Highmark's Weekly Capitol Hill Report

Issues for the week ending September 2, 2022

Federal Issues

Regulatory

HHS Meeting on COVID-19 Commercialization

On August 30, various stakeholders participated in the U.S. Department of Health and Human Services (HHS) COVID-19 Medical Countermeasures Commercialization meeting. This meeting convened health care stakeholders and HHS officials to hear from the U.S. government on potential transition plans for the commercialization of COVID-19 vaccines and therapeutics which is expected to be completed by mid-2023. Dawn O'Connell, HHS Assistant Secretary for Preparedness and Response released a detailed blog post summarizing the meeting and next steps.

Key highlights from the call include:

- Most products will be commercialized by early to mid-2023.
- Each product will have a unique commercial transition period dependent on federal supply, federal funding and manufacturer production bandwidth.
- HHS is committed to having accurate information on pricing, timelines and patient

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assistance programs from manufacturers, understanding that health plans need that information to set rates and bids.

- The Food and Drug Administration (FDA) is updating each product's Letter of Authorization to allow commercial sales and distribution while under an Emergency Use Authorization (EUA).

- The Office of the Assistance Secretary for Planning and Evaluation (ASPE) released a detailed report on coverage and reimbursement of these products the day after the meeting.

Why this matters: The specific transition plan will vary by product type, available funding, impacted age group (pediatric versus adults) and demand. Of note, decisions around COVID-19 commercialization will be made independently of any decisions about whether to end the public health emergency or to continue the authority to issue emergency use authorizations (EUAs).

Therapeutics
Tentative transition dates for COVID-19 therapeutics include:

- Evusheld (AstraZeneca's monoclonal antibody treatment): January 2023

- Lagevrio (Merck and Ridgeback's oral COVID-19 antiviral medicine): Early to Mid-2023

- Paxlovid (Pfizer's oral COVID-19 antiviral medicine): Mid-2023

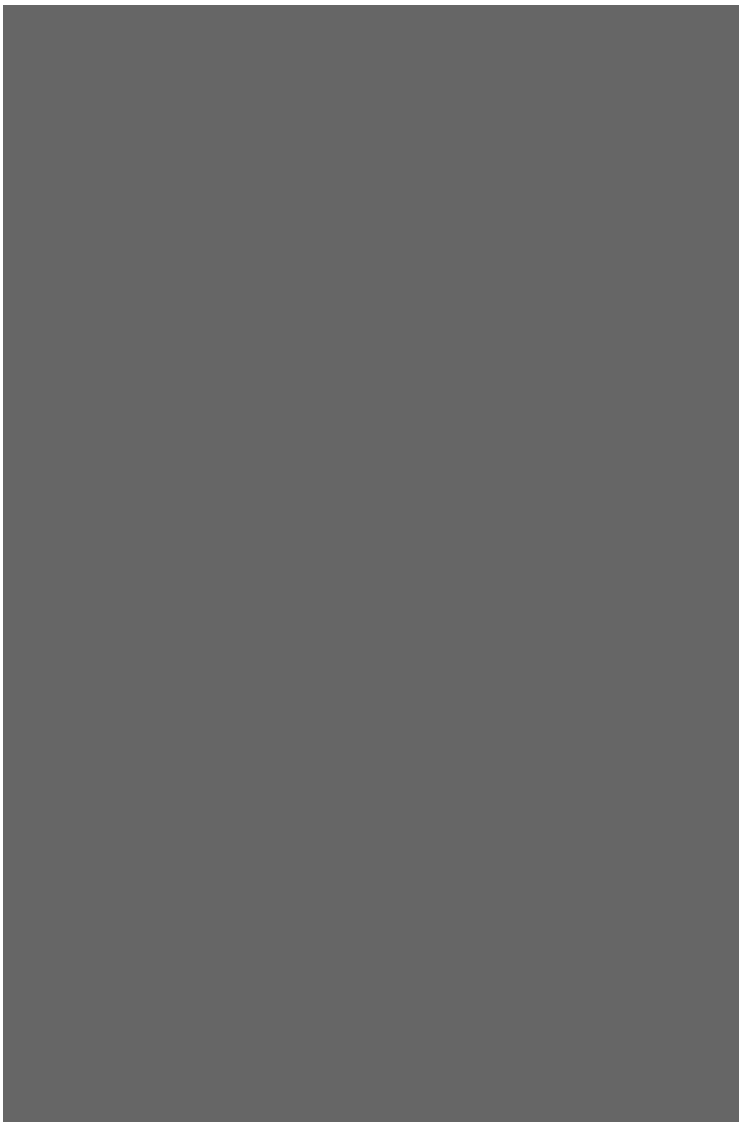
Eli Lilly's monoclonal antibody, bebtelovimab, became commercially available earlier this month and was touted as a case study for how other COVID-19 therapeutics would be transitioned to the commercial market. More information is forthcoming on ensuring access for the uninsured and individual pharma manufacturers patient assistance programs.

Vaccines

- **Behavioral Health Commission Established**
- **The Latest Guidance on Outpatient Emergency Departments**

The U.S. government indicated transition for the commercialization of vaccines will occur “as early as January 2023” following the fall vaccine campaign focused on the new omicron-specific COVID-19 boosters planned first for adults and later for children. Specific timing is dependent on funding and demand. Speakers recognized the need for future ACIP guidance on: the extent that ongoing vaccination will continue to be needed among different populations, vaccine schedules related to series and doses, booster frequency and interchangeability. Post-commercialization, the U.S. government indicated it will be transitioning to use the Vaccines for Children’s program for uninsured children and is seeking additional funding for a new similar program aimed at immunizing uninsured adults.

HHS heard feedback from stakeholders on numerous topics including the need for adequate lead time and transparency, pricing and reimbursement issues, the procurement process, ensuring equitable access, particularly for the uninsured and under-insured, ensuring an adequate supply, data reporting, the future role of pharmacists, and coverage and regulatory issues unique to specific insurance types. HHS indicated that it will continue to review questions from stakeholders and will share more information in the coming days.



CMS Issues First Medicaid Rule Tackling Looming Eligibility Redeterminations

The Centers for Medicare & Medicaid Services (CMS) issued a Notice of Proposed Rule Making (NPRM), which proposes numerous actions to make it easier for children, older adults, and people with lower incomes with Medicaid and Children's Health Insurance Program (CHIP) coverage to enroll in and retain vital health insurance. **Actions proposed in the rule include:**

- Requiring states to adhere to certain eligibility and enrollment policies, such as limiting renewals to once every 12 months, allowing new applicants 15 days (30 days if disabled) to respond to requests for information, and allowing 30 days to respond to requests for information needed for redeterminations
- Requiring states follow standard procedures for collecting updated contact information and handling returned mail
- Permitting states to transfer eligibility from Medicaid to CHIP when a family's income rises
- Limiting states' ability to restrict or impose additional conditions on CHIP enrollment; including prohibiting annual or lifetime benefit limits in CHIP
- Simplifying and promoting enrollment in the Medicare Savings Program

The rule is now open for a 60-day public comment period, which ends Nov. 6. CMS will include effective and compliance dates in the final rule.

This proposed rule follows President Biden's executive orders in April 2022 and January 2021 directing federal agencies to take action to expand affordable, quality health coverage, including by strengthening Medicaid and the Affordable Care Act.

CMS Announcement on the Medicare Part D Senior Savings Model

On Sept. 1, CMS sent messaging to Part D Senior Savings Model (PDSS) applicants noting the model will continue for 2023. However, there is uncertainty about the continuance of the model given the Inflation Reduction Act provision limiting insulin copays effective for 2023.

The Model aims to reduce Medicare expenditures while preserving or enhancing quality of care for beneficiaries by offering a Part D benefit design that includes stable, predictable copays for select insulins (no more than $35 per prescription for the month's supply) in the deductible, initial coverage, and coverage gap phases. The Model does this by offering supplemental benefits that apply after manufacturers provide a discounted price for a broad range of insulins.

HRSA Announces New Maternal and Infant Health Grant Opportunities

The Health Resources and Services Administration (HRSA) will invest over $20 million to address the nation's maternal and infant health crisis.

Why this matters: The United States has the highest maternal mortality rate of any developed nation and with a majority of pregnancy-related deaths deemed preventable. According to CDC data, Black women are more than three times as likely as White women to die from pregnancy-related causes. And, a black mother with a college education is at 60 percent greater risk for maternal death than a White or Hispanic woman with less than a high school education. The investments made by the administration are intended to address these disparities along with increase access to and coverage of high-quality maternal health services.

In addition to addressing mortality rates, the HRSA grants will support state-led maternal health innovation, improve maternal care in rural communities, and increase access to community-based doula.

COVID-19 Updates

Omicron Boosters: The Food and Drug Administration (FDA) amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 vaccines to authorize bivalent formulations of the vaccines to target Omicron subvariants. The updated boosters were authorized for use as a single booster dose at least two months following primary or booster vaccination. By updating the EUAs, the monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for individuals 12 years of age and older.

The FDA's Advisory Committee on Immunization Practices (ACIP) voted to recommend the use of the bivalent mRNA COVID-19 vaccines as a single-dose booster for all individuals ages 12 and older (Pfizer-BioNTech) and 18 and older (Moderna), at least two months following primary series or previous booster dose. The ACIP recommendation for the bivalent boosters was approved by a vote of 13-1. The recommendation will now move to Centers for Disease Control and Prevention Director Dr. Rochelle P. Walensky for her approval.

Telehealth for OUD Services During COVID-19 Associated with Reduced Risk of Overdose

On August 31, *JAMA Psychiatry* published a study that examined the role of emergency authorities to expand telehealth use for substance use disorder treatment and facilitate provision of medications for opioid use disorder (MOUD) during the COVID-19 pandemic. Buprenorphine, a controlled substance, is used in combination with counseling and behavioral therapies as a treatment for OUD called medication-assisted treatment (MAT). Researchers from CMS, CDC and NIDA examined data for 175,778 Medicare beneficiaries. They found that receipt of OUD-related telehealth services during the COVID-19 pandemic was associated with improved MOUD retention and lower odds of medically treated overdose. The findings, according to the authors, lend support for the permanent extension of Medicare telehealth flexibilities. The authors concluded by noting that "strategies to expand provision of MOUD and increase retention in care are urgently needed."

Why this matters: The current flexibilities that allow Medicare to pay for OUD and other services via telehealth without restrictions will expire 151 days after the public health emergency ends. However, the flexibility from the DEA that allows for the remote prescribing of controlled substances via telehealth will end when the PHE expires.

MAT has been found to be one of the most effective forms of therapy for OUD and during the pandemic has been able to be conducted via telehealth because of the DEA waiver. DEA has drafted special registration

rules for telemedicine as well as a rule for audio only telemedicine for buprenorphine initiation for treatment of OUD, but those rules have not yet been published. If the PHE ends imminently, it is highly likely that there would be a period of time during which the waivers expire but the rules are not yet finalized, and those currently benefiting from OUD treatment via telehealth would lose access to that service.

CMS Reports Annual Medicare Shared Savings Program Savings

The Centers for Medicare and Medicaid Services announced that the Medicare Shared Savings Program, through the Accountable Care Organizations (ACOs), saved Medicare $1.66 billion in 2021. The Shared Savings Program ACOs are made up of doctors, hospitals, and other health care providers who coordinate the delivery of high-quality care while avoiding unnecessary expenditures. Over 525,000 clinicians, servicing more than 11 million people, participate in the Shared Savings Programs. Almost all ACOs reported and met the quality standard required to share in savings under the Shared Savings Program. ACOs tended to have a higher performance rating for the services they provided compared to other clinicians not in the program. This includes higher performance for quality measures related to diabetes and blood pressure control; breast cancer and colorectal cancer and falls risk screening rates; flu vaccination; tobacco screening and smoking cessation; statin therapy for the treatment and prevention of cardiovascular disease.

CMS Report on Medicaid LTSS Demographics

The Centers for Medicare & Medicaid Services (CMS) released a new report examining Medicaid beneficiaries who use long-term services and supports (LTSS) across different home and community-based services (HCBS) and institutional categories during 2019. Institutional services include nursing facilities, intermediate care facilities for individuals with intellectual disabilities, and mental health facilities. HCBS includes personal care services, Section 1915(c) waiver programs, private duty nursing, and other services.

Why this matters: The report defined LTSS categories in two different ways – one based on categories traditionally tracked by CMS, the other based on categories in the American Rescue Plan Act (ARPA) of 2021 - and determined user counts separately for each definition. For example, using the ARPA definition, the report found that **8.8 million Medicaid beneficiaries across 50 states and the District of Columbia received LTSS in 2019**. Of the 8.8 million LTSS users, **1.7 million beneficiaries (19%) received institutional services**, **7.4 million (84.3%) received HCBS**, and **0.3 million (3.3%) received both**. Managed care covered 57.5 percent of the service users for LTSS, and fee-for-service (FFS) was the delivery system for 50.2 percent of the service users.

The full analysis also includes detailed charts on managed care and fee-for-service LTSS data by state.

Issue Brief: Unwinding the Medicaid Continuous Enrollment Provision

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) released an issue brief this month detailing implications of the unwinding of the continuous enrollment provision at the end of the Public Health Emergency (PHE) for Medicaid enrollees.

Why this matters : The report provides ***current HHS projections of the number of individuals predicted to lose Medicaid coverage*** at the end of the COVID-19 and outlines administrative actions that will help mitigate coverage loss.

Highlights from the issue brief include:

- At the end of the PHE, HHS projects that 17.4% of Medicaid and Children's Health Insurance Program (CHIP) enrollees (approximately 15 million individuals) will leave the program based on historical patterns of coverage loss.
- Approximately 9.5% of Medicaid enrollees (8.2 million) will leave Medicaid due to loss of eligibility and will need to transition to another source of coverage.
- Based on historical patterns, 7.9% (6.8 million) will lose Medicaid coverage due to administrative barriers, despite still being eligible (also called administrative churn).
- Children and young adults will be impacted disproportionately, with 5.3 million children and 4.7 million adults ages 18-34 predicted to lose Medicaid/CHIP coverage. Nearly one-third of those predicted to lose coverage are Latino (4.6 million) and 15% (2.2 million) are Black.
- Almost one-third (2.7 million) of those predicted to lose eligibility are expected to qualify for Marketplace premium tax credits. Among these individuals, over 60% (1.7 million) are expected to be eligible for zero-premium Marketplace plans under the provisions of the American Rescue Plan (ARP). Another 5 million would be expected to obtain other coverage, primarily employer-sponsored insurance.

CMS is beginning to take action including the release of a proposed rule to address loss of coverage due to administrative churn. The streamlining Eligibility and Enrollment Notice of Propose Rulemaking (NPRM) responds to President Biden's Executive Orders (January 2021 and April 2022) seeking to strengthen Medicaid and access to affordable, quality health coverage. CMS estimates that this proposed rule would remove barriers to enrollment and increase the number of eligible individuals who obtain coverage and are continuously enrolled in Medicaid and CHIP.

The full ASPE issue brief can be read here.

State Issues

New York

Regulatory

Coverage Mandates for Monkeypox

Last week, Governor Hochul extended Executive Order 10 which includes language requiring coverage of the monkeypox virus immunization, without any copayments, coinsurance, or annual deductibles, and waiving cost sharing for this immunization when provided out-of-network. It also requires coverage, without cost-sharing, for in-network doctor visits or laboratory testing necessary to diagnose the monkeypox virus.

The Department of Financial services issued a Circular Letter (CL 12) providing guidance on the coverage requirements. The CL is modeled on the coverage rules issued for COVID-19 testing, diagnosis and vaccines.

State Issues

Pennsylvania

Legislative

Behavioral Health Commission Established

The Behavioral Health Commission for Adult Mental Health, which was created as part of the recently enacted state budget (HB 1421), held its first meeting on August 18 and has three more meetings scheduled for September. The Commission is charged with producing a report with funding recommendations on several topics of importance to the health care industry, following appropriation by the legislature of $100 million of American Rescue Plan Act (ARPA) funding for adult mental health programs.

The following are among the topics that must be included in the Commission's report:

- Delivery of services by telemedicine
- Behavioral health rates, network adequacy, and mental health payment parity
- Integration of behavioral health and substance use disorder treatment
- Cultural competencies when providing behavioral health care
- The impact of social determinants of health on behavioral health
- The intersection of behavioral health and the criminal justice system
- Establishing an integrated care model to deliver timely psychiatric care in primary care settings

Appointed membership of the Commission includes, among others, the Acting Insurance Commissioner, the Chief Medical Officer, Department of Human Services, Office of Mental Health and Substance Abuse Services, the Executive Deputy Secretary of Drug and Alcohol Programs, and the Deputy Secretary of Health Resources and Services.

Meetings of the Commission are open to the public and will include both in-person and remote participation options. The website has details about attending remotely. Meetings are currently scheduled to be held on September 1, September 8, and September 15, 2022.

The Latest Guidance on Outpatient Emergency Departments

Last week, the Pennsylvania Department of Health (DOH) issued revised guidance to implement Outpatient Emergency Departments (OED).

The most significant revisions to the policy include:

- Removal of the geographic limitations to rural areas.
- Addition of mileage criteria that would not allow for the implementation of OEDs within 35 miles of an existing emergency department.

These changes are a result of multiple discussions between stakeholders including hospitals, members of the General Assembly, DOH, and the governor's office following the release of the original OED guidance early this year.

To be authorized to operate an OED, a hospital shall meet the following criteria:

- The main licensed hospital of an OED shall offer general acute care services.
- The OED shall be included as an outpatient location under the license of the hospital and must be located within a 35-mile radius of the main licensed hospital.
- At the time the OED begins operating, the OED shall have a catchment area that is no less than 35 miles of travel distance established by roadways to a main licensed hospital or a campus that offers emergency services and is not under common legal ownership with the OED or another OED that is not under common legal ownership.
- The hospital shall continue to meet the statutory definition of "hospital" as defined in Section 802.1 of the Health Care Facilities Act by devoting 51 percent or more of its total beds to inpatient care.

Recently, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule that would establish conditions of participation (CoP) for the newly created rural emergency hospitals (REH) which was established in the Consolidated Appropriations Act of 2021.

Why this matters: Currently, Pennsylvania law does not allow for REHs in the state. DOH has not yet issued a plan regarding how they propose to amend state law to create this new provider type and allow for REHs in the Commonwealth.

OEDs and REHs are two distinct model types. Both in theory can coexist if the state establishes the necessary provider type.

For additional information, reference DOH's updated documents:

- **Hospital guidance to implement an OED**
- **FAQ for innovative care models for hospitals**
- **Innovative hospital model matrix**

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/.**