Issues for the week ending April 29, 2022

Federal Issues

Regulatory

HHS Releases 2023 Notice of Benefit and Payment Parameters Final Rule

The Department of Health and Human Services (HHS) issued a pre-release version of the 2023 Notice of Benefit and Payment Parameters final rule. The Centers for Medicare and Medicaid Services (CMS) simultaneously published the Final 2023 Letter to Issuers in the Federally-facilitated Exchanges and Final 2023 Actuarial Value (AV) Calculator and Methodology. The final rule is expected to be published in the *Federal Register* in the next few days. A CMS fact sheet and press release are also available.

Why this matters: The Notice of Benefit and Payment Parameters is an annual rule released for the upcoming benefit year for Marketplace, also known as Exchange, coverage in the individual and small group markets.

An overview of key provisions of the final rule is below:

- **Standardized Plans.** Requires qualified health plan (QHP) issuers in Federally-facilitated Exchanges (FFEs) and State-based Exchanges using the Federal Platform (SBE-FPs) to offer standardized plan options at every

In this Issue:

metal level, every product network type, and throughout every service area that they offer non-standardize options for plan year 2023 and beyond. Healthcare.gov will differentially display these options. The Rule does not apply a meaningful difference standard.

- **New Network Adequacy Requirements.** Beginning plan year 2023, CMS will conduct network adequacy reviews based on time and distance standards in FFE states except states performing plan management functions that adhere to a standard as stringent as the federal standard. Issuers will be required to submit information about whether providers offer telehealth services. An appointment wait time standard will be implemented beginning plan year 2024.

- **Essential Community Providers (ECPs).** Increases the ECP threshold from 20 percent to 35 percent and requires that providers must be contracted within the lowest cost-sharing tier to count toward the threshold.

Regulatory

- **Executive Order 4 Extended**
- **Department of Financial Services Shares Proposed Bill on Group Capital Calculations**
- **Professional Employer Organizations Guidance**
- **Early Intervention Guidance; Final Assessments Forthcoming**

Industry Trends

Policy / Market Trends

- **New Research Demonstrates the Substantial Value of ARPA Tax Credits**
- **CMS Publishes Latest Enrollment Figures for Medicaid, CHIP**
- **CBO Presentation on Health Care Prices**

- **Nondiscrimination Protections.** Does not finalize nondiscrimination proposals related to sexual orientation and gender identity included in the proposed rule and will address this policy and public comments in forthcoming rulemaking on Section 1557 nondiscrimination in health care. Consistent with its previous notice of enforcement, HHS will continue to interpret and enforce section 1557 protections to prohibit discrimination on the basis of sexual orientation and gender identity in all aspects of health insurance coverage.

- **Essential Health Benefit (EHB) Nondiscrimination.** Effective January 1, 2023, an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions; and that a nondiscriminatory benefit design that provides EHB is one that is clinically-based. HHS will work with issuers to address compliance issues for issuers acting in good faith to comply with the refined EHB nondiscrimination policy.

- **AV De Minimis Ranges.** Narrows the AV de minimis ranges to +2/-2 percentage points for all individual and small group plans for bronze, silver, gold, and platinum levels of coverage as well as

a +5/-2 range for expanded bronze plans, +2/0 for individual market silver QHPs, and +1/0 for CSR variant plans.

- **HHS Risk Adjustment.** Finalizes two proposed risk adjustment model changes to replace the current severity illness factors in the adult models with: 1) an interacted hierarchical condition category (HCC) count model specification to the adult and child models; and 2) replace the current enrollment duration factors (EDF) in the adult model with an HCC-contingent EDF. The Rule does not finalize the proposed two-stage weighted approach model change.

- **Medical Loss Ratio (MLR).** Only provider incentives and bonuses tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. Only expenses directly related to activities that improve health care quality may be included as quality improvement activity (QIA) expenses for MLR reporting and rebate calculation purposes.

- **User Fees.** For plan year 2023, the user fee for issuers in FFEs is 2.75 percent of premiums and 2.25 percent of premiums for issuers in SBE-FPs.

These measures set the landscape for the upcoming HealthCare.Gov Open Enrollment Period, which will begin on November 1, 2022.

CMS Releases MA/Part D Final Rule for 2023

The Centers for Medicare & Medicaid Services (CMS) released the attached pre-publication version of a final regulation containing revisions to the Medicare Advantage and Part D Prescription Drug Benefit programs for CY 2023. CMS also issued a related press release and fact sheet.

Why this matters: This is an annual regulation for Medicare Advantage and Part D plans.

Highlights from the final rule include the following:

- CMS finalized the proposal to require Part D plans to apply all price concessions they receive from network pharmacies at the point of sale by revising the current definition of “negotiated [drug] price” to eliminate the current exception for contingent pharmacy price concessions from inclusion in the total pharmacy network price concessions that can be reasonably determined at the point of sale. Instead, the new definition would include the lowest net price a pharmacy could receive for a covered drug net of the maximum possible negative adjustment or incentive fees receivable under any contingency payment arrangements between the sponsor and pharmacy. However, CMS has delayed the effective date of this requirement to January 1, 2024.

- CMS finalized that the MA plan maximum out of pocket (MOOP) limit is calculated based on the accrual of all Medicare cost-sharing in the plan benefit, including amounts paid by the beneficiary, Medicaid, or other secondary insurance; and amounts remaining unpaid because of state limits.

- CMS finalized changes to marketing and communications requirements, including additional oversight for third-party marketing.

- CMS finalized a technical change to the COVID-19 disaster relief policy for 2023 Star Ratings that applies to three Health Outcomes Survey (HOS) measures: Monitoring Physical Activity, Reducing the Risk of Falling, and Improving Bladder Control.

- CMS finalized changes to regulations for D-SNPs including:
    - Require D-SNPs to establish and maintain one or more enrollee advisory committees in each state and consult with the committees on health equity.
    - Require SNP Health Risk Assessments (HRAs) to include questions on housing stability, food security, and access to transportation. However, CMS did not finalize the requirement that plans use specific standardized questions.
    - Apply unified appeals and grievance processes to additional categories of D-SNPs.
    - Create a mechanism to allow states to require that MA organizations establish a MA contract that only includes D-SNPs, which would allow for Star Ratings to reflect the D-SNPs' local performance.
    - Create a mechanism to allow states to require integrated beneficiary materials for D-SNPs.

CMS Proposes Changes to Medicare FFS Enrollment and Special Enrollment Periods

CMS issued a press release and fact sheet announcing a proposed rule implementing provisions of the Consolidated Appropriations Act, 2021 (CAA) and other revisions to fee-for-service (FFS) Medicare enrollment and eligibility rules effective January 1, 2023.

Why this matters: Notably, the rule aims to eliminate delays in coverage by providing Medicare coverage the month immediately after enrollment for individuals enrolling in the last three months of their initial enrollment period or in the General Enrollment Period. The proposed rule also would allow beneficiaries to receive Medicare Part B coverage without a late enrollment penalty. The proposed rule specifically addresses:

- Immunosuppressive drug coverage under Medicare Part B for certain individuals whose Medicare entitlement based on end-stage renal disease (ESRD) would otherwise end 36-months after they receive a successful kidney transplant provided they do not have certain other health coverage;
- Revised effective dates for FFS Medicare coverage for beneficiaries who enroll in the last three months of their initial enrollment period or in the General Enrollment Period;
- Several new FFS Medicare special enrollment periods (SEPs), including individuals losing Medicaid eligibility at the end of the public health emergency (PHE);
- Streamlined rules for state "buy-in" premium payments for certain dual-eligibles; and
- Administrative changes to simplify existing regulations on FFS enrollment forms.

CMS is proposing to establish five special enrollment periods (SEPs) under Medicare Parts A and B. Four of the proposed SEPs address specific exceptional conditions. The proposed SEPs for exceptional conditions include:

- Individuals impacted by an emergency or disaster (e.g., extreme weather-related events and other emergencies)
- Health plan or employer misrepresentation or providing incorrect information
- Formerly incarcerated individuals
- Coordination with termination of Medicaid
- Other exception conditions on a case-by-case basis for other unanticipated situations

The proposed rule would update regulations that affect a state's payment of Medicare Part A and B premiums on behalf of low-income individuals (often known as "state buy-in"), and specify that provisions of a state buy-in agreement must be documented in a state's Medicaid state plan. Additionally, the rule would limit states' retroactive Medicare Part B premium liability to 36 months for full-benefit dual eligible, to reduce the burden of retroactive recoupment, billing and claims processing on states, plans and providers.

Comments are due no later than 5 p.m. on June 27, 2022.

Increasing Access to COVID-19 Treatments

On Tuesday, President Biden announced new actions to make treatments available to patients and to ensure providers and patients understand the treatments' safety and efficacy. The goal is to help strengthen and further build the infrastructure to ensure that lifesaving treatments are quickly distributed and easy to access. The following actions were announced:

- **Nearly doubling the number of places oral antivirals are available.** The Administration will allow all pharmacy partners in the federal antiviral pharmacy program to order free oral antiviral treatments directly from the federal government. Pharmacies will also continue to be able to receive treatments from state and territorial health departments and through the Test-to-Treat initiative.
- **New efforts to provide Test-to-Treat sites.** These sites will co-locate testing and provide an assessment from a medical provider and oral antiviral treatments in one location. This effort will be in partnership with state, Tribal, and territorial governments, and with support and coordination from HHS and the Federal Emergency Management Agency.
- **More guidance and tools to understand and prescribe treatments.** The government will engage with the clinical community and offer resources to help doctors assess whether treatments are appropriate for their patients. Additional guidance and outreach will be provided to every state, pharmacy chain, and major medical association to increase awareness around eligibility, accessibility, contraindications, and prescribing considerations.
- **Communication to the public that treatments are safe, effective and widely available**. The Administration will focus on increasing public awareness and education on COVID-19 treatments. Specifically, that COVID-19 oral antiviral treatments must be taken within the first five days of symptom onset and understand its role in reducing the risk of severe disease and death from COVID-19.

New Resources on Coverage for Mental Health Benefits

On Wednesday, SAMHSA released resources to help inform Americans of their insurance benefits under the law and to help state insurance regulators and behavioral health staff better understand parity laws. These resources come after the 2022 Mental Health Parity and Addiction Equity Act (MHPAEA) Report to Congress developed by the Department of Labor, Health & Human Services and the Treasury. The agencies found instances of violations of the law and compliance challenges. The 2022 Report offered statutory recommendations to strengthen MHPAEA's consumer protections and better position the Departments to enforce the law.

- SAMHSA Resource – Know Your Rights: Parity for Mental Health and Substance Use Disorder Benefits
- SAMHSA Resource – Understanding Parity: A Guide to Resources for Families and Caregivers
- SAMHSA Resource – The Essential Aspects of Parity: A Training Tool for Policymakers
- HHS Press Release – HHS's New Mental Health and Substance Use Disorder Benefit Resources Will Help People Seeking Care to Better Understand Their Rights

---

QHP Certification Update

- On April 28, 2022, CMS released the final plan year (PY) 2023 qualified health plan (QHP) application templates, instructions, and supporting documents and review tools on the QHP certification website. Issuers applying for certification for QHPs, including stand-alone dental plans, should use these materials when applying for PY 2023 certification to participate in the federally-facilitated exchange (FFE). These materials reflect the guidance detailed in the final 2023 Notice of Benefit and Payment Parameters and the final 2023 Letter to Issuers in the FFE, which were published on the same day.

- Also on April 28, CMS opened the Plan Management and Market Wide Functions Portal in the Health Insurance Oversight System (HIOS). Issuers may now begin submitting their PY 2023 QHP applications.

- CMS announced the deadline to submit a complete QHP application is **1:00 p.m. ET on June 15, 2022.** For more information on the application materials required for the initial submission deadline, reference the QHP Certification Issuer Toolkit on the QHP certification website. CMS encourages issuers to submit application materials on a rolling basis and as early as possible to allow for sufficient processing of files and to ensure successful upload.

- Issuers have the opportunity to submit their QHP application for an optional Early Bird review. To quality for this review, complete QHP applications for PY 2023 must be submitted to HIOS or transferred from SERFF to HIOS by no later than **1:00 p.m. ET on May 18, 2022.** For more information on the application materials required to qualify for the Early Bird review, reference the QHP Certification Issuer Toolkit on the QHP certification website.

COVID-19 Updates

- The White House released a fact sheet outlining the impact on the Administration's COVID-19 programs if Congress does not pass legislation providing funding for COVID-19 response efforts. The fact sheet details how lack of funding would affect the nation's supply and response capabilities to test, treat, and vaccinate against COVID-19.

- Moderna announced that they have submitted a request to the Food and Drug Administration (FDA) for emergency use authorization (EUA) for its COVID-19 vaccine in children 6 months to under 6 years of age.

- The FDA recently granted emergency-use authorization for a COVID-19 breathalyzer test that can provide diagnostic results in three minutes. The test can be performed in a doctor's office, hospital, or mobile testing site by a trained practitioner.

State Issues

Delaware

Legislative

EOB Suppression Bill Reintroduced

House Bill 400 prohibits health carriers from specifying any defined sensitive health care services in Explanation of Benefits (EOB) forms. The bill allows health carriers to address the EOB form to the insured member, allows insured members to choose their preferred method of receiving said form, and precludes health carriers from sending the form when there is no payment liability for the visit or service provided. The Act also amends Title 31 to provide that any carrier providing health insurance to Medicaid recipients may not divulge defined sensitive health care services without the recipient's express written or telephone recorded consent. The Department of Insurance is required to issue guidance to health insurers within 1 year of enactment. The Division of Public Health is required to establish a plan to educate health care providers and staff of hospitals, medical offices, community health centers and school-based health centers to promote compliance with this Act within 1 year of enactment.

Why this matters: The ability of insured dependents and other insured members to receive confidential sensitive health care services without the knowledge of the insured policyholder is greatly impeded through traditional billing processes utilized by health insurers. The most frequent form used is an explanation of benefit (EOB) sent to the policyholder after anyone covered under the policy receives care. The lack of confidentiality for sensitive health care services can often result in insured members simply avoiding necessary health care.

Regulatory

Final Regulation Issued For Mandatory Minimum Payment Innovations in Health Insurance

The Delaware Department of Insurance issued its Final Regulatory Implementing Order for the 1322 Requirements for Mandatory Minimum Payment Innovations in Health Insurance. The purpose of this

regulation is to establish a process through which carriers must demonstrate compliance with requirements for mandatory minimum payment innovations, including alternative payment models, provider price increases, carrier investment in primary care, and other activities deemed necessary to support a robust system of primary care by January 1, 2026, pursuant to 18 Del.C. §334.

Why this matters: This regulation implements the requirements established pursuant to Senate Substitute 1 for Senate Bill 120, SS 1 for SB 120, through the expanded regulatory authority provided to the Delaware Department of Insurance. This regulation applies to insurers, health service corporations, and managed care organizations that deliver or issue for delivery in this State individual and group insurance policies or plans subject to regulation under Title 18 of the Delaware Code.

State Issues

New York

Legislative

Numerous Health Care Bills on Legislature's Docket

With just 16 session days left – and the chaotic primary election situation resulting from New York's top court striking down Congressional and state Senate redistricting maps – the push is on to take up hundreds of bills.

Bills in Committee this week: The following health care bills will be taken up in committee meetings this week.

- **Dense breast tissue S.7647 (Kaplan)/A.8614 (Gottfried)**: Allows a notice of dense breast tissue to be considered a determination of medical necessity for coverage of a breast ultrasound. In the Assembly, the bill is in the Insurance Committee.

- **Prescription drug information A.5411-B (McDonald)/S.4620 (Breslin):** The "patient Rx information and choice expansion act" requires that real-time, patient specific, prescription drug out-of-pocket cost details be provided at the point of prescribing to ensure patients have a better understanding of what the out-of-pocket costs will be for their medications and provide greater transparency overall.

Bills moved through committees last week:

- **Additional 30-day Rx supply A.7469 (Cruz)/S.4856 (Reichlin-Melnick)**: Requires policies that cover prescription drugs to include coverage of an immediate additional thirty-day supply of a prescription drug during a state disaster emergency. The bill moved to the floor in both houses.

- **Chest wall reconstruction A.8537 (Pheffer Amato)/ S.7881 (Stavisky)**: Mandates coverage and information on chest wall reconstruction surgery, known as “aesthetic flat closure,” after a mastectomy or partial mastectomy. The bill moved to the Assembly floor and is in the Senate Insurance Committee.

- **Lactation consultation A.8653 (Jackson)/S.8239 (Salazar)**: Requires insurance coverage for lactation consultant services. The bill moved to the Assembly floor and is in the Senate Insurance Committee.

- **Opioid treatment copay prohibition S.5690 (Harckham)/A 372 (Rosenthal L)**: Prohibits co-payments for treatment at an opioid treatment program. The bill moved to the Senate floor and has already passed the Assembly.

- **Fail-first/step therapy prohibition S.5909 (Kaminsky)/ A 3276 (Gunther)**: Prohibits the application of fail-first or step therapy protocols to coverage for the diagnosis and treatment of mental health conditions. The bill moved to the Senate floor and has already passed the Assembly.

- **Prior authorization S.8299 (Breslin)/A. 9908-A (McDonald)**: Exempts health care professionals from preauthorization requirements in certain circumstances (Gold carding). The bill moved to the Senate floor and is in the Assembly Insurance Committee.

- **Co-pay Accumulator S.5299 (Rivera)/A 1741 (Gottfried)**: A “co-pay accumulator” bill that requires insurance companies or pharmacy benefit managers to apply price reduction instruments for out-of-pocket expenses when calculating an insured individual's cost-sharing requirement. The bill has now moved to the floor in both houses.

Regulatory

Executive Order 4 Extended

Governor Hochul on Saturday once again extended Executive Order 4, Continuing the Declaration of a Statewide Disaster Emergency Due to Healthcare Staffing Shortages – now EO4.8, through May 30. The extension of the EO continues the provisions of the related circular letter (CL 9 of 2021) that suspends certain administrative actions including utilization review and timelines for appeals.

Department of Financial Services Shares Proposed Bill on Group Capital Calculations

The Department of Financial Services last week shared a draft of a bill it has submitted to the Legislature. The proposal, which is not yet been introduced, contains provisions related to group capital calculations and liquidity stress tests standards for holding companies, amends the requirements that a holding company file a notice of divesting control in a domestic insurer, and permits the Superintendent to share confidential information with third-party consultants or other entities. DFS has stated that the changes are intended to align with NAIC standards.

Professional Employer Organizations Guidance

The US Department of Labor last week revised its guide on Multiple Employer Welfare Arrangements, with updated guidance on PEOs. At this time it is not clear what it means or whether it might have an impact on small group rates here in New York.

Early Intervention Guidance; Final Assessments Forthcoming

DFS recently finalized the Circular Letter related to the legislation enacted last year creating an early intervention services pool (the $40 million covered lives assessment) as well as a Q&A. The Department of Health has not yet notified plans about the final assessments.

Industry Trends

Policy / Market Trends

New Research Demonstrates the Substantial Value of ARPA Tax Credits

AHIP released new and updated research showing the dire impacts if American Rescue Plan Act (ARPA) tax credits are allowed to expire at the end of 2022. According to research conducted by Avalere Health for AHIP, Americans buying their own health coverage are poised to face hundreds of dollars annually in higher premium share if these tax credit enhancements are not made permanent. For example:

- A 27-year-old earning $19,191 per year (149% FPL) could be facing an annual increase in out-of-pocket premium cost of almost $800 per year.
- A 46-year-old person earning $41,860 per year (325% FPL) could be facing an increase of $1,300.
- A 55-year-old couple earning $70,551 per year (405% FPL) could be facing an increase of more than $9,000.

Why this matters: Experts say nearly 3 million Americans would become uninsured if ARPA subsidies expire at the end of 2022 and over 10 million Americans would lose all or part of their premium subsidies but remain insured.

For more information, view the Avalere Health study on renewing ARPA subsidies for 2023 and the Morning Consult survey on voters' support for ARPA subsidies.

In an April 18, 2022 letter to Congress, the National Association of Insurance Commissioners (NAIC) urged lawmakers to extend the enhanced premium tax credits made available under the 2021 American Rescue Plan Act (ARPA).

CMS Publishes Latest Enrollment Figures for Medicaid, CHIP

On April 28, CMS released figures for Medicaid and the Children's Health Insurance Program (CHIP). As of January 2022, there were over 86.9 million people enrolled in Medicaid and CHIP, an increase of more than 1.1 million since the last report.

CBO Presentation on Health Care Prices

The Congressional Budget Office (CBO) recently presented information on health care prices for prescription drugs, hospital services and physician services to the Congressional Research Service (CRS). Some highlights from the presentation include the following:

- **Prescription drugs:** From 1980 to 2018, nationwide spending on prescription drugs purchased from pharmacies rose from $30 billion to $335 billion. And over the 10-year period from 2009 to 2018:
  - Nationwide per-person spending on prescription drugs purchased from pharmacies rose from $957 to $1,073 per year
  - Per-enrollee spending on prescription drugs purchased from pharmacies averaged about $2,700 per year in the Medicare Part D program and increased from $445 to $530 each year in the Medicaid program
  - The share of prescriptions dispensed for generic drugs rose from 75% to 90% nationwide, but in recent years, that growth has slowed.

- **Hospital and Physician Services**
  - Average annual growth rates for per-person spending for hospital and physician services increased 3.2% for commercial insurers vs. 1.8 percent in Medicare fee-for-service (FFS) from 2013-2018, while prices paid to providers over that same period increased at an annual rate of 2.7% for commercial insurers vs. 1.3 percent for Medicare FFS.
  - For hospitals' services as a whole, the prices paid by commercial insurers were more than double the prices paid by Medicare FFS, on average, in recent years.
  - Prices paid by commercial insurers for physicians' services varied substantially among states in 2017. Relative to Medicare's FFS prices, prices paid by commercial insurers were highest in Wisconsin, North Dakota, and Oregon.
  - The percentage of metropolitan statistical areas with hospital markets that were highly or very highly concentrated (as measured by a Herfindahl-Hirschman Index of more than 2,500) increased from 63 in 2010 to 70 in 2017.

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/.**