Highmark's Weekly Capitol Hill Report

Issues for the week ending August 19, 2022

Federal Issues

Regulatory

Biden Administration Issues Final Rule on Surprise Billing Payment Disputes

The U.S. Departments of Labor, Health & Human Services, and the Treasury Departments released a final rule implementing provisions of the No Surprises Act, a bipartisan law passed at the end of 2020 that aims to protect consumers from unexpected medical bills when receiving out-of-network care in certain situations.

Why this matters: Specifically, the rule focuses on the factors arbiters must weigh and consider when settling payment disputes for out-of-network care between insurers and providers. The final rule also finalizes certain disclosure requirements by health plans and issuers to nonparticipating providers, facilities, and providers of air ambulance services about the qualifying payment amount (QPA).

Background: Provider groups successfully challenged previous rulemaking, arguing that it unfairly favored insurers in determining payments for out-of-network care.

This new rule states that arbiters no longer have to start with that median in-network rate and must

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consider "all additional permissible information submitted by each party to determine which offer best reflects the appropriate out-of-network rate."

This final rule follows an Interim Final Rule published October 7, 2021, that addressed similar topics. Select provisions of that IFR – namely, how the QPA is to influence final payment determinations - were vacated by the U.S. District Court for the Eastern District of Texas in February (*Texas Medical Association v. HHS*) and July (*Lifenet v. HHS*). An additional Final Rule is expected before the end of 2022 and will focus on much the same content as the IFR with Comment Period published July 13, 2021, including the methodology for calculating Qualifying Payment Amounts (QPA).

Additional guidance, the Affordable Care Act Implementation FAQ Part 55, was released on the implementation of a number of NSA requirements, machine-readable file requirements, and internet-based self-service tool requirements under the Transparency in Coverage final rules. The Departments also released a brief status update on the federal IDR process covering the current implementation of the federal IDR process.

The ERISA Industry Committee (ERIC), which represents large employers that provide health plans, issued the following statement in response to the final rule:

“Instead of taking steps to lower health care costs — especially in these inflationary times — the federal departments watered down the surprise medical billing requirements that dictate how much an employer-sponsored self-insured health plan is required to pay when emergency services are furnished by an out-of-network provider and when an out-of-network provider furnishes services at an in-network medical facility.”

“Unfortunately, the final rule falls short of lowering health care costs for employer plan sponsors and ultimately, patients,” ERIC CEO Annette Guarisco Fildes said. “Instead of adhering to Congress’s original intent, the administration backtracked on limiting out-of-network payments to reasonable market-driven rates. The administration’s actions will not lower health care costs. To the contrary, plan sponsors and the employees to whom they provide health coverage will continue to be forced to line the pockets of medical providers that choose to remain out-of-network.”

FDA Issues Final Rule for OTC Hearing Aids

On August 16, the Food and Drug Administration (FDA) released a final rule establishing a new category of over-the-counter (OTC) hearing aids. This rule finalizes the draft rule that was issued on October 20, 2021.

Why this matters: The new category of OTC hearing aids covers certain air-conduction hearing aids intended for adults who have perceived mild to moderate hearing impairment. Hearing aids that do not meet

the requirements for the OTC category (e.g., hearing aids intended for adults with severe hearing impairment or users younger than age 18) are considered to be prescription devices.

In the rule, the FDA confirms they do not have the authority to require health insurers or Medicare to pay for or reimburse the cost of hearing aids or to offer financial incentives to obtain the devices. The effective date for the FDA rule is October 17, 2022.

Concurrent with this rule, the FDA also finalized its guidance for personal sound amplification products (PSAPs), which clarifies the differences between hearing aids and PSAPs and the regulatory requirements that apply to both products.

Greater availability of OTC hearing aids may have implications for hearing aid benefits that health plans may cover, especially for Medicare Advantage, Medicaid Managed Care, Medicare Supplemental plans and potentially commercial market coverage in the employer and individual markets.

Novel Employer Health Plan Sent Back to Lower Court

On Wednesday, the Fifth Circuit Court of Appeals refused to bless a novel health plan operating in violation of the U.S. Department of Labor's advisory opinion finding the plan did not meet its standards set for ERISA-governed plans. At the same time, the circuit court agreed with the district court's finding that the advisory opinion was arbitrary and capricious and remanded back to the district court to apply all relevant factors in determining whether the plan participants were qualified "working owners" and "bona fide partners."

Background: In 2020, federal district court judge Reed O'Connor overturned the Department's advisory opinion denying single-employer ERISA group health plan status to an arrangement proposed by a general partner and related limited partnership.

- The plaintiffs sought single-employer status and treatment of the benefit arrangement as an ERISA-governed plan, but the Department concluded the arrangement lacked an employment relationship, ownership interest, and sufficient employee-to-partner ratio, concluding that the business enterprise is a "sham" created as a means to provide health insurance coverage to the Limited Partners.

- Notably, the enterprise hires workers and in turn offers them entry to the plan by requiring them to opt into a data-sharing partnership wherein they agree to have their internet browsing and social media presence tracked in exchange for compensation for their time.

Why this matters: The case is being watched closely by federal and state regulators and other stakeholders as a potential new option to offer health insurance without complying with the traditional insurance protections under federal law, such as the Affordable Care Act.

CMS Issues Notice of Proposed Rule Making on Mandatory Reporting of Medicaid and CHIP Core Set Measures

CMS issued a notice of proposed rulemaking to promote consistent use of nationally standardized quality measures in Medicaid and Children's Health Insurance Program (CHIP). The rule sets three quality

measuring criteria that are designed to measure the quality of care for beneficiaries, monitor state-level care performance, and improve the quality of health care nationwide.

The rule proposes requirements for annual, mandatory state reporting of:

- the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP;
- the behavioral health measures in the Core Set of Adult Health Care Quality Measures for Medicaid; and
- the Core Sets of Health Home Quality Measures for Medicaid.

Why this matters: Reporting of these measures, which is currently voluntary for states, would become mandatory in federal fiscal year 2024. Annual reporting of these measures is intended to help identify gaps and disparities among the millions of people enrolled in Medicaid and CHIP and help improve the quality of care.

CMS Releases Plans for End of Public Health Emergency

On Thursday, the Centers for Medicare and Medicaid Services (CMS) released several new resources as part of its work to help states, providers, health plans, Medicare and Medicaid beneficiaries, and other stakeholders prepare for the end of the COVID-19 Public Health Emergency (PHE).

Throughout the PHE, CMS has used a combination of emergency authority waivers, regulations, enforcement discretion, and sub-regulatory guidance to ensure access to care and give health care providers the flexibilities needed to respond to COVID-19. Many of these waivers and broad flexibilities will terminate at the eventual end of the PHE (currently extended through October 13, 2022). HHS Secretary Becerra has committed to giving states and the health care community writ large 60 days' notice before ending the PHE (meaning the PHE is likely to be extended at least one more time). In the meantime, CMS has developed a roadmap for the eventual end of the PHE-related waivers and flexibilities and continues to release guidance, fact sheets, and other resources.

The material includes fact sheets on these waivers and flexibilities for each type of Medicare provider, including a MA and Part D fact sheet.

Key sections of that fact sheet include:

- The Part D "Refill-Too-Soon" edits and maximum day supply flexibilities around 90-day fills and early fills, as dictated under section 3714 of the CARES Act, will end with the PHE.
- Flexibilities on Part D home and mail-order deliveries will continue for the duration of the PHE.
- Benefit flexibilities for telehealth and other mid-year benefit enhancements in connection with the COVID-19 pandemic will continue for the duration of the PHE.
- The ability for Part D sponsors to waive prior authorization for medications to treat COVID-19 infections will continue for the duration of the PHE.

- For oral antivirals to treat COVID-19 infections, there is no beneficiary cost sharing and no deductible for these medications. This process will continue while oral antivirals are under the EUA and being procured by the federal government.

- The flexibility to permit Part D sponsors to pay pharmacy claims for dispensing fees without enrollee cost sharing for oral antivirals, will continue for the duration of the PHE.

- Various flexibilities for MA and PDPs regarding appeals and timeframes for filing a request for a reconsideration are included in the fact sheet.

This material was released on the same day the media reported (see *Wall Street Journal* article) the federal government's plans to transition costs of COVID-19 vaccines and treatments to the private sector. The WSJ article notes how Eli Lilly transitioned its monoclonal antibody to the commercial market this month, the need for a solution to maintain access for the uninsured, the recognition there will be varying timetables for transitioning different products to the commercial market, and special considerations for Medicare/Medicaid. HHS will host an Aug. 30 meeting with stakeholders to discuss the potential transition of COVID-19 countermeasures to the commercial market.

More Resources:

- CMS Press Release
- CMS Roadmap
- Health Care Resiliency Fact Sheet
- CMS COVID-19 Webpage
- PHE Unwinding Guidance for State Medicaid Programs

COVID-19 Updates

- **Anticipated PHE Extension:** The COVID-19 public health emergency (PHE) is expected to be renewed beyond October 13, 2022, when it is currently set to expire. The Administration has promised to give states and stakeholders 60 days advance notice of the PHE expiration and that 60-day mark has passed.

- **Updated FDA Guidance:** The Food and Drug Administration (FDA) updated guidance regarding COVID-19 antigen tests in an effort to reduce the risk of false negative results. The FDA now recommends repeat testing following a negative result whether or not an individual has COVID-19 symptoms. The guidance notes that antigen tests are "less likely to detect the SARS-CoV-2 virus" than polymerase chain reaction (PCR) tests. The FDA now recommends "multiple tests over a certain time period, such as 2-3 days, especially when the people using the tests don't have COVID-19 symptoms."

Monkeypox Update: White House Seeks to Accelerate Access to Vaccines & Treatments

The White House announced new initiatives related to the Administration's response to the monkeypox outbreak.

Why this matters: The Department of Health and Human Services (HHS) will make available **1.8 million doses of JYNNEOS vaccine for order by jurisdictions** across the country on August 22. Earlier this week, HHS allocated and began distributing 442,000 doses of the vaccine, the first allocation following the Food and Drug Administration's (FDA) Emergency Use Authority (EUA) declaration allowing for intradermal administration of the vaccine, which allows up to 5 doses per vial. Representatives from the Administration for Strategic Preparedness and Response (ASPR) noted that some patients may still receive the 500 mL subcutaneous injection, which would reduce the number of potential doses available.

HHS is also launching a pilot program to provide additional targeted vaccine allocations to state and local health departments in jurisdictions that are hosting large events that attract gay, bisexual, and other men who have sex with men in the coming weeks and months.

ASPR is making **50,000 courses of TPOXX available to jurisdictions** for prepositioning, to facilitate timely access to the medication. This allocation strategy is intended to make the treatment more readily available for providers and patients. Administration officials indicate that further data needs to be collected on TPOXX safety and effectiveness.

The Centers for Disease Control and Prevention (CDC) has identified over 14,000 cases of monkeypox in the U.S., with 98% of cases found in people assigned as male sex at birth and 93% among men who have sex with men. Risk to children remains extremely low.
Additional Administration resources on monkeypox are listed below:

- Video: How to Administer a JYNNEOS Vaccine Intradermally
- Prevent the Spread of Monkeypox (Updated)
- Infection Control in Healthcare Settings (Updated)

State Issues

New York

Regulatory

2023 Rates Announced

The Department of Financial Services (DFS) last week announced final rate decisions for the 2023 individual and small group markets. Highmark New York's average approved rates:

Individual – 12.8% (20.5% requested)
Small group - 10.7% (15.3% requested)

Overall, DFS reduced insurers' requested rates roughly by half. In the individual market, DFS reduced the rates from the 18.7% average increase requested to 9.7% (a 48% cut) and cut small group rates from an

average requested increase of 16.5% to 7.9% (a 52% reduction). The Department noted many of the same factors Highmark has cited as contributing to the rising cost of medical care — including hospital stays and increased drug costs, increased utilization of services as New Yorkers catch up on care postponed during the pandemic, and inflation — which continue to be the main drivers of premium increases.

However, DFS said its rate decisions “prioritize the financial wellbeing of consumers while ensuring that New Yorkers have access to a robust, stable health insurance market.” In a statement responding to the announcement, the NY Health Plan Association pointed out the original rates submitted by plans were reasonable and reflected the underlying factors driving up costs, and expressed disappointment that the final approved rates did not fully account for these factors.

State Issues

Pennsylvania

Regulatory

Governor Wolf Signs Executive Order Barring Use of State Funds for Conversion Therapy

Gov. Tom Wolf signed an executive order barring the use of state dollars for conversion therapy. The order directs agencies to promote "evidence-based best practices" and update their policies and procedures "to better support LGBTQIA+ employees and residents. The order directs the Insurance Department "to discourage commercial insurers from providing reimbursement for conversion therapy, to the extent permitted by law," and to "investigate" any reports that commercial insurance claims have been used to cover the cost of conversation therapy. The order also directs the department to investigate "any complaints" that insurers are "automatically or categorically denying or excluding coverage of gender-related care."

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/.**