

*Wynne Health Group Weekly*



**FRAMING THE WEEK**

With only nine days left until inauguration, Congressional Democrats begin the process, as [outlined](#) by House Speaker Nancy Pelosi (D-CA), of **holding President Donald Trump accountable** for inciting the deadly Capitol siege last week, starting with a request today for unanimous consent (and likely a roll call vote tomorrow) on a [resolution](#) calling on Vice President Mike Pence to invoke the 25<sup>th</sup> Amendment to remove Trump from office. Absent cooperation from Pence, the House will begin impeachment procedures. However, the actual timing, particularly of the expected Senate trial, remains in flux as Democrats seek to not hamper President-elect Joe Biden from executing his agenda and, most urgently, strengthening the federal government's response to the coronavirus pandemic.

This week, Biden is expected to layout the groundwork for a **new COVID-19 relief and stimulus package**, calling the \$900 billion relief measure in the year-end spending bill a "down payment." Based on the broad strokes [described](#) by Biden at a news conference last Friday, the overall price tag of the package appears likely north of \$1 trillion – an amount that was previously a nonstarter under the Republican-controlled Senate. In addition, with Democrats in control of the Senate, albeit by a razor-thin margin, Senate Republican Leader Mitch McConnell's (R-KY) redline on liability protections is less of a threat. Biden's proposal is expected to include billions of dollars to bolster vaccine distribution; billions of dollars for state and local governments; tens of millions of dollars for schools; additional relief for small businesses, particularly minority-owned and women-owned businesses; rental assistance; and \$2,000 in stimulus payments.

While we expect earnest efforts by the new administration to rally bipartisan support for the package (to clear the 60-vote threshold to break a filibuster), **budget reconciliation** will be considered as a back-up pathway for delivering these measures. That legislative approach has several restrictions, however, regarding when and how it can be deployed. Current Senate rules allow separate reconciliation bills addressing spending, tax, and debt limit to move in a single fiscal year, but not multiple reconciliation bills addressing an individual subject (e.g., two reconciliation bills in the same fiscal year that include new spending would be prohibited). Plus, Congress will first need to adopt a budget resolution for the current 2021 fiscal year in order to formally begin the budget reconciliation process, which may delay getting federal aid out the door quickly. Finally, the eligibility of the discretionary spending components of the COVID relief package (i.e., those that do not implicate tax revenues or entitlement spending) is also in question.

In the meantime, the Biden transition team is pushing for Senate Republican committee chairs, who remain in control until January 20, to schedule **confirmation hearings for Biden's nominees** – including Xavier Becerra for Secretary of Health and Human Services, Dr. Vivek Murthy for Surgeon General, and Neera Tanden for Director of the Office of Management and Budget (OMB). While the nominees are expected to have no trouble getting through the Democratic-controlled Senate, they are currently unlikely to be confirmed by day one of the Biden presidency.

On the regulatory front, and just days before Trump administration's last day, the final rule for the **2022 Notice of Benefit and Payment Parameters** [arrived](#) at OMB for review. The Exchange rule includes a number of wide-reaching proposals, including provisions that would allow states to use private sector entities to enroll individual market consumers in qualified health plans (QHPs). If finalized, the incoming Biden administration would have fewer options available to modify any of its more controversial provisions, though it intends to temporarily freeze the rule along with any others that have been finalized but not yet gone into effect.

Later this week (January 14), the **Medicare and Payment Access Commission (MedPAC)** will convene to [discuss](#) payment adequacy recommendations concerning the Medicare fee-for-service payment systems in 2022 leading up to its March Report to Congress.

An overview of health policy events of interest in the coming week is included below for your convenience.

### **THIS WEEK IN HEALTH POLICY**

#### **Wed. (1/13)**

- **9:30am-2:30pm – ONC Meeting: Health IT** – The Office of the National Coordinator for Health Information Technology (ONC) convenes a meeting of the Health IT Advisory Committee to discuss issues of interoperability, privacy and security, and patient access, and to address any administrative matters. [Details.](#)

#### **Thurs. (1/14)**

- **10:45am-5:00pm – MedPAC** – The Medicare Payment Advisory Committee (MedPAC) convenes a virtual public meeting to discuss Medicare payment and policy issues. [Details.](#)

#### **Fri. (1/15)**

- **9:30am-1:15pm – MedPAC** – The Medicare Payment Advisory Committee (MedPAC) convenes a virtual public meeting to discuss Medicare payment and policy issues. [Details.](#)

### **FEATURED WHG ANALYSIS**

- **WHG Catalogue of COVID-19 Government Response** – November Edition – In the Policy Hub Insight Bank [here](#).
- **California v. Texas: Analysis of Supreme Court Oral Arguments** – In the Policy Hub Insight Bank [here](#).

### **REGULATORY LOOKBACK**

#### **Fri. (1/8)**

- **HHS** issued a [final rule](#), “Securing Updated and Necessary Statutory Evaluations Timely” (SUNSET rule). The final rule aims to enforce the statutory mandate for HHS to conduct periodic retrospective reviews of certain regulations. [Details.](#)
- **HHS** [announced](#) it will expand the Home Health Value-Based Purchasing (HHVBP) Model. The expansion will be implemented through rulemaking no earlier than January 1, 2022. [Details.](#)

#### **Thurs. (1/7)**

- **FDA** [announced](#) a request for nominations for the National Mammography [Quality](#) Assurance Advisory Committee in the Center for Devices and Radiological Health. The FDA is also

soliciting industry organizations that are interested in participating in the selection of nonvoting members for the Committee. Nominations are due February 7. [Details](#).

- **FDA** [announced](#) a request for nominations for consumer representatives to serve on several advisory committees and panels. Nominations are due February 7. [Details](#).
- **CMS** released a memo that explains how Medicare Advantage Plans, Prescription Drug Plans, and Medicare-Medicaid Plans can request COVID-19 vaccine data (COVAX) data from CMS regarding their enrollees, subject to approval, to assist with case management, care coordination, and other population-based activities to improve health. [Details](#).

#### **Wed. (1/6)**

- **USPSTF** [announced](#) a request for nominations to serve on the task force. Selected members will serve a four-year term. Nominations are due March 15. [Details](#).

#### **Tue. (1/5)**

- **FDA** [issued](#) final guidance on the Safer Technologies Program (SteP) for Medical Devices. [Details](#).

#### **Mon. (1/4)**

- **GAO** issued a request for nominations for the State All Payer Claims Databases Advisory Committee. Letters of nominations and resumes are due by Jan. 27. [Details](#).

### **CATALOG OF MAJOR YEAR-END REGULATORY DEVELOPMENTS**

Below, we include a brief overview of the major regulatory developments that occurred during the final two weeks of December 2020. Please let us know if you have any questions on any of these items.

#### **Centers for Disease Control and Prevention**

- 12/22/20: the CDC released a [request for nominations](#) for membership to the Advisory Committee on Breast Cancer in Young Women. Nominations are due March 12, 2021.

#### **Centers for Medicare & Medicaid Services**

- 12/31/20: Pursuant to the SUPPORT Act, CMS [finalized a rule](#) naming new transaction standards for the Medicare Part D e-prescribing program. The new standards are intended to ensure secure electronic prior authorization request and response transmissions.
- 12/31/20: CMS [finalized a rule](#) modifying a number of key regulations for the Medicaid Drug Rebate Program in order to better promote value-based purchasing arrangements for pharmaceutical drugs in Medicaid ([WHG summary](#)).

#### **Federal Emergency Management Agency**

- 12/30/20: FEMA issued a [temporary final rule](#) extending its April 2020 decision to allocate certain health and medical resources for domestic use. Under this rule, certain scarce and critical materials may not be exported out of the United States without explicit approval from FEMA. The rule now remains in effect until June 30, 2021.

#### **Food and Drug Administration**

- 12/29/20: The FDA issued a [request for nominations](#) for voting members to serve on the Technical Electronic Product Radiation Safety Standards Committee. Nominations are due February 27, 2021.

#### **Health and Human Services**

- 12/22/20: Pursuant to President Trump's 2020 drug pricing executive order ([details](#)), HHS [finalized a rule](#) that would require entities participating in the 340B drug pricing program to offer insulin

and injectable epinephrine to low-income patients at the price the health center purchased these drugs through the 340B program. WHG's summary on the proposed rule is available [here](#).

## COMMENT & APPLICATION DEADLINES

- **Rolling:** HRSA is seeking nominations of qualified candidates for appointment to the National Advisory Council on Migrant Health (NACMH). Nominations will be accepted on a rolling, continuous basis. [Details](#).
- **Jan. 15:** AHRQ [announced](#) a request for scientific information submissions to inform its review on Maternal and Childhood Outcomes Associated with the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). [Details](#).
- **Jan. 15:** CMS seeks nominations for two Technical Expert Panels (TEPs): one related to developing a measure to assess patient receipt of important information following an outpatient procedure in of hospital outpatient department (HOPD) and ambulatory surgical centers (ASCs); and one focused on the creation, reassessment, and application of outpatient imaging outcome and efficiency measures. [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](#).
- **Feb. 5:** CMS issued a [call for public comment](#) on which episode-based cost measures to develop for the next wave of Merit-Based Incentive Payment System (MIPS) measures. The measures developed during this wave could impact performance-based Medicare payment adjustments for MIPS-eligible clinicians for CY 2022 or CY 2023. [Details](#).
- **Feb. 12:** OHRP is seeking nominations of qualified candidates for appointment to the Secretary’s Advisory Committee on Human Research Protections. [Details](#).
- **Feb. 12:** FEMA seeks comments on a [proposed rule](#) to revise the “Estimated cost of the assistance,” which is one of the factors FEMA’s Public Assistance Program considers when evaluating requests from states for major disaster declarations and making recommendations to the President. [Details](#).
- **Feb. 16:** CMS seeks comment on plans for a new Review Choice Demonstration for inpatient rehabilitation facility (IRF) services. [Details](#).
- **Feb. 19:** FDA [announced](#) a request for nominations for members to serve on the National Mammography Quality Assurance Advisory Committee in the Center for Devices and Radiological Health. [Details](#).
- **Feb. 22:** HRSA announced a maternal health-focused Notice of Funding Opportunity (NOFO) – Primary Care Training and Enhancement-Community Prevention and Maternal Health. [Details](#).
- **March 4:** The HHS Office of Minority Health is seeking nominations of qualified candidates for appointment to the Advisory Committee on Minority Health. [Details](#).
- **March 15:** HRSA announced a maternal and child health-focused Notice of Funding Opportunity (NOFO) – Early Childhood Comprehensive Systems: Health Integration Prenatal-to-Three Program. [Details](#).

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