is finished. Final dollar figures for each program and the top-tier disputes still need to be negotiated as part of a larger budget deal, but for now signs suggest Congress is still on track for adoption of the Omnibus in December, hopefully before the December 8th deadline.

Facilities and Administrative (F&A) Costs Hearing

On Tuesday, the House Labor HHS Appropriations Subcommittee held an oversight hearing on the Role of Facilities and Administrative (F&A) Costs in Supporting NIH-Funded Research. A webcast of the hearing and copies of witness testimony can be found here.

Witnesses included:

- 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

In his opening statement Chairman Tom Cole (R-OK) noted the provisions in both the House and Senate FY18 Labor HHS bills, as well as the current Continuing Resolution, that would effectively block the Trump Administration's proposal to cap F&A costs on NIH grants at 10 percent by requiring NIH to continue to reimburse overhead costs by following the current rules.

The witnesses were unanimous in that capping F&A costs at 10 percent as purposed by the Administration, would be disastrous for their institutions. Dr. Keith Yamamoto said that facilities costs are "essential" to academic research and that draconian cuts or caps would damage research, researchers, research outcomes, American health and American competitiveness. Dr. Kelvin Droegemeier said that the implications of capping F&A cost would be less research performed. He noted that only institutions that have sufficient resources will be able to accept grants and those who cannot would not be able to compete, or at least not at the same level.

To start the questioning, Chairman Cole asked how institution would react if the Administration's cap was enacted. The witnesses in some form all indicated that they would have to scale back research, close labs, curtail training, hire fewer students, and lay off employees. The research institutions indicated that they do not have the financial resources to make up the difference in these costs, including at the state level.

Rep. Andy Harris (R-MD) pushed back on some of the criticism of the Trump administration's proposal and said it was worth reexamining how NIH doles out money for F&A costs. As he has in the past, he pointed out that foundations do not pay as much in F&A costs as the federal government, however, his focus this time was on young investigators. He noted that the question was not whether we are going to fund F&A costs, but whether the amount we are going to fund is the appropriate amount. He said that he would like to see Congress cap some F&A costs for researchers with multiple NIH grants, directing the savings to fund younger researchers. All of the witnesses agreed that young investigators should be a focus, but also agreed that capping F&A costs was not the way to solve the problem. Dr. Droegemeier pointed out that it becomes more expensive to do research over time as researchers grow their labs and add staff and more expensive equipment, so capping F&A costs for more senior researchers who have multiple NIH grants is not a feasible solution.

Overall the hearing was positive towards research universities and it was very clear from all the witnesses that a cap on indirect costs would be problematic to universities on many levels.

A more detailed summary of the hearing is attached.

CHILDREN'S HEALTH INSURANCE PROGRAM AND OTHER HEALTH PROGRAM EXTENSIONS

Children's Health Insurance Program

On Thursday, House Majority Leader Kevin McCarthy (R-CA) announced that the House will next week be taking up a bill that would extend funding for the Children's Health Insurance Program. As previously reported, the House Energy and Commerce Committee earlier this month advanced legislation on a 28-23 party-line vote to fund CHIP for five years, as well as legislation to continue money for community health centers and other safety net programs for two years. Democrats have objected to the way the measure would increase costs for wealthier seniors on Medicare and cut Obamacare's Prevention and Public Health Fund, among other steps, to pay for the bills.

Earlier this month, Committee Chairman Greg Walden (R-OR) asked his Democratic colleagues to suggest offsets that may be more amenable than those in the committee passed bill. Walden said in a statement that he has not received any

Democratic offers, but Democrats contend they have put suggestions on the table such as closing the doughnut hole for Medicare Part D.

Pallone has suggested that the process to reauthorize CHIP could be lengthy if the House passes a partisan bill and the Senate does not act quickly to pass their bipartisan measure. The two likely would have to be reconciled through conference negotiations, which he claims would push off a deal until the end of the year.

McCarthy said the reason the bill must be done next week is because Minnesota is about to run out of funds. Federal funding for CHIP expired September 30, but nine states and territories including Minnesota received redistribution funds from the Centers for Medicare and Medicaid Services that are left over from previous fiscal year allotments.

Medicare Extenders Legislation

The Senate Finance Committee is finalizing bipartisan legislation renewing a series of Medicare programs and other health initiatives otherwise slated to expire this year. The bill would fund several Medicare extenders, such as provisions aimed at aiding low-volume or rural health care providers, as well as reauthorize federally backed outreach aimed at low-income beneficiaries. It also proposes eliminating an annual limit on beneficiaries' spending for certain physical therapy services, in line with a deal announced by lawmakers on the House Ways and Means and Energy and Commerce committees. The bill includes new funding through 2019 for a number of initiatives run by HHS, such as a home visiting program for at-risk families and an abstinence education program. The draft does not detail how the spending would be offset. A summary of the proposed legislation is attached.

MARKET STABILIZATION

This week, Senator Hatch (R-UT), Chairman of the Senate Finance Committee, and Rep Brady (R-TX), Chairman of the House Ways and Means Committee, announced they had a bicameral agreement on a package to provide funding for the cost sharing reductions (CSR) and repeal the individual and employer mandates. As the legislation is not expected to garner the 60 votes necessary for passage in the Senate due to Democratic opposition, its most immediate effect could be to complicate efforts to move the Alexander/Murray stabilization package. At this point, it is not anticipated final action on the Alexander/Murray bill will happen until closer to the end of the year.

On Wednesday, the Congressional Budget Office (CBO) released a score of Alexander/Murray. CBO found the bill would reduce the deficit by $3.8 billion between 2018 and 2027 and would not substantially change the number of Americans with health insurance.

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