Highmark's Weekly Capitol Hill Report

Issues for the week ending July 2, 2021

Federal Issues

Legislative

House Republicans Announce Healthy Future Task Force

House Republican Leader Kevin McCarthy (R-CA) has announced the formation of the "Healthy Future Task Force," which will craft legislative proposals and help shape the Republican health care agenda in the U.S. House.

The group will be co-led by Brett Guthrie (R-KY), Ranking Member on the House Energy and Commerce Health Subcommittee, and Devin Nunes (R-CA), Ranking Member on the House Ways and Means Health Subcommittee.

- Other members include: Tom Cole (R-OK); Larry Bucshon, M.D. (R-IN); Morgan Griffith (R-VA); **Mike Kelly (R-PA)**; Richard Hudson (R-NC); Brad Wenstrup, D.P.M. (R-OH); Rick Allen (R-GA); Bruce Westerman (R-AR); Jim Banks (R-IN); Kevin Hern (R-OK); **John Joyce, M.D. (R-PA)**; Greg Murphy, M.D. (R-NC); Beth Van Duyne (R-TX); Mariannette Miller-Meeks, M.D. (R-IA); Victoria Spartz (R-IN)

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Federal Issues

Regulatory

First Surprise Billing Interim Final Rule Released

The U.S. Departments of Health and Human Services, Labor, and the Treasury released a pre-publication version of a rule addressing issues related to implementation of the No Surprises Act, which generally will prohibit balance billing commercially insured patients, including patients in ERISA-covered plans, starting January 1, 2022.

Background: Surprise billing happens when people unknowingly get care from providers that are outside of their health plan's network and can happen for both emergency and non-emergency care. Balance billing, when patients are billed for the remainder of what their insurance does not pay, is currently prohibited in both Medicare and Medicaid. This rule extends similar protections to employer-sponsored and commercial health plans beginning on or after January 1, 2022.

Why this matters: This rule is expansive and only the first in an expected series of rules and other regulatory actions required as part of the law prohibiting health care providers and facilities from balance billing patients for certain out-of-network care, including out-of-network emergency services and care from out-of-network providers at in-network facilities. The law was passed as part of the Consolidated Appropriations Act, signed December 27, 2020.

This rule primarily details health insurance requirements regarding surprise medical billing in Section 102 of the No Surprises Act, including definitions of terms and the scope of covered services to protect patients from surprise bills when treated for emergency services, care after being stabilized, and non-emergency care at participating health care facilities.

The rule also establishes the methodology for calculating the Qualifying Payment Amount (QPA), an amount that will be used in most circumstances covered by the law to determine an insured enrollee's required cost-sharing, as well as to guide the award determination during Independent Dispute Resolution (IDR), while seeking additional information on a number of items.

Other components of the rule include:

- Discussion and examples detailing circumstances in which state law shall apply and the interaction between state law and ERISA.
- Interim rules and requests for comments address sections of the law that would prohibit air ambulance providers from balance billing patients.
- Health plan requirements for making an initial payment or notice of denial, including the timeline for such beginning with a clean claim and the process and rules for filing complaints against group health plans and health insurance issuers.
- Finally, the No Surprises Act re-codified the patient protections related to choice of health care professional, including for emergency services, making minor changes to the prior rules and extending their applicability to grandfathered plans.
- Model notices for Group Health Plans and Health Insurance Issuers were also released.

The regulations are applicable to plan years and policy years beginning January 1, 2022. Comments are due 60 days following publication of the rule in the Federal Register.

This rule does not address the independent dispute resolution (IDR) process between plans and providers, transparency requirements, or price comparison tools that are outlined in the No Surprises Act. The agencies intend to issue rules covering those topics later this year.

The Administration's press release, including links to two fact sheets, can be found here.

CMS Releases Marketplace Rule to Update Payment Parameters, Section 1332 Guidance, and Improve Health Insurance Markets for 2022 and Beyond

The Centers for Medicare and Medicaid Services (CMS) released a pre-publication proposed rule on Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond.

Why this matters: Many of these changes were signaled in Part Two of the 2022 Notice of Benefits and Payment Parameters (NBPP) published in May. Notably, CMS proposes to:

- **User Fees**: Change the 2022 user fee rate to 2.75% percent of premiums for issuers in Federally-Facilitated Exchanges (FFEs) and 2.75% for State Based Exchange issuers, an increase from rates finalized in January, but lower than current 2021 user fee rates.

- **Open Enrollment Period Extension**: Beginning with plan year 2022 and beyond, proposes to extend the annual open enrollment period so consumers can enroll from November 1 through January 15 (currently ends on December 15).
- **Monthly SEP for Low-income Consumers**: Give states the option to adopt a new special enrollment period (SEP) for APTC-eligible consumers with household incomes under 150% federal poverty level (FPL).
- **State Exchange Direct Enrollment Option**: Repeal the Exchange Direct Enrollment (EDE) option, finalized under the Trump Administration in January, which allowed states to enroll consumers in Exchange coverage through private sector websites. No states had yet indicated interest in implementing the Exchange Direct Enrollment option.
- **1332 Waiver Guidance Modifications**: Together with the Department of the Treasury, reverse the 2018 State Relief and Empowerment Waiver guidance, incorporated in Part 1 of the 2022 Payment Notice under the Trump Administration in January, which provided flexibility for certain waiver procedures. The Departments largely revert to the prior Obama Administration guidance issued in 2015.
- **Repeal of Separate Billing**: Repeal the separate billing requirements for qualified health plans that offer coverage for abortion services.
- **Standard Plans**: Seeks input on plan design and differential display of standard plans prior to proposing in future rulemaking.

The proposed rule will be published in the *Federal Register* on July 1 and comments are due July 28. CMS also issued a press release and fact sheet.

CMS Opens HealthCare.Gov to Consumers Who Receive Unemployment Compensation

The Centers for Medicare & Medicaid Services (CMS) announced beginning July 1, consumers who received or are approved to receive unemployment compensation for any week beginning in 2021 may submit a new application or update their existing application on HealthCare.Gov. This temporary benefit was included in the American Rescue Plan Act enacted earlier this year.

Why this matters: Consumers receiving unemployment compensation may update their application and enrollment between July 1 and August 15, when the federal Special Enrollment Period closes.

CMS Proposes Calendar Year 2022 Home Health Prospective Payment System Rate Update

On June 28, the Centers for Medicare & Medicaid Services (CMS) took action to improve home health care for older adults and people with disabilities through a proposed rule that aims to accelerate the shift from paying for Medicare home health services based on volume to a system that pays for value and quality by proposing a nationwide expansion of the Home Health Value-Based Purchasing (HHVBP) Model.

This rule also includes proposals and routine updates to the Medicare Home Health Prospective Payment System (HH PPS) and the home infusion therapy services payment rates for Calendar Year (CY) 2022, in accordance with existing statutory and regulatory requirements. This rule proposes to make permanent changes to the home health Conditions of Participation (CoP) that were implemented during the COVID-19 Public Health Emergency (PHE).

Please see the CMS fact sheet on the updated proposed rule for additional information.

CMS Releases Summary Report for ACA Permanent Risk Adjustment Program for 2020 Benefit Year

The Centers for Medicare & Medicaid Services (CMS) released a new report that includes summary information and state- and insurer-specific payment amounts under the permanent risk adjustment program established under the Affordable Care Act (ACA). Risk adjustment payment transfers for the 2020 benefit year totaled approximately $11.2 billion, with nearly $5.6 billion in payments and $5.6 billion in charges – representing about 9.9 percent of premiums in the individual market and about 4.0 percent of premiums in the small-group market.

COVID-19 Updates

- The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) announced $250 million in grant awards to 73 local governments as part of a new, two-year initiative to identify and implement best practices for improving health literacy to enhance COVID-19 vaccination and other mitigation practices among underserved populations. Over the next two years, awardee projects will demonstrate the effectiveness of working with local community-based organizations to develop health literacy plans to increase the availability, acceptability, and use of COVID-19 public health information and services by racial and ethnic minority populations.
- HHS hosted an update on the National Vaccine Month of Action. Dr. Anthony Fauci, Director of the National Institute for Allergy and Infectious Disease, answered public questions on misinformation associated with the COVID-19 vaccine and the best strategies to combat misinformation and vaccine hesitancy. The Made to Save campaign also highlighted work by several community-based organizations including Arkansas Coalition of Marshallese, South Dakota Voices for Peace, and Doctors for America, to reach out to their communities, provide education and resources, and help get more people vaccinated.

Reporting Portal for Provider Relief Funds Reopened

The Health Resources and Services Administration (HRSA) July 1, 2021, opened the Provider Relief Fund (PRF) reporting portal for providers to begin reporting to the government that they used federal emergency relief funds for health care-related expenses or lost revenues attributable to COVID-19.

Providers that received PRF payments from April 10, 2020, through June 30, 2020, have until September 30, 2021, to submit the required information to HRSA. Hospitals and other health care providers that received PRF money after June 30, 2020, will need to report about the use of the funds at later dates as outlined in HRSA's June 11, 2021 update on PRF requirements.

HRSA also released new resources about reporting, including a toolkit and fact sheet, and HRSA will host a recorded webcast on July 8, 2021, at 3 p.m. ET to provide technical assistance about reporting for PRF recipients. Participants must register to attend.

Industry position: The American Hospital Association has been pressing the Biden administration to give providers more time to use federal funding, as demonstrated in this June 29, 2021 letter to Health and Human Services Secretary Xavier Becerra.

Why this matters: Hospitals have been asking that funding received prior to June 30, 2020, should be able to be used through the end of the COVID-19 public health emergency or, at a minimum, through the end of 2021.

U.S. Supreme Court Will Hear 340B Drug Pricing Case

The Supreme Court of the United States July 2, 2021, decided to hear the American Hospital Association's (AHA) petition asking to reverse a federal appeals court decision that significantly cuts payments to certain hospitals that participate in the 340B Drug Pricing Program, threatening access to care in communities.

Lawsuit procedural history: The AHA and others in February appealed to the Supreme Court a lawsuit challenging the U.S. Department of Health and Human Services (HHS) nearly 30 percent cut to 2018 and 2019 Medicare outpatient prospective payment system drug payments for certain hospitals participating in the 340B program. A district court had sided with the AHA and found that the payment reductions were unlawful. However, last July, two members of the three-judge panel of the U.S. Court of Appeals agreed to overturn that ruling, despite a spirited dissent questioning the majority's deference to the government's position.

This announcement comes at the same time as drug manufacturer Boehringer Ingelheim (BI) announced plans to stop shipping 340B-purchased drugs to hospitals' contract pharmacies, for orders placed on or after August 1, 2021.

Community health centers, HIV/AIDS clinics, and other federal grantee-covered entities are exempt from this new policy, which applies to all BI products except the company's specialty drugs OFEV, Gilotrif, and Praxbind. Hospitals without an in-house pharmacy must designate a single contract pharmacy location to receive and dispense BI products, and hospitals must register with drug manufacturer vendor 340B ESP to make that designation.

BI announced the new policy in letters to covered entities dated June 30, 2021, and posted a list of National Drug Codes to which the policy applies. This is the seventh drug manufacturer to announce 340B contract pharmacy restrictions, joining Eli Lilly, AstraZeneca, Sanofi, Novartis, Novo Nordisk, and United Therapeutics.

Why this matters: The U.S. Health Resources and Services Administration (HRSA) **notified** the six companies during May that their policies have resulted in overcharges and are in direct violation of the 340B statute. HRSA said they must immediately begin offering their drugs at the 340B ceiling price through contract pharmacy arrangements, and repay entities for overcharges. Continued non-compliance could result in civil monetary penalties. If BI follows through with its policy, HRSA likely will determine that its restrictions, too, violate the 340B statute.

State Issues

Pennsylvania

Legislative

Governor Wolf Signs Two Health Care Bills

Last week, Governor Wolf signed two key proposals to support the health care community.

The final approval for Senate Bill 425 and Senate Bill 115 comes after they were introduced in previous sessions and numerous stakeholder negotiations. The legislation will:

- **Clarify informed consent (SB 425):** Prime sponsored by Senator John Gordner (R-Columbia), this proposal clarifies the process for physicians to obtain informed consent from patients and ensures they have complete access to the information they need to make informed decisions. The bill addresses a 2017 Pennsylvania Supreme Court decision that limited a physician's ability to delegate the duty to obtain informed consent prior to specified procedures.
- **Support the health care workforce (SB 115):** Prime sponsored by Senator Lisa Boscola (D-Northampton), Senate Bill 115 allows nurses who meet uniform licensing standards to practice across state lines.

Industry Trends

Policy / Market Trends

Supreme Court Leaves in Place Ruling Upholding CMS's Site Neutrality Rule

The U.S. Supreme Court declined a request by the American Hospital Association (AHA) and others that it take up their challenge to CMS's site neutrality rule. American Hospital Association v. Becerra (20-1113). This effectively ends the AHA's challenge to those regulations, leaving in place the D.C. Circuit's decision upholding them.

Why this matters: The AHA's case challenged the decision by CMS, in the 2019 OPPS Rule, to cut reimbursement rates for E&M services at hospital outpatient off-campus provider- based departments (PBDs) by 60% to approximate what CMS pays freestanding physician offices for the same services. This change was designed, in part, to remedy the incentive that the disparity had created to move services to PBDs to obtain higher reimbursement amounts.

The AHA and other entities challenged the rule as beyond the scope of CMS's authority and the U.S. District Court for the District of Columbia agreed. In July of 2020, the U.S. Court of Appeals for the D.C. Circuit overturned the district court opinion, finding (under Chevron) the statute did not foreclose CMS's interpretation of the statute and, at the very least, CMS's rule was entitled to deference as involve a reasonable interpretation of an ambiguous statute.

Because the Supreme Court declined to take up the case, the D.C. Circuit's decision remains in place and, consequently, so does the CMS site neutrality rule.

AHIP Submits Formal Request for Aducanumab NCD

AHIP submitted a formal request for a National Coverage Determination (NCD) for aducanumab (marketed as Aduhelm) to the Centers for Medicare & Medicaid Services (CMS). Aducanumab is a drug recently approved by the Food and Drug Administration (FDA) for treatment of Alzheimer's disease.

AHIP asked CMS to develop a national coverage policy for aducanumab that would apply to the Medicare population, including Medicare Advantage organizations, and specify if, and under what conditions, Medicare will cover aducanumab.

Why this matters: An NCD is urgently needed to provide a consistent national approach to seniors' access to the drug under Medicare, due to the unique combination of challenges aducanumab's approval has created for the Medicare program and the people it serves. The most critical challenges are the limited clinical evidence demonstrating efficacy and the serious safety risks that aducanumab poses for Medicare patients. Further, the broad label indication means an NCD is necessary to enable CMS to carefully consider the impact on the Medicare program and the people it serves.

The Pennsylvania General Assembly returns to session in September.

The Delaware Legislature concluded session on June 30.

The New York Legislature concluded session on June 10.

The West Virginia Legislature concluded session on April 10.

Congress

The U.S. House and U.S. Senate are in recess this week.

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/.**