Highmark's Weekly Capitol Hill Report

Issues for the week ending July 7, 2023

Federal Issues

Regulatory

Administration Releases Proposed Rule Impacting Short-Term Limited Duration Plans & Excepted Benefits

The Departments of Health and Human Services, Labor, and Treasury (the Departments) released a pre-publication version of a proposed rule on Short-term Limited Duration Insurance (STLDI) and Excepted Benefits Plans. **Comments are due on Monday, September 11**. A fact sheet is also available. The proposed rule will be published in the *Federal Register* on July 12.

Why this matters: In an afternoon White House event, the President highlighted these actions along with several other reports and guidance aimed at further lowering health care costs and protecting consumers from "surprise junk fees." In addition, the Administration **released new surprise billing FAQs** and a request for information on medical payment products.

Regarding Short-Term Limited Duration Insurance, the proposed rule:

- **Redefines** "short-term" insurance to a maximum of 3 months after the original effective date.

In this Issue:

- **Revises** the definition of “limited-duration” to mean the maximum permitted duration for STLDI is no longer than 4 months in total, including any renewals or extensions.
- **Amends** notice requirements to specifically state STLDI is not comprehensive coverage and clarify differences between STLDI and comprehensive coverage.
- **Seeks** comments on ways to help consumers distinguish STLDI plans from comprehensive coverage, such as prohibiting sale during annual open enrollment.
- **Grandfathers** existing STLDI policies sold or issued before the effective date of the final rule (including subsequent renewal or extension) with respect to new definitions of duration and renewability, but must comply with revised notice requirements for renewals and extensions.

Industry Trends

Policy / Market Trends

- **CMS Shares Resources for Improving Access to Care for Individuals Living with Disabilities**
- **CMS Posts State-Directed Payment Approvals**

Regarding Excepted Benefits, the proposed rule:

- **Requires** all benefits paid under fixed indemnity plans categorized as excepted benefits must be reported as income and subject to income taxes.
- **Introduces** new requirements for hospital indemnity and other fixed indemnity plans to retain their classification as "excepted benefits that are not coordinated."
- **Solicits** comments on Specified Disease coverage and Level-Funded plans

Regarding subregulatory guidance around the No Surprises Act:

- The guidance ties the definition of “in-network” for the purposes of surprise billing to how the cost-sharing is treated for the Maximum Out-of-Pocket (MOOP) limit. Essentially, the guidance specifies that if a health plan applies a contract as in-network for surprise billing, it must also treat that contract as in-network for the MOOP limit or vice versa.
- The guidance also requires providers to disclose other “surprise” fees that come in the form of facility fees and to confirm these fees, when charged by out-of-network providers for the applicable health care services covered by the law, also cannot be balance billed to the patient.

No Surprises Act Report: The Department of Health and Human Services also issued the first in a series of reports to Congress on the impact of the No Surprises Act. The report establishes a framework for evaluation of the law’s impact on surprise billing, health care costs, and consolidation that will be used in future reports evaluating the impact of the law.

Medical Credit Cards RFI: Finally, the Department of Health and Human Services has joined the Consumer Financial Protection Bureau and Department of the Treasury in issuing a Request for Information (RFI) seeking public comment on the prevalence, nature, and impact of medical credit cards and other medical payment products on consumers and on the health care system, expressing concern that the financial vehicles offer "teaser" interest rates.

HHS Issues Proposed Remedy for 340B Payment Cuts From 2018 to 2022

Following last year's unanimous Supreme Court decision in favor of the American Hospital Association (AHA) and others, the Department of Health and Human Services last week issued its proposed remedy for the unlawful payment cuts to certain hospitals that participate in the 340B Drug Pricing Program.

HHS' proposed rule contains two central components:

- **First**, HHS would repay 340B hospitals that were unlawfully underpaid from 2018 to 2022 in a single-lump sum payment. The proposed rule contains the calculations of the amounts owed to the approximately 1,600 affected 340B covered entity hospitals.

- **Second,** HHS proposes to recoup funds from those hospitals that received increased rates for non-drug services from 2018 to 2022. The Centers for Medicare & Medicaid Services (CMS) proposes to recoup these funds by adjusting the outpatient prospective payment system conversion factor by minus 0.5% starting in calendar year 2025, making this adjustment until the full amount is offset, which CMS estimates to be 16 years.

Comments on the proposed rule are due by Sept. 5.

Why this matters: After more than five years of litigation and a unanimous Supreme Court victory, 340B hospitals will finally be paid back what they deserve so they can continue providing care to their patients and communities.

AHA perspective: The AHA stated it is gratified that HHS agreed with its position that these hospitals must be promptly repaid in full with a single lump-sum. At the same time, the AHA is disappointed that HHS has chosen to recoup funds from other hospitals that cannot afford additional Medicare payment cuts, including rural sole community, cancer and children's hospitals that were initially exempted from HHS' illegal policy.

Background: CMS was required to issue remedies to 340B providers pursuant to a Supreme Court decision that held the formula CMS adopted in 2018 to reimburse hospitals for 340B-acquired drugs and biologicals was unlawful. Prior to 2018, CMS reimbursed all hospitals for separately payable outpatient drugs at a rate of average sales price (ASP) plus 6%. Starting in 2018, CMS modified the payment formula 340B-acquired drugs to an adjusted ASP amount minus 22.5%.

FDA Grants Traditional Approval of Alzheimer's Treatment Leqembi

The Food and Drug Administration (FDA) granted traditional approval to Leqembi, an anti-amyloid monoclonal antibody developed and manufactured by Eisai and Biogen, to slow the progression of

Alzheimer's Disease. Previously, this drug and another in its class (Aduhelm) had received FDA approval under an accelerated approval pathway.

Why this matters: With traditional approval now granted, Leqembi qualifies for broader coverage under Medicare. Leqembi has shown to delay cognitive decline by 5.3 months following 18 months of treatment compared to placebo, with researchers anticipating further delays in disease progression following further treatment. However, Eisai and Biogen have indicated their price tag is $26,500 per year, of which:

- **Medicare fee-for-service** will cover 80% with beneficiaries paying the balance, absent any supplemental coverage.
- **Medicare Advantage plans** will provide coverage in accordance with CMS' national coverage determination (NCD) for this class of drugs.

In a fact sheet published earlier this month, the Centers for Medicare & Medicaid Services (CMS) stated Medicare would cover the drug in appropriate settings that support the collection of real-world information to study the usefulness of amyloid monoclonal antibodies such as Leqembi for Medicare beneficiaries. **CMS stated that to get Medicare coverage people will need to:**

- Be enrolled in Medicare;
- Be diagnosed with mild cognitive impairment or mild Alzheimer's disease dementia; and,
- Have a physician participating in a registry with an appropriate clinical team and follow-up care.

The Campaign for Sustainable Rx Pricing (CSRxP) – an advocacy organization which includes BCBSA, AHIP & the AHA - has sounded the alarm over the current price of $26,500 per year for Leqembi.

A CMS-facilitated registry is now open for clinicians to access, and CMS anticipates that other registries will soon be available and posted on the CMS website. Under the Medicare National Coverage Determination, if FDA grants traditional approval to other drugs in this class, Medicare will cover them using this same coverage framework.

CMS also released:

- **A statement** on the FDA's announcement
- **Fact sheets** for clinicians and patients available at this resource page
- **A Glossary** for data element in the registry
- **A new study** on its NCD with evidence page for Alzheimer's treatments

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CMS Releases 2024 Home Health Prospective Payment System Proposed Rule

On June 30, 2023, the Centers for Medicare & Medicaid Services (CMS) issued the calendar year (CY) 2024 Home Health Prospective Payment System (HH PPS) Rate Update proposed rule, which would update Medicare payment policies and rates for Home Health Agencies (HHAs).

Why this matters: The proposed rule would reduce reimbursements to home health providers by 2.2% in CY 2024. The reduction is the product of a 3% market basket update, a minus 5.1%

adjustment related to the Patient-Driven Groupings Model and other factors. Among other proposals, CMS also proposed modifications to the home health value-based purchasing program by replacing five current metrics with a claims-based discharge measure, an outcome and improvement discharge function score and a within-stay measure for potentially preventable hospitalizations. These changes would take effect in 2025 and CMS projects they would save $3.38 billion through 2027.

Comments to the proposed rule are due August 29, 2023.

FDA Issues Final Guidance on Direct-to-Consumer Labels and Ads

The Food and Drug Administration (FDA) published final guidance on how drug manufacturers and others conduct direct-to-consumer (DTC) advertising and promotion of prescription drugs in a consumer-friendly way.

Why it matters: The final guidance encourages a communication structure where efficacy and safety information are portrayed to consumers in quantitative terms, aiding consumer comprehension and decision-making.

The details: The guidance finalizes draft guidance released by the agency in October 2018 and outlines the following recommendations and changes:

- Providing quantitative efficacy or risk information for the control group, when applicable
- Presenting probability information in terms of absolute frequencies, percentages, and relative frequencies
- Formatting quantitative efficacy or risk information
- Using visual aids to illustrate quantitative efficacy or risk information

Thought bubble: The U.S. is one of two countries that allow drug manufactures to directly advertise their products to consumers, increasing inappropriate utilization of Rx and raising spending unnecessarily.

Insurers and other stakeholders have long advocated for guardrails for DTC advertising and support the agency's final guidance.

State Issues

Delaware

Legislative

Legislation Introduced to Establish Delaware Easy Enrollment Health Insurance Program

House Bill 257, introduced last week, would direct the Insurance Commissioner, in collaboration with the Department of Labor, Department of Health and Social Services, and Department of Finance to develop the Delaware Easy Enrollment Health Insurance Program.

Why this matters: Under this program, individuals filing state tax forms or unemployment compensation applications will be able to select that they currently have health insurance or that they would like assistance in determining their eligibility (or their dependents) for any of the following: Medicaid, Delaware Healthy Children Program, or affordability assistance in an Affordable Care Act Exchange plan.

- The goal of the program is to maximize enrollment of eligible individuals in health care programs to improve access and reduce insurance costs for all residents of Delaware.

According to the Delaware Department of Insurance (DOI), all states offering such a program have state-based exchanges, except for Virginia and Illinois who are operating only CHIP/Medicaid components until they complete their transition to state-based. As such, there is a de facto nullification of the bill's DOI/ACA provisions due to Delaware's federally-facilitated status.

This bill will be considered during the next legislative session in January 2024.

Regulatory

Regulatory Updates

- **Large Group Model Language Posted:** DFS has posted the large group medical model language section updates to the DFS website. The changes from the Individual/Small Group Rider have been incorporated into the medical model language sections. Updated sections can be identified by looking at the "Date Issued" on the DFS website.

- **Consolidated PBM Regulation Proposed:** DFS has a proposed consolidated regulation related to pharmacy benefit managers. This regulation may have implications for health plans that either have PBMs, contract with PBMs or have affiliates that assume functions that could trigger PBM licensure or registration requirements. Comments are due to the Department by July 24, 2023.

- **Updated Cybersecurity Regulation Proposed:** DFS has issued an updated proposed Second Amendment to DFS's Cybersecurity Regulation (23 NYCRR Part 500), reflecting revisions made as a result comments received earlier this year. There is a 45-day comment period, with all comments due by August 14th.

Industry Trends

Policy / Market Trends

CMS Shares Resources for Improving Access to Care for Individuals Living with Disabilities

In conjunction with Disability Pride Month and the anniversary of the Americans with Disability Act (ADA), the Centers for Medicare & Medicaid Services Office of Minority Health (CMS OMH) posted a new article highlighting the unique health care challenges and barriers faced by those living with a disability.

CMS OMH shared several resources pertaining to care for individuals living with disabilities, including:

- Improving Access to Care for People with Disabilities
- Getting the Care You Need: Guide for People with Disabilities
- Autism Spectrum Disorder (ASD) Disparities in Medicare Fee-For-Service Beneficiaries
- How Does Disability Affect Access to Health Care for Non-Dual Eligible Beneficiaries?
- Modernizing Health Care to Improve Physical Accessibility

CMS Posts State-Directed Payment Approvals

On Monday, July 3, the Centers for Medicare & Medicaid Services (CMS) began posting publishing all state-directed payment (SDP) preprints on Medicaid.gov on the Approved State Directed Payment Preprints web page. The page includes links to a revised state directed payments preprint form, as well as a Preprint addendum tables in an Excel workbook.

CMS notes that SDP preprints approved on or after February 1, 2023, are posted, and the site will be updated regularly. As of the release date, SDP approvals were posted for AZ, HI, IL, KY, MD, NC, OR, PA, PR, TN, WA, WV. The types of SDPs posted range from minimum and maximum fee schedules and “targeted investment” payments to uniform rate increases and value-based payments. Approved SDPs are directed to providers such as dental services, academic medical centers, ambulances, behavioral health services, nursing homes, primary care providers, and patient centered medical homes.

For more information on state directed payments, visit the CMS state directed payments Guidance Page.

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/.**