

1.22.18 – 1.26.18 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: after voting on the Continuing Resolution (CR) through February 8th on Monday, the House was in recess for the week as previously scheduled.

BUDGET AND APPROPRIATIONS

FY19 Budget Request

Even without a final budget for FY18, the Trump administration announced plans Wednesday to proceed with a fiscal 2019 budget next month anyway. Under the 1974 budget act that created the modern budget process, the president is required by statute to submit a budget request for each new fiscal year by the first Monday in February. The administration this week announced that they plan to miss that deadline by a week, unveiling its request on February 12 or later. The Office of Management and Budget attributed the delay to the recent government shutdown.

FY18 Appropriations

Following a three-day government shutdown, both the Senate (81-18) and House (266-159) on Monday passed a continuing resolution reopening the government until February 8. The CR also contained a six-year reauthorization of the Children's Health Insurance Program (CHIP) and would delay or suspend three taxes imposed under the 2010 health care law. As part of the agreement to reopen the government, GOP leaders pledged to immediately consider immigration legislation if leaders do not reach a deal on immigration before Feb. 8.

The pathway toward an omnibus spending bill or any additional stopgap measures, plus remaining health care program renewals and extensions, including the renewal of federal health centers, the extension of expired Medicare provider payments, and reversal of cuts to disproportionate share hospital payments, continues to be blocked, however, by a long-standing disagreement over adjustments to statutory spending caps. Lawmakers were reportedly close to an agreement prior to last weekend's government shutdown, but without adjusted spending caps, the FY18 spending bills cannot be finalized.

In agreeing to that latest CR, congressional leaders had said they were hoping to get a deal on spending limits and immigration by the time the latest stopgap expires. Majority Whip John Cornyn (R-TX), however, said on Wednesday that lawmakers may need to pass additional continuing resolutions to accommodate decisions on spending caps, plus an immigration compromise. Even if an agreement to raise spending limits were reached by early March, Congress would need time to compile and pass an omnibus, potentially pushing a final FY18 spending package until March or later.

Once an agreement is reached, senators on both sides of the aisle say they expect Congress to provide new funding for the opioid epidemic as part of a spending caps deal, but it's not clear how much will be appropriated.

PANDEMIC PREPAREDNESS

On Tuesday, the Senate HELP Committee held its second hearing on the reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA), which expires in September. PAHPA authorizes funding for HHS to undertake many activities to prepare for and respond to natural disasters, natural pandemics, and biological threats. This includes funding for the National Strategic Stockpile of medical countermeasures. The hearing included the following witnesses:

- Dr. Tom Inglesby: Director of Center for Health Security, Johns Hopkins Bloomberg School of Public Health

- Dr. John Dreyzehner: Commissioner, Tennessee Department of Health
- Brent MacGregor: Senior Vice President for Commercial Operations, Seqirus
- Dr. Steven Krug: Chair, Disaster Preparedness Advisory Council of the American Academy of Pediatrics

The hearing focused on barriers to innovating medical countermeasures. It was repeatedly discussed by the witnesses that there is no commercial market for most medical countermeasures, which deters drug and device companies from investing capital in MCM research and development. Therefore, they encouraged Congress to provide HHS authority to assist companies for their MCM innovations in order to catalyze innovation. Senators also discussed the impact the current influenza outbreak is having on hospitals nationwide. Witnesses told the committee that fully funding the Hospital Preparedness Program is one important step to mitigate future flu outbreaks.

TRUMP ADMINISTRATION

HHS Secretary

On Wednesday, the Senate voted to approve the nomination of Alex Azar to be Secretary of the Department of Health and Human Services (HHS) by a vote of 55 - 43. Senators Carper (D-DE), Coons (D-DE), Donnelly (D-IN), Jones (D-AL), Heitkamp (D-ND), Manchin (D-WV) and King (I-VT) voted with Republicans in approving the nomination. Sen. Paul (R-KY), who disagrees with Azar's stance on drug reimportation, was the only Republican present who voted "no."

Azar takes the helm of HHS amid Administration efforts to loosen or overturn the Affordable Care Act's rules and regulations. When asked how he might approach the position, one insider told reporters that Scott Gottlieb, the widely praised Food and Drug Administration (FDA) Administrator, may be the model. Azar is also reportedly expected to conduct a "listening tour" on Capitol Hill to solicit ideas from Members and establish a friendlier relationship with the Hill than former Secretary Price had during his short tenure.

Opioid Public Health Emergency

Late last Friday, the Trump Administration [announced](#) it is extending the opioid misuse and overdose public health emergency declaration. The declaration, which was set to expire on Tuesday, will now be extended until April 23rd.

Medicaid Work Requirement Lawsuit

On Wednesday, a group of Kentucky Medicaid beneficiaries sued the Centers for Medicare and Medicaid Services (CMS) to block implementation of Kentucky's new Medicaid program, called Kentucky HEALTH. As reported previously, CMS recently approved Kentucky's Medicaid 1115 waiver which allows the state to make several major changes to its Medicaid program. Most notable in Kentucky HEALTH is its requirement that all able-bodied adults perform at least 20 hours a week of employment, work training, or other forms of community engagement. The new Kentucky plan also includes other major provisions:

- Requires the use of specialize health saving account
- Charges monthly premiums on adults who qualified for Medicaid under the Affordable Care Act's Medicaid Expansion
- Ends retroactive enrollment, which is common in hospitals in expansion states, to cover emergency services for eligible individuals who were previously uninsured

CMS approved the Kentucky HEALTH waiver on January 12th, claiming the changes to its Medicaid program "promote Medicaid's objectives" by "improv(ing) health and wellness and help individuals and families attain and retain capability for independence or self-care."

Opponents of the changes made by Kentucky HEALTH estimate implementing the plan will result in as many as 100,000 Kentuckians losing Medicaid coverage. A group of 15 Medicaid beneficiaries sued CMS to block the entire waiver, not just the work requirement. Their central argument is that CMS intended to “fundamentally transform” Medicaid in a manner in contravention of its mission to improve access to health, and granting such a transformative waiver exceeded its regulatory authority. Kentucky Governor Matt Bevin had threatened to repeal Kentucky’s Medicaid expansion for 400,000 Kentuckians if opponents brought suit. As of yet, Bevin has not ended Medicaid Expansion.

With nine other states with pending Medicaid 1115 waivers with similar work requirements and other features, this case is surely to have national impact. Regardless of the outcome of this case, experts believe it is likely to be appealed eventually to the US Supreme Court.

SUBSTANCE USE AND MENTAL HEALTH

Senate HELP Committee hearing on Opioids

On February 8th, the Senate Health, Education, Labor and Pensions (HELP) Committee will hold a hearing on the impact of the opioid misuse and overdose epidemic on children and families. Staff had indicated that this may be the last hearing on opioids at the Committee before work shifts to “CARA 2.0,” the upcoming legislative package of authorizing bills to address the epidemic. Witnesses at the hearing are expected to include:

- Becky Savage, Co-Founder of the 525 Foundation
- Stephen Patrick, Assistant Professor of Pediatrics and Health Policy in the Division of Neonatology at Vanderbilt University Medical Center
- William Bell, President and CEO of Casey Family Programs

Senate Homeland Security Committee Hearing on Fentanyl

On Thursday, the Senate Homeland Security & Governmental Affairs Subcommittee on Investigations held a hearing entitled *Combating the Opioid Crisis: Exploiting Vulnerabilities in International Mail*. A webcast of the hearing can be found [here](#).

At the hearing, senators called for tougher screening of international mail shipments to prevent overseas drug manufacturers from sending deadly narcotics to the United States. They also discussed the results of a [report](#) released on Wednesday that showed how easy it is to purchase the powerful opioid fentanyl online. The investigation examined six online fentanyl sellers, which subcommittee Chairman Rob Portman (R-OH) said were “shockingly easy” to find. “All you had to do was search ‘fentanyl for sale,’” he said. While the investigators never purchased any fentanyl, they initiated conversations about how to purchase and ship it, and online sellers were apparently responsive. Portman said that they preferred to use the U.S. Postal Service compared to private carriers like FedEx because “the chances of the drugs getting seized were so insignificant that delivery was essentially guaranteed.”

Portman wants the Postal Service to require all packages to have “advanced electronic data” that includes names and addresses, cargo descriptions and weight. The data can help law enforcement identify packages that might be higher-risk or more suspicious and screen them more closely. He has introduced a bipartisan bill (S. 372) to require that data on shipments. Currently only about a third of international Postal Service shipments include this kind of data, since not all foreign postal operators provide it. Both Portman and Carper acknowledged that requiring more shipment data wouldn’t by itself solve a problem as complicated as opioid abuse, but hoped the bill could be part of a more far-reaching legislative effort on drug abuse this year.

Todd Owen, a field operations official with Customs and Border Protection, told committee members the data would be helpful for stopping those shipments. Carriers like FedEx and commercial importers already include this shipping data, and Owen described how CBP analyzes the data to identify risky shipments, which they can put a hold on and examine more quickly.

Joseph Murphy, the State Department's chief of international postal affairs, said the international consortium that governs the global mail system is requiring all participating countries to have an advanced-electronic data system in place by 2020. But he said that even if systems will be in place by then, there is no deadline for countries to actually collect and report the data. Murphy also raised questions about whether the use of this data would be as effective as in other areas where it is used, such as aviation security and intellectual property rights issues.

Senator Carper (D-DE) called on the Trump administration to engage with Beijing to help disrupt the supply since most of the illicit fentanyl sent to the U.S. comes from China. While witnesses said China had increased its efforts to crack down on fentanyl manufacturers, the country's leaders didn't view the issue with the same urgency.

Members of both parties hope to reach a deal in the coming weeks to raise annual appropriations caps that includes more funding for opioid abuse. Portman noted several other policy areas that he'd like to see Congress address, including prescription drug monitoring programs and Medicaid payments to substance abuse treatment centers.

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