This Week in Health Policy, Congressional Lookback, Regulatory Lookback, Comment & Application Deadlines

Wynne Health Group Weekly

FRAMING THE WEEK

Congress returns this week to a full plate of contentious issues **– coronavirus relief and fiscal year (FY) 2021 spending** – as the December 11 deadline for extending government funding approaches. An impasse remains on the overall price tag of a relief bill as House Speaker Nancy Pelosi (D-CA) continues to push for a $2.2 trillion package and Senate Majority Leader Mitch McConnell (R-KY) is sticking to $500 billion.

Sen. Rob Portman (R-OH) is spearheading a bipartisan "targeted" relief package that would provide federal funding for **coronavirus vaccine** development and distribution, another round of **Paycheck Protection Program** loans for small businesses, and enhanced **unemployment benefits**. Alternatively, some relief measures could be tacked on to the FY 2021 spending package if negotiations on a standalone stimulus package fail.

Additional funding for vaccine distribution is particularly critical as states prepare to allocate a limited supply of vaccine doses. Of note, the Centers for Disease Control and Prevention (CDC) has scheduled an emergency meeting for tomorrow (December 1) to vote on their recommendation of who should receive the coronavirus vaccine first once one is authorized by the Food and Drug Administration (FDA). The meeting precedes the meeting of the FDA's Vaccines and Related Biological Products Advisory Committee on December 10 to discuss emergency use authorization of the Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age and older. Prior to the Thanksgiving holiday, Pfizer announced that their coronavirus vaccine is 95 percent effective.

Lawmakers appear on track to reach a deal on an **omnibus spending package** and avert a government shutdown. A renewed effort to include **surprise billing measures** in the spending package is building as retiring Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN) and Sen. Bill Cassidy (R-LA) have reached a bipartisan solution "that is supported by large bipartisan majorities" in the Senate HELP Committee, the House Energy and Commerce Committee, and the House Education and Labor Committee.

Alexander and Cassidy have not yet released legislative text, but their proposal combines elements of previously debated solutions. Of note, a health care provider would be provided with an "interim payment" that is "based on where the patient lives and where they receive care" – which sounds to be the median contracted rate. "Independent Dispute Resolution" (i.e., baseball-style arbitration) could be used "if a health care provider determines the interim payment is unfair." It is unclear what would be considered "unfair" and if the arbitration option would become available if a certain payment threshold is reached – for example, $750, which was the amount previously agreed to by Alexander and E&C leaders. The House Ways and Means Committee has not yet expressed support for this dual approach of benchmark payments and limited arbitration.

In addition, a conference committee is reconciling differences between the Senate and House versions of the **National Defense Authorization Act (NDAA)** (S. 4049 and H.R. 6395). A vote on final passage is anticipated in early December, and President Trump is expected to sign the bill into law shortly thereafter. Both bills include varying levels of support for the federal government's COVID-19 response. The Senate version would authorize $44 million for vaccine and biotechnology research supported by the Department of Defense. The House version would provide more generous funding through a $1 billion Pandemic Preparedness and Resilience National Security Fund, which would include $200 million to purchase goods or services from small businesses in response to the COVID-19 pandemic; $50 million to produce medical countermeasures against novel threats; and $750 million to support research and development efforts related to biopreparedness and pandemic preparedness and resilience.

The **Medicare Payment Advisory Commission (MedPAC)** is scheduled to convene later this week (December 3 and 4). While the agenda has not yet been published, commissioners may continue their discussions on telehealth, access to care in rural areas, among other topics.

An overview of health policy events of interest in the coming week is posted to Policy Hub and included below for your convenience.

THIS WEEK IN HEALTH POLICY

Tue. (12/1)

- **2:00pm-5:00pm – CDC Meeting: COVID-19 Vaccine** – CDC convenes a meeting of the Advisory Committee on Immunization Practices to discuss allocation of initial supplies of COVID-19 vaccine. Details.

Wed. (12/2)

- **2:00pm-3:00pm – CMS Call: Physician Self-Referral Law** – CMS hosts a Special Open Door Forum to discuss the final rule released on November 20, to modernize and clarify the regulations that interpret the federal physician self-referral law. The dial-in number is 1-888-455-1397 and passcode ID # is 2037400.

Thurs. (12/3)

- **TBD – MedPAC** – The Medicare Payment Advisory Committee (MedPAC) convenes a virtual public meeting to discuss Medicare payment and policy issues. Details.

Fri. (12/4)

- **TBD – MedPAC** – MedPAC convenes a virtual public meeting to discuss Medicare payment and policy issues. Details.

FEATURED WHG ANALYSIS

- ***California v. Texas*: Analysis of Supreme Court Oral Arguments** – In the Policy Hub Insight Bank here.
- **WHG Issue Brief: COVID-19 Vaccine State of Play –** In the Policy Hub Insight Bank here.
- **WHG Catalogue of COVID-19 Government Response** – October Edition – In the Policy Hub Insight Bank here.

CONGRESSIONAL LOOKBACK

Wed. (11/18)

- ***The Hill*** hosted a virtual series of panel discussions focused on diabetes and the future of health care reform. The panelists consisted of experts in the field of diabetes as well as lawmakers who focus on advancing legislative reforms to improve diabetes care. Details.

REGULATORY LOOKBACK

Fri. (11/20)

- **CMS** issued an interim final rule with comment period (IFC) to implement the Most Favored Nation (MFN) Model, pursuant to President Trump's executive order (EO) on Lowering Drug Prices by Putting America First. Comments are due January 26, 2021. Details.
- **HHS OIG** issued a final rule that explicitly excludes drug rebates that manufacturers pay to pharmacy benefit managers (PBMs) and Medicare Part D plans from the current discount safe harbor, thereby eliminating their protection under the federal anti-kickback statute. Details.
- **CMS** finalized a rule implementing highly-anticipated reforms to the Physician Self-Referral Law (the "Stark Law"). Details.
- **OIG** issued a complementary final rule delineating modifications to the Federal Anti-Kickback Statute (AKS), including relevant civil monetary penalty (CMP) provisions (Beneficiary Inducements CMP). Details.
- **CMS** issued a final rule codifying changes to the Organ Procurement Organization (OPO) Conditions for Coverage (CfCs) that OPOs must meet to receive Medicare and Medicaid payment. Details.
- **OASH** released the draft Vaccines National Strategic Plan 2021-2025 for public comment. The updated plan will recommend vaccine strategies for all Americans and guide vaccine initiatives over the next five years. Comments are due by Dec. 3. Details.

Thurs. (11/19)

- **FDA** issued draft guidance entitled "Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the Biologics Price Competition and Innovation (BPCI) Act." The guidance is intended to inform prospective applications and facilitate the development of proposed biosimilars and proposed interchangeable biosimilars. Comments are due January 19, 2021. Details.
- **FDA** published a consolidated list of medical devices that have received emergency use authorization (EUA) for the COVID-19 public health emergency. Details.
- **FDA** released draft guidance on cross labeling oncology drugs in combination regimens. Comments are due by January 1, 2021. Details.

Wed. (11/18)

- **HHS** updated its FAQs for the Provider Relief Fund and clarified two key points related to reporting requirements. Details.

Tue. (11/17)

- **CDC** announced a pediatric immunization-focused Notice of Funding Opportunity (NOFO) – US Enhanced Surveillance Network to Assess Burden, Natural History, and Effectiveness of Vaccines to Prevent Enteric and Respiratory Viruses in Children. LOIs are due by Jan. 7, with applications are due by February 8, 2021. Details.
- **HRSA** announced a grant titled "Leadership Education in Neurodevelopmental and Other Related Disabilities (LEND)," aimed at supporting graduate-level training in maternal and child health interdisciplinary leadership education in neurodevelopmental and related disabilities programs. Applications are due February 16, 2021. Details.

Mon. (11/16)

- **FDA** issued draft guidance electromagnetic compatibility (EMC) of medical devices. The guidance is intended to describe relevant information that should be provided in a premarket submission to support a claim of EMC for electrically powered medical devices and medical devices with electrical or electronic functions. Details.
- **NIH** announced that the preliminary data from Moderna's Phase 3 COVID-19 vaccine trial demonstrates that the candidate (mRNA-1273) is safe and 94.5 percent effective. This analysis comes from an independent data and safety monitoring board (DSMB) overseeing the phase 3 trial. Details.
- **OASH** is soliciting information to better understand what steps stakeholders are taking to transform chronic disease management for conditions such as hypertension, chronic lower respiratory disorders, and cognitive impairment, among aging populations in underserved areas. Comments are due on December 22. Details.

COMMENT & APPLICATION DEADLINES

- **Dec. 1:** FDA seeks comment on draft guidance for developing drugs and biologics for adjuvant treatment of renal cell carcinoma and bladder cancer. Details.
- **Dec. 3:** CMS released the proposed methodology and data sources to determine federal payments for program year (PY) 2022 for states that have established a Basic Health Program. Comments due Dec. 3. Details.
- **Dec. 3:** OASH is accepting comments on the draft Vaccines National Strategic Plan 2021-2025 for public comment. The updated plan will recommend vaccine strategies for all Americans and guide vaccine initiatives over the next five years. Details.
- **Dec. 4:** HHS announced a new proposed rule, "Securing Updated and Necessary Statutory Evaluations Timely," which could significantly impact current regulations and future rulemaking. Details.
- **Dec. 11:** AHRQ seeks scientific information submissions to inform its review on Malnutrition in Hospitalized Adults. Details.
- **Dec. 14:** NIOSH announced a request for information regarding the use of "elastomeric half-mask respirators" healthcare settings during the COVID-19 pandemic. Details.
- **Dec. 14:** HHS issued a proposed rule that would add a Smallpox Countermeasures Injury Table for designated covered smallpox countermeasures. Details.
- **Dec. 14:** FDA requests nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) and the Medical Devices Advisory Committee (MDAC) device panels in the Center for Devices and Radiological Health. Details.
- **Dec. 18:** HHS announced a request for information (RFI) regarding research integrity and the responsible conduct of research. Details.
- **Dec. 22:** OASH is soliciting information to better understand what steps stakeholders are taking to transform chronic disease management for conditions such as hypertension, chronic lower respiratory disorders, and cognitive impairment, among aging populations in underserved areas. Details.
- **Jan. 1:** FDA seeks comment on draft guidance on cross labeling oncology drugs in combination regimens. Details.
- **Jan. 4:** FDA seeks comments on a proposal to publish a summary of the FDA's review of Risk Evaluation and Mitigation Strategy (REMS) assessments. Details.
- **Jan. 5:** CDC announced a funding opportunity for "PrEP Choice: Increasing the Use of HIV Pre-exposure Prophylaxis in an Era of Choices." The application deadline is January 5, 2021. Details.
- **Jan. 18:** CMS announced that the Community Health Access and Rural Transformation (CHART) model is open for applications. Letters of intent are due by January 18, 2021. Details.

- **Jan 19:** FDA seeks comment on draft guidance entitled "Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the Biologics Price Competition and Innovation (BPCI) Act." Details.
- **Jan. 21:** HRSA announced a Notice of Funding Opportunity for the Behavioral Health Workforce Education and Training (BHWET) Program for Professionals for FY 2021. Details.
- **Jan. 26**: CMS issued an interim final rule with comment period (IFC) to implement the Most Favored Nation (MFN) Model, pursuant to President Trump's executive order (EO) on Lowering Drug Prices by Putting America First. Details.

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