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

Wynne Health Group Weekly

FRAMING THE WEEK

Progress around passage of a large **coronavirus relief package** this year has diminished as both parties have retreated to their respective corners, maintaining their pre-election positions on the topline figures for federal aid. President Trump didn't provide much clarity as he urged Congress in a tweet to pass a "big and focused" relief package. The impasse on coronavirus relief does not appear to have hampered ongoing efforts to pass an **omnibus spending package for fiscal year 2021** ahead of the December 11 government shutdown deadline as the Senate Majority released their bills last week and both sides have stated they want to avoid a shutdown. This all seems to be a recipe for a short-term spending bill into late February or early March, with a limited coronavirus relief package attached.

In the meantime, the House is scheduled to **vote on a series of relatively uncontroversial health-related bills** relating to public health, health disparities, regulation of generic drugs and orphan drugs, curbing the opioid crisis, and veteran health (described below), though Senate action on these measures is unclear. The Trump administration is expected to proceed with **policymaking through regulations**, as several highly anticipated rules await review at the Office of Management and Budget (OMB).

Negotiation on an attempt to get a longer-term coronavirus relief package is still likely as House Speaker Nancy Pelosi (D-CA) and Senate Democratic Leader Chuck Schumer (D-NY) are pushing for the $2.4 trillion Heroes Act as "the starting point" for negotiations, contending that the record-breaking COVID-19 infections and hospitalizations and high unemployment numbers warrant the multi-trillion dollar response. The U.S. has recorded more than 100,000 new coronavirus cases for 12 days in a row and nearly 70,000 current hospitalizations, according to the COVID Tracking Project.

Senate Majority Leader Mitch McConnell (R-KY) points to the increase of 638,000 jobs in October and 1.0 percentage point drop in the unemployment rate to 6.9 percent as indicators that a more modest stimulus package costing $500 billion is sufficient. Still, the possibility that Democrats may flip the Senate in January, though slim, may motivate Republicans to try to strike a deal this year while they still have an ally in the White House. Democrats would like to clear the decks for the incoming Biden Administration with a larger package.

President Trump is expected to finalize a slate of **new rules** in the coming weeks. Currently at the Office of Management and Budget (OMB) for review are the final rules for the CY 2021 Medicare **Physician Fee Schedule** and the **Hospital Outpatient Prospective Payment System**. Also under review is the final rule that would allow **pharmaceutical manufacturer discounts** to be passed through directly to patients at the point of sale – a previously abandoned regulatory initiative that President Trump recently revived through Executive Order.

In addition, two rules which have cleared OMB review may be published in the *Federal Register* as early as this week – a proposed rule that would modify existing **HIPAA** rules that act as barriers to coordinated

care and a final rule that would modify 42 CFR Part 2 confidentiality requirements for **substance use disorder patient records**.

It is also possible that the Trump administration will soon release next steps on its long-anticipated **Most Favored Nations** (MFN) demonstration model – an outgrowth of the International Pricing Index (IPI) model for Medicare Part B the administration originally previewed in 2018. The precise nature of these next steps is presently unclear, though some are anticipating the release of an **interim final rule** to effectuate the MFN provisions that would implicate Part B. Any potential feature of the MFN model that would extend to Part D may come in the form of a proposed rule – a customary approach that the Centers for Medicare and Medicaid Services (CMS) has taken when considering mandatory demonstration models, though one which is not formally required by statute.

This week, the Senate is scheduled to consider several judicial and executive nominees. As for the House, votes are scheduled for the following bills. While the measures are expected to pass, it remains to be seen whether the Senate will take up the House bills this session.

Public Health

- **Securing America From Epidemics Act (H.R. 6334)** would authorize the United States to participate in the Coalition for Epidemic Preparedness Innovations (CEPI), an alliance of countries and private partners whose mission is to finance and coordinate the development of vaccines for high-priority, epidemic-potential threats.
- **FASTER Act of 2020 (H.R. 2117)** would (1) require Centers for Disease Control and Prevention (CDC) to expand and intensify collection of food allergy data; (2) require food labels to include sesame as a major allergen; (3) allow the Food and Drug Administration (FDA), through regulation, to add other food ingredients as major allergens based on the prevalence and severity of allergic reactions; and (4) require the FDA to include patient experience data on treatment for patients with food allergies in its report on patient experience data. There is no related bill in the Senate.
- **Bipartisan Solution to Cyclical Violence Act of 2020 (H.R. 5855)** would create a grant program at the Department of Health and Human Services (HHS) to support trauma centers with violence intervention and violence prevention programs. Program support would be provided to conduct research to reduce the incidence of re-injury and re-incarceration caused by intentional violent trauma, including intimate partner violence. There is no related bill in the Senate.

Health Disparities

- **NIMHD Research Endowment Revitalization Act of 2020 (H.R. 4499)** would authorize the National Institute on Minority Health and Health Disparities to facilitate research on minority health disparities through research endowments at current or former centers of excellence. The Senate passed an identical bill (S. 2927) by voice vote in May 2020.

FDA Regulation of Drugs

- **MODERN Labeling Act of 2020 (H.R. 5668)** would authorize the FDA to require modifications of outdated labeling for generic drugs. Identical language is included in the Lower Health Care Costs Act (S. 1895), the bipartisan health care package championed by Senate Health, Education, Labor and Pensions Committee Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA).
- **Fairness in Orphan Drug Exclusivity Act (H.R. 4712)** would update the Orphan Drug Act to require manufacturers seeking orphan status for any drug to show they have no reasonable

expectation of recovering research and development costs through sales in the U.S. for the entirety of the seven-year exclusivity period. A related bill (S. 3271) with minor differences in the Senate has bipartisan support.

Opioid Crisis

- **State Opioid Response Grant Authorization Act of 2020 (H.R. 2466)** would authorize the Substance Abuse and Mental Health Services Administration (SAMHSA) State Opioid Response Grants program through FY 2026. There is no related bill in the Senate.
- **Easy MAT for Opioid Addiction Act (H.R. 2281)** would require the Drug Enforcement Agency (DEA) to revise regulations to allow a practitioner to administer up to a three-day supply of medication-assisted treatment (MAT). Current regulations allow up to a one-day supply of MAT, for a total of up to three days. There is no related bill in the Senate.
- **Block, Report, And Suspend Shipments Act of 2020 (H.R. 3878)** would create additional requirements for drug manufacturers and distributors who discover a suspicious order for controlled substances. In addition to reporting the suspicious order to DEA, the bill would require a manufacturer or distributor to exercise due diligence, decline to fill the order or series of orders, notify DEA of each suspicious order or series of orders and the indicators that led to the belief that filling such orders would be a violation. There is no related bill in the Senate.
- **DEBAR Act of 2020 (H.R. 4806)** would amend the Controlled Substances Act to allow the Attorney General to prohibit any registrant from manufacturing, distributing, or dispensing a controlled substance or a list I chemical if that registrant meets or has met any of the conditions for suspension or revocation of registration under subsection (a) of the Act, or is found unfit to manufacture, distribute, or dispense a controlled substance or a list I chemical. There is no related bill in the Senate.
- **Ensuring Compliance Against Drug Diversion Act of 2019 (H.R. 4812)** would terminate the controlled substance registration of any registrant if the registrant dies, ceases legal existence, discontinues business or professional practice, or surrenders registration. There is no related bill in the Senate.
- **FENTANYL Results Act (H.R. 7990)** would authorize two programs through the State Department aimed at building foreign law enforcement capacity and increasing global cooperation to curb synthetic drug trafficking. A companion bill in the Senate (S. 4514) has bipartisan support.

Veteran Health

- **Improving Safety and Security for Veterans Act of 2019 (S. 3147)** would require the Department of Veterans Affairs (VA) to report on patient safety and quality of care and the steps the VA has taken to improve care at VA medical centers. The Senate passed the bill by unanimous consent in December 2019.

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

Mon. (11/16)

- **9:30am-4:00pm – FDA Meeting: Antimicrobial Drugs** – FDA hosts a meeting titled, "Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial Animal Drugs." Details.
- **12:00pm-1:15pm – BPC Webinar: 2020 Election** – The Bipartisan Policy Center (BPC) hosts a webinar titled, "The 2020 Election's Impact on Health Care." Details.

Tue. (11/17)

- **9:00am-5:30pm – HHS Meeting: Tick-Borne Disease** – HHS convenes a meeting of the Tick-Borne Disease Working Group to review chapters and the template for the 2020 report to the HHS Secretary and Congress. Details.
- **1:00pm-4:30pm – FDA Meeting: Medical Devices** – FDA hosts a meeting titled, "FDA's Communications About the Safety of Medical Devices." Details.
- **5:00pm-6:00pm – CMS Call: COVID-19** – CMS hosts a call for hospitals, health systems, and providers to ask questions of agency officials regarding CMS's temporary actions. Details.

Wed. (11/18)

- **12:00pm – The Hill Discussion: Diabetes** – The Hill hosts a discussion titled, "Diabetes and the Future of Healthcare Reform," featuring Congressional Diabetes Caucus Co-Chairs Diana DeGette (D-CO) and Tom Reed (R-NY), among other speakers. Details.
- **12:15pm-1:15pm – FDA Town Hall: COVID-19** – FDA hosts a virtual town hall titled, "Coronavirus (COVID-19) Test Development and Validation." Details.
- **1:00pm-2:00pm – NIHCM: COVID-19 Vaccine** – The National Institute for Health Care Management (NIHCM) Foundation hosts a webinar titled, "The Future of the COVID-19 Response: The New Administration, Vaccines, and the Health Care System." Details.
- **4:30pm-5:00pm – CMS Call: COVID-19** – CMS hosts a call for nursing homes to provide targeted updates on the agency's latest COVID-19 guidance. Details.
- **5:00pm-6:30pm – NAM Webinar: COVID-19 Vaccine** – The National Academy of Medicine hosts a webinar titled, "COVID-19 Vaccine Update: Development, Approval, Allocation, and Distribution in the United States." Details.

Thurs. (11/19)

- **9:00am-12:30pm – FDA Meeting: Biosimilars** – FDA hosts a meeting on the reauthorization of the Biosimilar User Fee Act (BsUFA) for fiscal years (FYs) 2023 through 2027. Details.
- **9:00am-4:00pm – FDA Conference: Cannabinoids** – FDA's Office of Women's Health hosts a meeting titled, "CBD & Other Cannabinoids: Sex and Gender Differences in Use and Responses." Details.
- **12:30pm – NQF Webinar: COVID-19** – The National Quality Forum hosts a webinar titled, "Behavioral Healthcare Access and Quality: Lessons Learned During the COVID-19 Pandemic." Details.
- **1:00pm-2:00pm – FDA Webcast: Lung Cancer** – The FDA Oncology Center of Excellence hosts a webcast titled, "Conversation on Cancer – Lung Cancer: It Can Happen to Anyone." Details.
- **2:00pm-3:00pm – CMS Forum: Rural Health** – CMS hosts a Rural Health Open Door Forum, featuring remarks from CMS Administrator Seema Verma and updated regarding the Hospital Price Transparency Final Rule, IFC-4 rule, and the COVID-19 vaccine provider toolkits. Details.

Fri. (11/20)

- **8:00am-1:00pm – CDC Meeting: Women's Health** – CDC convenes a meeting of the Advisory Committee on Breast Cancer in Young Women to discuss breast cancer, mental/behavioral health, sexual health, genetics and genomics, and provider engagement. Details.
- **1:00pm-2:00pm – FDA Webcast: Prescription Drugs** – FDA hosts a webcast to discuss upcoming changes to the Office Prescription Drug Promotion's Core Launch Review Process. Details.
- **3:00pm-5:30pm – HHS Meeting: Minority Health** – HHS convenes a meeting of the Advisory Committee on Minority Health to finalize recommendations for improving access to and utilization of clinical preventive services among racial and ethnic minority populations. Details.

Additional Multi-Day Events

- **November 17-November 18 – AHP Symposium: Health Policy** – The Alliance for Health Policy (AHP) hosts its post-election symposium. Details.
- **November 18-November 19 – HHS Meeting: Health Statistics** – HHS convenes a meeting of the National Committee on Vital and Health Statistics to discuss various health date policy topics and its work plan for the upcoming 12-month period. Details.

FEATURED WHG ANALYSIS

- ***California v. Texas*: Analysis of Supreme Court Oral Arguments** – In the Policy Hub Insight Bank here.
- **WHG 2020 Election Preview** – 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

Tue. (11/10)

- **The United States Supreme Court** heard oral arguments in the case of California v. Texas, regarding the constitutionality of the Affordable Care Act. Details.
- **Senate Appropriations Committee** Chairman Richard Shelby (R-AL) released drafts of all 12 FY 2021 appropriations bills. A WHG summary of key health-related provisions is available here. A WHG summary of the key nutrition-related provisions is available here.
- **MedPAC** convened for Day Two of its virtual November public meeting and held sessions on separately payable drugs in the hospital outpatient payment system, and Medicare Advantage for enrollees with ESRD. All WHG session summaries are available on Policy Hub here.

Mon. (11/9)

- **MedPAC** convened for Day One of its virtual November public meeting and held sessions on the expansion of telehealth in Medicare; beneficiary access to care in rural areas; the effect of pharmaceutical rebates on risk adjustment in Part D; and improving competition among Part D's benchmark plans. All WHG session summaries are available on Policy Hub here.

REGULATORY LOOKBACK

Fri. (11/13)

- **CMS** released its first Federal Health Insurance Exchange Weekly Enrollment Snapshot, detailing Open Enrollment information for Nov. 1-7, 2020. A total of 818,365 individuals

selected plans through HealthCare.gov in the first week of 2021 Open Enrollment. Of this total, 173,344 consumers were new to the Exchanges, while 645,021 were consumers renewing coverage. Details.

Tue. (11/10)

- **AHRQ** is soliciting scientific information submissions to inform its review on Malnutrition in Hospitalized Adults. The AHRQ's Evidence-based Practice Centers (EPC) Program has been commissioned to review the available evidence on this topic and are seeking to identify as many studies as possible. Submissions are due December 11. Details.

Mon. (11/9)

- **CMS** issued the 2020 final rule (press release; fact sheet) addressing managed care in Medicaid and the Children's Health Insurance Program (CHIP). Details.
- **FDA** issued final guidance on enhancing the diversity of clinical trial populations, including eligibility criteria, enrollment practices, and trial design. Details.

COMMENT & APPLICATION DEADLINES

- **Nov. 18:** CMS announced that it extended the public comment period for the request for information (RFI) titled, "Recommended Measure Set for Medicaid-Funded Home and Community-Based Services." Details.
- **Nov. 30:** FDA announced two quality management maturity (QMM) pilot programs: one for domestic drug product manufacturers of prescription and over-the-counter OTC drug products; and one for foreign facilities manufacturing APIs that are used in FDA-regulated prescription and OTC drugs. Details.
- **Nov. 30:** CMS released Part II of its Advance Notice of Methodological Changes for MA Capitation Rates and Part D Payment Policies for CY 2022 Details.
- **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. 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.
- **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. 21:** HRSA announced a Notice of Funding Opportunity for the Behavioral Health Workforce Education and Training (BHWET) Program for Professionals for FY 2021. Details.

WHG Contacts for Inquiries
Alyssa Llamas: alyssa@wynnehealth.com; (562) 207-8807
Geoff Werth: geoff@wynnehealth.com; (202) 285-7397
Taylor Cowey: taylor@wynnehealth.com; (203) 848-7720

Wynne Health Group