

**Wynne Health Group Weekly**



**FRAMING THE WEEK**

Congressional Democrats return with the same to-do list but with a more tenuous political landscape. Following Sen. Joe Manchin's (D-WV) announcement that he will not support the Build Back Better Act (BBBA) as currently proposed, Democrats will work to revise the package to a more pared down version that may possibly exclude some of its more contentious elements. As another major priority, Congress will also continue working to pass a spending package for fiscal year (FY) 2022. However, the pressure to pass both vehicles will continue to mount as the mid-term elections grow nearer and legislators seek major wins to secure their positions.

The rise in COVID-19 surges in the wake of the Omicron variant will also add pressure on Congress to act, especially in light of the pandemic preparedness and public health infrastructure funding included in the BBBA (e.g., \$1.3 billion for the Office of the Assistant Secretary for Preparedness and Response to support surge capacity, expand vaccine productions capacity, mitigate supply chain risks, etc.).

- **BBBA, January 2022** – Senate Majority Leader Chuck Schumer (D-NY) [aims](#) to hold a vote on “a revised version of the House-passed Build Back Better Act” this month. Though Schumer said the vote would be “very early in the new year,” negotiations over a scaled-back version of the \$1.75 trillion social spending package that Sen. Manchin would support could take weeks or months. We anticipate that the revised BBBA will retain at least some of the major health-focused provisions, such as extending the temporary increase in ACA Marketplace premium tax credits (which expire at the end of 2022). Manchin has previously expressed opposition to provisions addressing the Medicaid expansion coverage gap and expanding Medicare benefits. As for drug pricing – another Democratic priority – Sen. Bill Cassidy (R-LA) has commented that he anticipates Republicans may be willing to support the Senate Finance Committee’s recent language on inflation rebates as that was originally advanced by Sens. Wyden (D-OR) and Grassley (R-IA) in the 116<sup>th</sup> Congress.
- **FY 2022 Appropriations, February 18, 2022** – The continuing resolution ([P.L. 117-70](#)) expires February 18, 2022. While the return of earmarks, formally known as “Community Project Funding,” motivates both parties to pass FY 2022 appropriations, whether top appropriators will be able to reach a deal remains to be seen.

Regulatory Updates

The Centers for Medicare & Medicaid Services (CMS) **released three major regulations** during the final two weeks of 2021. In brief, these regulations included:

- **The [proposed rule](#) for the 2023 Notice of Benefit and Payment Parameters** – Among a number of proposed changes, this proposed rule would require all issuers in the Federally-facilitated Marketplace and State-based Marketplaces on the Federal Platform **to offer standardized plan options** for every product network type, metal type, and plan classification, as well as in every

service area where the issuer will offer Marketplace plans. The rule would also **enhance access to providers** through re-instating network adequacy reviews and requiring issuers to include 35 percent of available essential community providers (ECPs) in their networks. Last, the rule would **prohibit issuers from discriminating** on the basis of sexual orientation and gender identity.

- **The [final rule](#) for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) payments for 2022** – The final rule includes a permanent payment increase of at least 5 percent pay increase for DME in 2022. Specifically, former competitive bidding areas (CBAs) will see a 5 percent payment increase, while items in non-CBAs will receive increases from 5.1-5.4 percent. In addition, CMS will continue paying suppliers a 50/50 blended payment rate of adjusted and unadjusted fee schedule rates for furnishing items and services in rural and non-contiguous areas once the public health emergency ends. Last, CMS did not finalize the previously proposed categories of supplies and accessories and fee schedule amounts for three types of continuous glucose monitoring (CGM) systems, though the final rule did classify adjunctive CGMs under the Medicare Part B benefit for DME. CMS added it does not believe at this time that it is necessary to further stratify the types of CGMs beyond the two categories of non-adjunctive and adjunctive CGMs.
- **The [final rule](#) to rescind the Most Favored Nation (MFN) model** – This rule finalized the August 2021 proposed rule to rescind the rule, citing concern for implementing the MFN model during the COVID-19 pandemic. Additional comments in the final rule also urged against the implementation of any model that would test international or domestic reference pricing now or in the future and raised concerns about access to Part B drugs. Of note, the final rule references the September 2021 Department of Health and Human Services (HHS) [Comprehensive Plan for Addressing High Drug Prices \(WHG summary\)](#) and details that the agency is exploring models that could reduce Part B drug prices, including value-based payments that link the payment to the clinical value provided to the patient.

Additional regulatory actions taken during the holiday season include implementing a new Medicaid option to support [community-based mobile crisis intervention services](#) (pursuant to the American Rescue Plan) and [rescinding](#) the Georgia Medicaid work requirements.

Looking ahead, the Biden-Harris Administration is expected to issue a slate of [new regulations](#) that span a range of health care policy priority areas, including pharmaceutical regulations, Medicaid eligibility, health IT and interoperability, and care coordination and preventive care, among others ([WHG summary](#) of the Fall 2021 Unified Regulatory Agenda).

Key anticipated rulemaking in the first quarter of 2022 include:

- **Care Coordination, January 2022** – Pursuant to the CARE Act, the Office for Civil Rights (OCR) is slated to issue a [proposed rule](#) to better harmonize the 42 CFR part 2 (part 2) confidentiality requirements with certain permissions and requirements of the HIPAA Rules and the HITECH Act.
- **Interoperability, February 2022** – CMS is expected to issue a [proposed rule](#) that would place new requirements on Medicare Advantage plans, Medicaid managed care plans, CHIP managed care entities, Medicaid and CHIP fee-for-service entities, and Qualified Health Plans to improve electronic exchange of health care data and implement electronic prior authorization programs. As a reminder, the Trump Administration proposed a similar regulation in 2020 that did not include MA and was ultimately withdrawn.

- **Commercial Insurance, February 2022** – CMS is planning to [propose](#) amendments to the final rules regarding religious and moral exemptions and accommodations regarding coverage of certain preventive services under the Affordable Care Act.

#### FEATURED WHG ANALYSIS

- **WHG Issue Brief on Health Equity Implications of Potential Telehealth Reform Under Medicare** – In the Policy Hub Insight Bank [here](#).
- **WHG Side-by-Side of Live Drug Pricing Proposals Under Consideration for Reconciliation** – In the Policy Hub Insight Bank [here](#).
- **WHG Side-by-Side of Medicaid Expansion Gap Bills** – In the Policy Hub Insight Bank [here](#).
- **WHG Side-by-Side of Health Technology Assessment Models** – In the Policy Hub Insight Bank [here](#).
- **WHG Updated 2021 Legislative and Regulatory Outlook** – In the Policy Hub Insight Bank [here](#).
- **WHG Chart Key Federal Public Option Bills in the 117<sup>th</sup> Congress; Side-by-Side Comparison** – In the Policy Hub Insight Bank [here](#).

#### CONGRESSIONAL LOOKBACK

#### REGULATORY LOOKBACK

##### Fri (12/17)

- **CMS** released a [final rule with comment period](#) addressing Medicare GME and IME for teaching hospitals. [Details](#).

##### Thurs. (12/16)

- **The FDA** [issued](#) a request for nominations for voting members to serve on the Medical Devices Advisory Committee device panels. Nominations are due February 15. [Details](#).

##### Tues. (12/14)

- **HRSA** [announced](#) that approximately \$9 billion in Provider Relief Fund (PRF) Phase 4 payments will start to be distributed. [Details](#).
- **CDC** [updated](#) the ICD-10-CM code set with 11 new Z codes describing SDOH, such as housing, food insecurity, education, and environment. [Details](#).
- **The White House** [announced](#) an Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government. [Details](#).
- **CMS** [released](#) a State Medicaid Director Letter to provide guidance on new requirements for state Medicaid programs pursuant to the CAA of 2021. [Details](#).

##### Mon. (12/13)

- **The GAO** [released](#) a report on the populations most likely to be affected by behavioral health conditions as a result of the COVID-19 pandemic and the status of related federal relief funding. [Details](#).
- **CMS** [released](#) a CMCS CIB describing 2022 updates, including those related to oral health and antibiotic resistance, to the Child and Adult Core Sets. [Details](#).

#### COMMENT & APPLICATION DEADLINES

- **January 8:** The FDA [issued](#) draft guidance on considerations for the use of RWD and RWE to support regulatory decision-making for drug and biological products. [Details](#).

- **January 18:** The FDA issued a [proposed rule](#) and [draft guidance](#) to improve access to hearing aids through the establishment of an over-the-counter (OTC) hearing aid category. [Details.](#)
- **January 21:** The FDA [issued](#) draft guidance on data standards for drug and biological product submissions containing real-world data (RWD). [Details.](#)
- **January 24:** HHS, DOL, the Treasury, and OPM [issued](#) an IFC to implement the health insurance plan reporting requirements on prescription drug and health care spending. [Details.](#)
- **January 25:** NIOSH published a [notice](#) extending the public comment period for the previously announced request for information (RFI) on interventions to support health worker mental health. [Details.](#)
- **February 2:** The FDA [issued](#) draft guidance on content of premarket submissions for device software functions. [Details.](#)
- **February 15:** The FDA [issued](#) a request for nominations for voting members to serve on the Medical Devices Advisory Committee device panels. [Details.](#)
- **February 22:** The USDA [announced](#) \$1.15 billion in grant funding for rural broadband access. [Details.](#)
- **April 22:** The NIH [announced](#) a \$1 million prize competition for innovative diagnostics technologies to help improve maternal health. [Details.](#)

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