Issues for the week ending December 30, 2022

Federal Issues

Legislative

Congress Returns After Late-Year Passage of Spending Bill

The 118th Congress convened this week, after the previous Congress took until December 23 to wrap up its work in the form of an omnibus appropriations package. House Republicans will begin to organize their new majority with the selection of leaders and committee chairs. Meanwhile, the Senate, which will remain under control of the Democrats, will not return to legislative action until January 23.

Recapping last year, on December 23, Congress cleared H.R. 2617, the Consolidated Appropriations Act of 2023 by a House vote of 225-201 and Senate vote of 68-29.

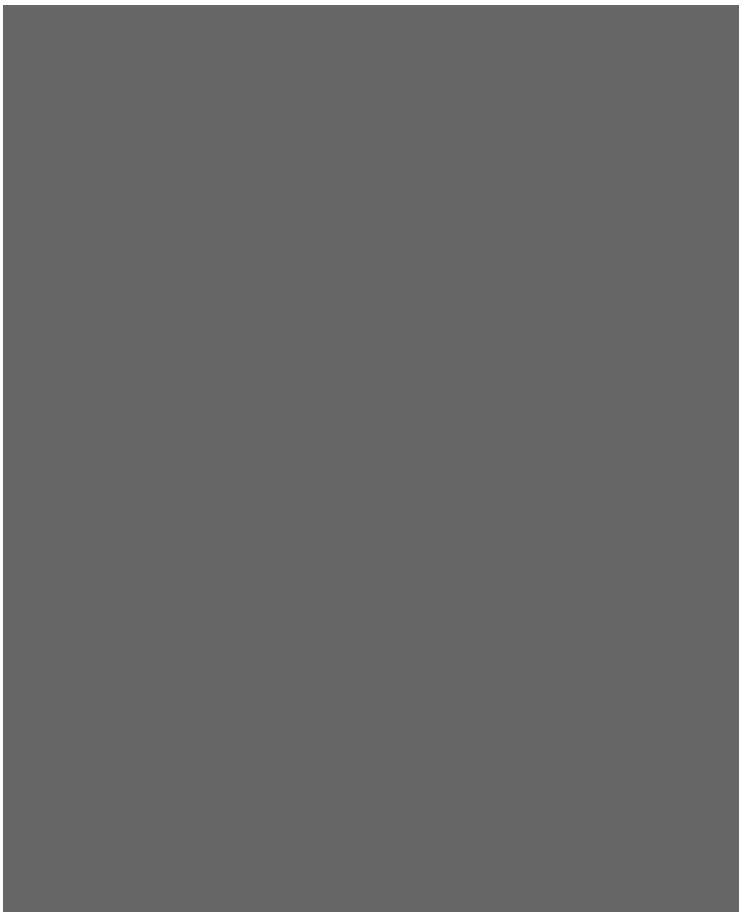
Why it matters: Passage of the $1.7 trillion omnibus spending bill "clears the decks" for the new Congress and addresses several health-related concerns. **Some of the highlights include:**

- **Telehealth**
  - The safe harbor to offer telehealth in High Deductible Health Plans (HDHPs) with Health Savings Accounts (HSAs); and Medicare telehealth flexibilities

In this Issue:

enacted during COVID are extended through 2024

- **Mental Health/Substance Use Disorder (SUD)** –
    - Establishes Medicare coverage of marriage and family therapists and licensed professional counselors beginning 2024.
    - Reauthorizes several key mental health programs, including the National Suicide Prevention Lifeline Program, the Community Mental Health Service Block Grants, and Substance Use and Prevention, Treatment, and Recovery Block Grants.
    - Expands treatment for opioid-use disorders, promotes behavioral health integration, and reauthorizes programs that support mental health/SUD prevention, treatment, and recovery.
    - Provides grants to states to enforce federal mental health and SUD parity laws.



- **Medicare Physician Payment Cuts**
    - The legislation offers partial relief from Medicare Physician Fee Schedule cuts, providing an additional 2.5% boost in 2023 and 1.25% in 2024.
    - The 4% statutory Pay-As-You-Go (PAYGO) sequester will be postponed for two years.
- **Medicaid**
    - The bill ends the Maintenance of Eligibility (MOE) provision that required states to maintain the enrollment of anyone who was enrolled as of March 2020 to be eligible for the enhanced federal matching (FMAP) rate. States will be permitted to begin disenrolling people who are no longer eligible on April 1, 2023 with the enhanced FMAP phasing down over the rest of the calendar year.
    - All states will be required to continuously cover children under age 12 in Medicaid and CHIP for 12 months, regardless of changes in circumstances.
    - The American Rescue Plan Act's state plan option to provide 12 months of postpartum Medicaid coverage (rather than the standard 60 days) will be made permanent.
    - State Medicaid and CHIP programs will be required in 2025 to publish searchable provider directories that describe whether the provider is taking new patients, cultural/linguistic capabilities, whether telehealth is available and other information.

Still on the table: Several items did not make it into the final package and could see further activity in 2023. They include:

- **Electronic prior authorization in Medicare Advantage** (although CMS did issue a proposed rule on the subject in December)
- **Insulin copay caps** in commercial market
- Increased Department of Labor **mental health parity enforcement** authority
- **Dialysis parity legislation**
- **Pharmaceutical Benefits Manager (PBM) transparency** legislation

Insurer perspective: BCBSA issued a press release applauding the bipartisan legislation and highlighting provisions that closely align with key health care priorities that increase access and lower costs for consumers and patients, including:

- Helping seniors better access and afford marriage and family therapists
- Supporting new moms by making 12-month postpartum coverage in Medicaid a permanent state option
- Lowering costs for patients by extending pre-deductible telehealth coverage for high-deductible health plans
- Expanding telehealth services and support for patients with additional flexibility
- Stabilizing Medicaid coverage in Puerto Rico for five years
- Providing more clarity to the end of the Public Health Emergency and Medicaid coverage

BCBSA CEO Kim Keck added, "We look forward to building on these successes with leaders of both parties to advance common-sense solutions that expand coverage, improve care and lower costs."

Federal Issues

Regulatory

Tri-Agencies Release Partial No Surprises Act Implementation Report, Raise Fees, and Delay Rx Reporting

On Friday, December 23, the Departments of Health and Human Services, Labor, and the Treasury released new guidance regarding the No Surprises Act.

- **First**, they released a partial report detailing two quarters' worth of implementation of the No Surprises Act's core prohibition on balance billing in private insurance and independent dispute resolution (IDR) process to determine an out-of-network provider's payment amount. The report is largely dictated by Congress.
    - As expected, the report documents a rocky start to the first year of the law's implementation, dominated by litigation over the correct treatment of plan-sourced qualifying payment amounts (QPA) in the IDR entity's final determination as well as by **a caseload of cases referred to the IDR process that is almost ten times in excess of the estimated volume**, leading to substantial delays in case resolutions. Importantly, the report omits data requiring a report on the number of times the payment amount determined (or agreed to) exceeds the QPA, specified by items and services, but will presumably be released in a subsequent report once the data are cleaned.

- **Second**, CMS updated guidance amending its prior 2023 guidance issued in October 2022 to increase the administrative fee for the Federal IDR process from $50 to $350 per party for disputes initiated during the calendar year beginning January 1, 2023. The guidance notes the significant increase is due to supplemental data analysis and increasing expenditures in carrying out the Federal IDR process since the development of the prior 2023 guidance, though it is possible the increase will deter some parties from referring a case to the IDR process, as the administrative fee, unlike the IDR entity's fee, cannot be refunded.

- **Third**, the Departments delayed by about one month the compliance deadline for 2020 and 2021 prescription drug reporting data as required by the No Surprises Act. This data is not made public but will be analyzed in the aggregate and discussed in a report released by the Departments. The guidance also provides further flexibility for reporting the data and addressed several outstanding questions, including:

    • Multiple Submissions by the Same Reporting Entity Allowed
    • Submissions by Multiple Reporting Entities Allowed
    • Aggregation Restriction Suspended
    • Submission of Premium and Life-Years Data by Email Available for Certain Group Health Plans
    • Reporting on Vaccines Optional
    • Reporting Amounts Not Applied to the Deductible or Out-of-Pocket Maximum Optional

More Resources:

- Link to Q2/Q3 2022 NSA Report
- Link to 2023 Fee Guidance
- Link to FAQ Rx Data Reporting Guidance

CMS Proposes Standards for Health Care Attachments Transactions and Electronic Signatures to Ease Prior Auth Burdens

A proposed rule was published that would apply to all providers and health plans and their business associates performing electronic exchange of clinical and administrative data via health care attachments to support electronic health care transactions, such as prior authorization of services and claims adjudication.

Why this matters: As CMS notes, today, transmitting health care attachments is still primarily a manual process and, at this time, there are no adopted HIPAA standards, implementation guides, or operating rules for health care attachments or electronic signatures. To reduce the use of manual processes (e.g., fax, web portals, mail) by providers to respond health plan requests for additional information beyond what is in a HIPAA transaction, CMS proposes to adopt standards for health care attachments transactions.

In addition, CMS proposes to define the term "electronic signature" as broadly as possible to ensure that it meets health care providers' and health plans' needs now and can also encompass future electronic signature technologies. The scope would be limited to attachment information transmitted electronically in electronic health care attachments transactions (not regulate electronic signatures in other contexts). CMS

proposes to change the current standard used X12 278, Version 5010 to the X12 278, Version 6020. In general, all of these proposals have been recommended by NCVHS, a statutory advisory committee responsible for providing HHS with recommendations on health information policy and standards. These recommendations have also been endorsed by WEDI a public-private coalition formed by HHS to serve as an advisory body on the use of health IT aimed at health care information exchange. Technical aspects of these proposals are discussed further in the rule.

Comments to the rule are due March 21, 2023.

CMS Issues 340B Drug Payment Update for Medicare Advantage Organizations

On December 20, the Centers for Medicare & Medicaid Services (CMS) released a memorandum to Medicare Advantage Organizations (MAOs) concerning Medicare Outpatient Prospective Payment System (OPPS) payment rates for 340B drugs.

Starting in 2018, CMS began applying a payment formula of Average Sales Price (ASP) minus 22.5% for these drugs, rather than ASP plus 6%, which is the formula used for non-340B drugs.

Background: The Supreme Court held on June 15, 2022 that CMS' 2018 340B drug formula was unlawful, as CMS may not vary payment rates for 340B drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs. The Supreme Court remanded the case to the United States District Court for the District of Columbia to determine remedies. On September 28, 2022, the District Court granted the American Hospital Association's motion "to vacate the portion of the 340B reimbursement rate in the 2022 OPPS Rule that is still in effect for the remainder of this year" determining "the prospective portion of the 2022 reimbursement rate shall be vacated because it is defective and because vacating this portion of the 2022 OPPS Rule will not cause substantial disruption."

Following the September 28 decision, CMS updated its website to indicate it will revert to paying the default rate (generally ASP plus 6%) for 340B-acquired drugs for the remainder of CY 2022 and will reprocess claims paid on or after September 28, 2022, using the default rate. CMS has uploaded the revised OPPS drug files in the October 2022 Update of the OPPS and confirmed that payment rates for non-drug items and services have not changed for the remainder of CY 2022.

Memorandum: CMS indicated previously, and reiterates in the memorandum, that it "will address the remedy for 340B drug payments from CYs 2018-2022 in future rulemaking prior to the CY 2024 OPPS/ASC proposed rule."

It reminds MAOs they must pay non-contracted providers or facilities for services and items at least the amount they would have received under Original Medicare payment rules, in accordance with the statute.

The statute also states that CMS may not require MAOs to contract with a particular healthcare provider or use particular pricing structures with their contracted providers. Therefore, MAOs that contract with a provider or facility eligible for 340B drugs can negotiate the terms and conditions of payment directly with the provider or facility and CMS cannot interfere in the payment rates that MAOs set in contracts with providers and facilities.

CMS Releases Public Comments for Access to Coverage, Care in Medicaid, CHIP RFI

CMS released a report summarizing public comments received in response to the February 2022 request for information (RFI): Access to Coverage and Care in Medicaid & the Children's Health Insurance Program (CHIP).

Why this matters: The RFI could inform future rulemaking expected regarding access to care in fee-for-service Medicaid as well as under Medicaid managed care, which covers the majority of the now-90 million Medicaid enrollees.

Among the key findings in the report were addressing equity and cultural competence, including the collection of socioeconomic data to better inform culturally competent care, reimbursement rates as a key driver in provider participation, and aligning approaches among payment regulations and compliance. Common recommendations relate to data, systems and information technology (and the need for systems coordination); provider availability and network adequacy (including national minimum standards for wait times, network breadth, and "realized" access to care); and addressing lower reimbursement rates to providers.

- Link to Report
- Link to Summary
- Link to Appendices

HealthCare.gov Enrollment as of December 2022

On Tuesday, the Department of Health and Human Services announced that Affordable Care Act marketplace enrollment has reached 11.5 million people as of December 15, 2022 – a milestone marking the deadline for coverage starting January 1, 2023. About 1.8 million more people have signed up for health insurance, or an 18% increase, from this time last year. With several major national insurers reentering Exchanges, ninety-two percent of HealthCare.gov enrollees will have access to options from three or more insurance companies when they shop for plans. The HealthCare.gov Marketplace Open Enrollment remains open until January 15, 2023. People who do not currently have health insurance or are already in a Marketplace plan can update their applications until January 15, 2023 for coverage beginning February 1, 2023. The next snapshot of national plan selections, including state-based Marketplaces, will be released January 11, 2023.

Biden Administration Proposes New Conscience Rights Protections

The Department of Health and Human Services' Office of Civil Rights proposed a new rule which would partially rescind the Trump administration's 2019 final rule expanding conscience protections to health care workers.

Why this matters: The new proposal seeks to retain, with some modifications, certain provisions of the 2019 final rule but eliminate others "because they are redundant or confusing, because they undermine the balance Congress struck between safeguarding conscience rights and protecting access to health care access, or because significant questions have been raised as to their legal authorization."

The rule notes three federal district courts have vacated the 2019 final rule prior to it taking effect and expressed concerns with a number of statutory interpretations the rule had made regarding the breadth of the underlying federal statutes governing conscience protections, such as the Church Amendments, section 245 of the PHS Act, the Weldon Amendment, and the Affordable Care Act. The proposed rule would retain the 2019 final rule's treatment of OCR as the centralized HHS office tasked with receiving and investigating complaints and enforcing the various federal statutes. The rule also proposes to retain a number of provisions related to complaint handling and investigations.

Finally, the rule proposes to retain the 2019 rule's voluntary notice provisions, with some modifications to address concerns identified by stakeholders.

State Issues

New York

Legislative

Health Care Legislation Signed By Governor

Governor Hochul last week acted on several bills Highmark has been following:

- **Clinical peer reviewer (A.879/S.8113)** – Vetoed; would have required plans to hire or contract with clinicians of same specialty for all adverse determinations.

- **Copay accumulator (A.1741-A/S.5299)** – Requires health plans to apply drug manufacturer coupons to members' cost sharing. A chapter amendment was accepted to limit application of the legislation to brand name drugs without AB generic equivalents and change the effective date to 7/1/23.

- **Medically fragile children (A.289-C/S.2121-C)** – Establishes medical necessity review criteria for this population; requires coverage. The governor and sponsors agreed to an amendment that calls out the §4904 process, the internal appeal, and applies a heightened clinical peer reviewer standard to that for medically fragile children. The initial review remains the same as current law: a physician with license, or a non-physician health care practitioner with same or similar specialty of the treatment under review. The language requires that internal appeals be reviewed by a physician with same or similar specialty of the treatment under appeal, and then the external appeal process remains the same, conducted by physician with same or similar specialty and at least 5 years of experience.

- **The PRICE Act (S.4620-C/A.5411-D)** - Enacts the "Patient Rx Information and Choice Expansion" (PRICE) Act, which requires health plans to provide members of their providers with real-time information on prescription cost, benefit and coverage data. There is a pending chapter amendment which provides more specific instruction as to how plans must provide information.

- **Prohibits step therapy protocols in behavioral health (A.3276/S.5909**) - Vetoed

- **Prohibits copayment at opioid treatment programs (A.372/S.5690)** – Prohibits plans from imposing copayments on treatment provided by opioid outpatient treatment programs, interpreted by outside counsel to include state-certified methadone clinics, and other addiction programs including clinics, primary care settings and mental health clinics where buprenorphine and naltrexone injections are used. Effective 1/1/23.

- **Medication synchronization in Medicaid (A.187/S.431-A)** – Requires plans to cover synchronization of refills for members with multiple prescriptions.

- **Requires 30-day coverage of prescriptions during emergency (A.7469/S.4856)** – Allows members to get an extra 30-day supply of prescriptions during an emergency. Effective immediately.

- **Colorectal cancer screening in accord with ACS guidelines (A.2085/S.906-B)** – Requires plans to cover screening in line with American Cancer Society Guidelines (currently, starting at age 45) without cost sharing. Effective immediately.

- **Coverage of PReP and PEP (A.1807/S.5688)** – Requires such coverage which is already required under federal preventive services requirements. Under an agreement with the Legislature, there will be a chapter amendment to limit applicability to large group policies; it is unclear at this point if it will also be applicable to large group policies without prescription coverage. Effective immediately.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: **http://legis.delaware.gov/.**
New York Legislation: **https://nyassembly.gov/leg/**
Pennsylvania Legislation: **www.legis.state.pa.us.**
West Virginia Legislation: **http://www.legis.state.wv.us/**
For copies of congressional bills, access the Thomas website – **http://thomas.loc.gov/.**