Highmark's Weekly Capitol Hill Report

Issues for the week ending March 3, 2023

Federal Issues

Regulatory

Updates on COVID-19 Commercialization

The U.S. Department of Health and Human Services (HHS) hosted a meeting on COVID-19 commercialization, including the transition of manufacturing, procurement, distribution, and pricing of COVID-19 products and services to the commercial market. The meeting convened a broad array of health care stakeholders and HHS officials to hear from the U.S. government on the commercialization of COVID-19 vaccines and therapeutics.

It is important to note decisions around COVID-19 commercialization are separate from the end of the public health emergency or the authority to issue emergency use authorizations (EUA).

Why this matters : Regarding the commercialization of vaccines, the U.S. government indicated the transition will likely occur in Fall 2023 as part of the adoption of a new strain of the vaccine. In addition, the Department shared updated tentative transition dates for some COVID-19 therapeutics including:

- Lagevrio (Merck and Ridgeback's oral COVID-19 antiviral medicine), which is targeted for late Fall 2023.

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Delaware

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- Paxlovid Pfizer's oral COVID-19 antiviral medicine, which has yet to be determined. The Department had previously planned for a mid-2023 transition but has retracted that date. Of note, commercialization is not tied to FDA's evaluation of approval of Paxlovid, with a decision planned for May 2023.

Although no other timeline estimates for treatments were given, HHS reiterated that timelines will depend on depletion of the federal supply and manufacturer readiness to undergo commercialization.

The Administration for Strategic Preparedness & Response (ASPR) issued a blog post highlighting the meeting, and these Frequently Asked Questions and ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) resource page may also be helpful to Plans.

New York
Legislative
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Pennsylvania
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HHS's Office of Civil Rights Strengthens Oversight with New Enforcement Arm

On Monday, the Department of Health and Human Services' announced the reorganization of three divisions within the Office of Civil Rights. Namely, a new Enforcement Division has been formed alongside a Policy Division and Strategic Planning Division.

Why this matters: The move demonstrates an increasing emphasis by OCR on its enforcement powers over key federal laws, including HIPAA, HITECH, and various federal civil rights and religious conscience protections. Notably, HHS has seen a significant increase in complaints over the last few years, with 51,000 received in 2022—two-thirds of which relate to alleged violations of health information privacy and security laws, as our health care system becomes more connected and data-heavy. Moreover, OCR reports 714 breaches in 2021, each affecting 500 or more individuals—a jump from 663 in 2020. OCR states it is modeling its restructuring with that of the civil rights office at the Department of Education and is designed to provide focus to each division using OCR's limited resources.

DEA Proposes Rules for Permanent Telemedicine Flexibilities

The Drug Enforcement Administration (DEA) announced the proposal of permanent rules for prescribing controlled medications via telemedicine after the expiration of the COVID-19 public health emergency (PHE), under which access to telemedicine services had been expanded.

Why this matters: The proposed rules intend to provide safeguards for a narrow subset of telemedicine consultations – consultations that are conducted by a medical practitioner that has never conducted an in-person evaluation of a patient and result in the prescribing of a controlled medication. **For these types of consultations, the proposed rules would allow a practitioner to prescribe the following:**

- 30-day supply of a Schedule III-V non-narcotic controlled medication.
- 30-day supply of buprenorphine for the treatment of opioid use disorder.

The proposed rules **do not affect**:

- Telemedicine consultations that do not involve the prescribing of controlled medications.
- Telemedicine consultations by a medical practitioner that has previously conducted an in-person medical examination of a patient.
- Telemedicine consultations and prescriptions by a medical practitioner to whom a patient has been referred, as long as the referring medical practitioner has previously conducted an in-person medical examination of the patient.

Next steps: There is a 30-day comment period from March 1; the rule goes into effect May 11 when the COVID-19 public health emergency (PHE) ends, but providers may continue to see patients for which they established virtual relationships during the pandemic for up to 180 days past May 11.

Comments are due on March 26.

CMS Denies Request to Reconsider Medicare Coverage for Alzheimer's Monoclonal Antibody Treatment

CMS has responded to a request from the Alzheimer's Association to reconsider the final national coverage determination (NCD) for the Food and Drug Administration (FDA)-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease, stating that the agency would not reconsider the NCD at this time.

The request for reconsideration of CMS' initial NCD decision was made after the FDA granted accelerated approval to Leqembi, a new anti-amyloid monoclonal from Eisai and Biogen. CMS acknowledged their standard differs from the criteria used by the FDA and the evidence for the monoclonal antibody treatment does not currently meet CMS' criteria to determine if a medication is reasonable and necessary. If a monoclonal antibody directed against amyloid for the treatment of Alzheimer's disease subsequently receives traditional FDA approval, CMS will provide broader coverage using the framework announced last year, under Coverage with Evidence Development (CED), on the same day.

CMS Releases Fact Sheet on End of the COVID-19 PHE & Information on State Timelines for Initiating Unwinding-Related Eligibility Renewals

- CMS released a fact sheet, *CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency.* The fact sheet outlines how certain policies related to the PHE will change when the PHE expires, including beneficiary access to vaccines, testing, and treatments, telehealth services, and other care delivery flexibilities. The fact sheet also confirms that the PHE

will expire at the end of the day on May 11, meaning May 12 will be the first day that coverage mandates tied to the PHE will no longer be in place.

- CMS posted the anticipated state timelines for initiating unwinding-related renewals as of February 24, 2023. The chart details the expected first month that each state or territory will begin initiating eligibility renewals as well as the anticipated effective date for the first procedural eligibility terminations. The earliest date that states may begin terminating the eligibility of Medicaid enrollees is April 1, 2023, following the end of the Families First Coronavirus Response Act's continuous coverage requirement on March 31. States were permitted to begin initiating renewals on February 1. A handful states, including Arizona, Arkansas, Idaho, Iowa, New Hampshire, Ohio, South Dakota, and West Virginia, began initiating renewals in February and will begin terminating eligibility for enrollees on April 1. Most remaining states and territories plan to begin renewals in March and April, meaning that they would begin terminating the eligibility of enrollees beginning in May and June. Two U.S. Territories, Guam and the U.S. Virgin Islands, still have not determined when renewals will resume.

Independent Dispute Resolution Determinations Resume Following *No Surprises Act* Court Decision

The Departments of Health and Human Services, Labor and Treasury (Departments) announced that certified Independent Dispute Resolution (IDR) entities (IDREs) have resumed processing payment determinations for disputes involving items or services furnished before Oct. 25, 2022.

IDREs will continue to hold issuance of payment determinations for disputes that involve items or services furnished on or after Oct. 25, 2022 until the Departments issue further guidance. More information is available here. All other Federal IDR process timelines continue to apply. Therefore, disputing parties should continue to engage in open negotiations and all other aspects of the IDR process, including submitting fees and offers.

CMS Issues Proposed Rule Updating Parameters of Medicaid Disproportionate Share Hospital Program

The Centers for Medicare & Medicaid Services (CMS) proposed a rule to update the regulatory requirements of the Medicaid disproportionate share hospital (DSH) program in response to the Consolidated Appropriations Act of 2021 (CAA 2021).

Background: Distinct from the Medicare DSH program, the Medicaid DSH program provides federal funding allotments to states to provide supplemental Medicaid payments to qualifying hospitals serving uninsured and Medicaid patients.

- States generally have flexibility to target these DSH payments to hospitals.

- However, under federal law, payments to hospitals cannot exceed the "hospital-specific DSH limit" – i.e., the costs a hospital incurred for providing inpatient and outpatient hospital services during the year to certain Medicaid and uninsured patients, less other payments it received from uninsured patients and under the Social Security Act.

Why this matters: CAA 2021 modified the Medicaid portion of the hospital-specific DSH limit calculation to include only costs and payments for services delivered to patients for whom Medicaid is the primary payer for such services. Accordingly, the proposed rule would update provisions related to third-party payments to exclude costs and payments for services provided to Medicaid beneficiaries with other sources of coverage, including Medicare and commercial insurance. It would also clarify regulatory language for the DSH program, including payment and financing definitions, refine administrative procedures for state compliance with federal regulations, and remove regulatory requirements that CMS said have been "difficult to administer and do not further the program's objectives."

Comments to the proposed rule are due April 25, 2023.

CMS Issues Guidance Outlining Medicaid and CHIP Accessibility Requirements

CMS issued guidance for Medicaid and Children's Health Insurance Program (CHIP) agencies on federal requirements and flexibilities in providing language services to individuals with limited English proficiency (LEP) and effective communication to individuals with disabilities to ensure compliance.

Why this matters: The guidance outlines language access and effective communication requirements for Medicaid and CHIP in federal Medicaid and CHIP regulations, under Section 1557 of the ACA, Title VI of the Civil Rights Act of 1964, the Americans with Disabilities Act, Section 504 of the Rehabilitation Act, and implementing regulations. It also outlines the parameters and processes for claiming federal Medicaid and CHIP funds for language access services, noting an increased federal match is available for allowable expenditures for translation or interpretation services in connection with the enrollment, retention, and receipt of covered services by children of families for whom English is not the primary language.

State Issues

Delaware

Legislative

Doula Medicaid Coverage Legislation Introduced

House Bill 80 was introduced last week, which would require that doula services be covered by Medicaid in Delaware by January 1, 2024. It follows up on HB 343 from the 151st General Assembly which required the Division of Medicaid and Medical Assistance to submit a plan for implementing this coverage and draws on that completed report.

Why this matters: Births with a doula have been found by the American Pregnancy Association to be less likely to require pain medication and less likely to result in a birth via cesarean section.

The Maternal Mortality Review on infant and fetal death found that the most common accompanying issues were related to providing a family with support in making medical decisions impacting their care, easily accessing care, and effectively communicating with healthcare professionals.

State Issues

New York

Legislative

Legislature Holds Health Budget Hearing

The Assembly Ways & Means and Senate Finance committees last week held their joint hearing on the Executive Budget's health spending proposals. Over the course of nearly eight hours, lawmakers heard testimony from and asked questions of the Department of Health's Commissioner and Medicaid Director and the Superintendent of the Department of Financial Services, as well as representatives of more than two dozen organizations and advocacy groups.

Remarks presented by HPA's president and CEO Eric Linzer focused on four key issues included in HPA's written testimony, calling for lawmakers to take the following positions on provisions in the budget:

- Oppose the pay and pursue proposal that would require plans to pay hospitals for emergency services and any resulting inpatient admission before those institutions would have to submit information to determine whether the service or treatment was medically necessary;
- Restore funding that the Governor's budget eliminated dedicated to the Medicaid quality pools, arguing this money is vital to support plan efforts to improve health outcomes for New York's most vulnerable underserved populations;
- Reverse the planned carve-out of the pharmacy benefit from the Medicaid managed care program, scheduled to take effect April 1; and
- Reject the proposed "reform" of the managed long term care program, advocating that lawmakers have time to review the interim report – provided to the Legislature only the night before the hearing – in order to better understand the impact any changes might have in disrupting the care delivered to patients in the MLTC program.

State Issues

Pennsylvania

Legislative

Senate Committee Advances Prohibition on Cost Sharing for Breast MRI and BRCA Gene Testing Legislation

On Tuesday, February 28, the Senate Banking and Insurance Committee advanced Senate Bill 8 (K. Ward, R-Westmoreland). Senate Bill 8 prohibits cost sharing MRIs for individuals with dense breast tissue and for genetic counseling and genetic testing for the BRCA1 and BRCA2 gene mutation for individuals believed to be at an increased risk due to personal or family history of breast or ovarian cancer. Senate Bill 8 now awaits consideration from the full Senate.

State Issues

West Virginia
Legislative

House Committee Advances Prior Authorization Legislation
On Friday, March 3, the House Health and Human Resources Committee advanced Senate Bill 267 (Takubo, R-Kanawha). Senate Bill 267 proposes significant changes to prior authorization request timelines, appeal timelines and gold carding standards. Senate Bill 267 now awaits consideration from the full House.

House Advances Insulin Cap Legislation
On Friday, March 3, the House advanced Senate Bill 577 (Maroney, R-Marshall) and now awaits consideration from the Governor. Senate Bill 577 proposes $35 copay cap on insulin per 30-day supply and further seeks to impose a $100 copay cap on diabetic devices per 30-day supply.

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/.**