Highmark's Weekly Capitol Hill Report

Issues for the week ending September 24, 2021

Federal Issues

Legislative

Lawmakers Continue Work on Reconciliation, Government Funding

Democratic lawmakers continued to work through the weekend in search of an agreement on a budget reconciliation package. The work comes after President Biden met with key House and Senate negotiators last week to urge them to reach an agreement on a path forward. It appears they have agreed on a menu of options from which to negotiate, however, the size and scope of the package remain sticking points, with key senators demanding the package be reduced from the current $3.5 trillion price tag.

Nonetheless, on Saturday, the House Budget Committee moved forward with a markup consolidating the language that passed key committees earlier in the month into a single legislative package. The move brings the package one step closer to a floor vote, although it still must be taken up by the Rules Committee and it is unclear if House Speaker Nancy Pelosi (D-CA) has the votes to pass the package in its current form.

On a separate track, the House last week passed a continuing resolution (CR) to keep the government

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funded through Dec. 3, as well as provisions to suspend the debt ceiling and provide hurricane relief. The House package is not expected to pass the Senate, with Republican Leader McConnell holding firm to his pledge not to support a CR that includes debt ceiling relief. With government funding set to expire on Friday, a resolution is unclear, although passage of a shorter-term CR without a debt ceiling provision appears likely.

State Issues

New York

Regulatory

- **Vaccine Mandate for Health Care Workers**
- **Department of Health Commissioner Resigns**
- **Regulations Extended**

Federal Issues

Regulatory

CMS Announces It Will Pay for COVID-19 Booster Shots Without Patient Cost-Sharing

The Centers for Medicare & Medicaid Services (CMS) announced it will provide coverage for COVID-19 vaccines and their administration, including booster shots, for Medicare beneficiaries without cost-sharing.

CMS issued a corresponding press release discussing booster shot coverage emphasizing that nearly all Medicaid and CHIP beneficiaries and nearly all individuals enrolled in commercial coverage would receive the booster dose and administration without cost-sharing. The Biden Administration also updated the CDC COVID-19 Vaccination Program Provider Requirements and Support and the CMS COVID-19 Provider Toolkit in conjunction with the announcement.

Biden Administration Issues New Guidance on COVID-19 Workplace Safety for Federal Contractors

The Biden Administration, through the Safer Federal Workforce Task Force, released new guidance on COVID-19 workplace safety protocols for federal contractors and subcontractors.

According to the guidance, employees of covered contractors must be fully vaccinated by December 8, 2021, unless they are legally entitled to an accommodation.

The guidance also requires masking and physical distancing while in covered contractor workplaces and designation by covered contractors of a person or persons to coordinate COVID-19 workplace safety efforts at covered contractor workplaces.

The Administration will issue guidance by October 8 for agencies to add a clause related to these COVID-19 workplace safety protocols to covered Federal procurement solicitations and contracts subject to the Federal Acquisition Regulation (FAR).

Updates from Federal Health Agencies

- The Centers for Medicare & Medicaid Services (CMS) awarded $15 million in planning grants to 20 states to support expanding community-based mobile crisis intervention services for Medicaid beneficiaries. The planning grants, funded by the American Rescue Plan, provide an opportunity for state Medicaid agencies to integrate community-based mobile crisis intervention services into their Medicaid programs and help individuals who are experiencing a substance use-related or mental health crisis outside a hospital or facility setting.

- **COVID Updates**
  - Pfizer announced results from a pediatric trial that found the COVID-19 vaccine is safe and effective in children aged 5 to 11. The company plans to file for emergency use with the Food and Drug Administration in the coming weeks.
  - Johnson & Johnson stated that its COVID-19 booster shot strengthens protection against moderate illness and severe disease. The company said a late-stage clinical trial found that giving a second shot of the single-dose vaccine produced 75% protection against moderate and severe disease globally, and 94% protection in the United States.
  - The Advisory Committee on Immunization Practices (ACIP) at the Centers for Disease Control and Prevention (CDC) voted in favor of the use of a booster shot of the Pfizer-BioNTech COVID-19 vaccine in certain populations. The endorsement comes after the U.S. Food and Drug Administration (FDA) amended its emergency use authorization (EUA) yesterday for the vaccine, to be administered at least six months after completion of the original two doses for certain populations. The authorization applies to:

    - individuals 65 years of age and older;
    - individuals 18 through 64 years of age at high risk of severe COVID-19; and
    - individuals 18 through 64 years of age whose frequent institutional or occupational exposure to COVID-19 puts them at high risk of serious complications if infected.

CDC Recommends Pfizer Booster Shots For Select Populations Consistent with FDA Authorization

Dr. Rochelle Walensky, Director of the Centers for Disease Control and Prevention (CDC), announced updated interim guidance on COVID-19 booster shots. The guidance not only adopted the Advisory Committee on Immunization Practices (ACIP) recommendations, but also expanded on them by adding individuals who are at high risk of exposure due to occupational or institutional settings, including healthcare workers and other people whose jobs put them at risk. While deviating from the ACIP recommendations is unusual, the CDC noted that the expansion is in line with the Food and Drug Administration recommendation.

The CDC's expanded recommendation, authorized by Dr. Walensky:

- People aged 65 years and older and residents in long-term care settings **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- Aged 50–64 years with underlying medical conditions **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- Aged 18–49 years with underlying medical conditions **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and
- Aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

In the coming days and weeks, the Administration will address recommendations related to the Moderna and J&J vaccines as data is available.

HRSA Announces Funding to Strengthen Maternal and Child Health

The U.S. Department of Health and Human Services (HHS) announced nearly $350 million in awards to every state across the nation to support safe pregnancies and healthy babies. The U.S. lags behind developed nations on maternal and infant outcomes, particularly among African-American, Latinx, and Native American populations. Funding will expand home visiting services to families most in need, increase access to doulas, address health disparities in infant deaths, and improve data reporting on maternal mortality. The Health Resources and Services Administration (HRSA) is making these key investments through the following maternal and child health programs:

- The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, which supports pregnant people and parents with young children who live in communities that face greater risks and barriers to achieving positive maternal and child health outcomes.

- The Healthy Start Initiative supports communities where the infant mortality rate is 1.5 times the national average. Funding to this initiative will particularly support
    - Community-Based Doulas
    - Infant Health Equity
    - State Systems Developmental Initiative

TEFCA Common Agreement Released for Public Comment, AHIP to Respond

The Sequoia Project (RCE)* released a Common Agreement for public comment. The agreement comes as a response to the 21st Century Cures Act's directive to the Office of the National Coordinator for Health Information Technology (ONC) to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally."

Why this matters: The Common Agreement would establish the infrastructure model and governing approach for users in different information exchange networks to securely share information under commonly agreed-to expectations and rules. The goal of the Common Agreement is to establish a floor of

universal interoperability across the country for health care using baseline legal and technical requirements for secure information sharing.

Responses are due October 21, 2021.

The RCE will be hosting a series of webinars to review topics in the Common Agreement. To participate, please register with the RCE's website.

**The Sequoia Project is the Recognized Coordinating Entity (RCE) for the Trusted Exchange Framework and Common Agreement (TEFCA) work, acting under a cooperative agreement from the HHS Office of the National Coordinator for Health Information Technology (ONC).*

U.S. Supreme Court Schedules Oral Arguments for 340B Reimbursement Cuts

The U.S. Supreme Court announced that it will hear oral arguments on November 30, 2021 in the clash between hospitals and the U.S. Department of Health and Human Services (HHS) over Medicare Part B reimbursement cuts.

During July, the court announced that it would hear the case, *American Hospital Association et. al. v. Xavier Becerra*. Hospitals have been in a legal battle since 2018, when nearly 30 percent cuts in Part B-related 340B drug reimbursements began under the Trump Administration. The Supreme Court agreed to intervene after a 2-1 decision in support of the cuts was handed down by the U.S. District of Columbia (DC) Court of Appeals during July 2020.

A decision by the Supreme Court is not expected until the spring of 2022, months after the Biden Administration determines whether to retain the controversial cuts. The Biden Administration surprised 340B hospitals during July when it proposed to keep the cuts in the Centers for Medicare & Medicaid Services' proposed 2022 outpatient prospective payment rule.

Why this matters: The AHA, joined by member hospitals and health systems and other national organizations representing 340B hospitals in February appealed to the Supreme Court a lawsuit challenging the U.S. Department of Health and Human Services' nearly 30% 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.

HRSA Refers 6 Drug Manufacturers to the OIG for Potential Penalties for Continued Refusals of 340B Contract Pharmacy Pricing

The Health Resources & Services Administration (HRSA) September 22, 2021, referred the cases of six drug companies to the U.S. Health and Human Services (HHS) Office of Inspector General (OIG) for what HRSA has concluded are continued violations of federal 340B law requiring discounts on drugs dispensed at contract pharmacies.

Michelle Herzog, acting director of HRSA's Office of Pharmacy Affairs, sent letters to Eli Lilly, AstraZeneca, Novartis, Novo Nordisk, Sanofi, and United Therapeutics informing the companies about the referrals. The

OIG, an independent office within HHS, now must decide whether the companies should be assessed civil monetary penalties for “knowingly and intentionally” overcharging 340B covered entities. American Hospital Association (AHA) General Counsel Melinda Hatton said, “we requested that HRSA take this action and urge the OIG to move swiftly in an effort to provide relief for the hospitals adversely affected by this unlawful conduct.”

All six companies receiving the latest letters had received prior letters from HRSA notifying them that their actions violated the law, and all six have sued in federal courts to block the government’s enforcement of the 340B statute against them. An additional two companies—Boehringer Ingelheim and Merck—also have implemented 340B pricing restrictions on contract pharmacy arrangements but those companies have not yet received government notices informing them that they are violating federal law.

Why this matters: 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.

State Issues

New York

Regulatory

Vaccine Mandate for Health Care Workers

Monday, September 27 marked the deadline for when health care workers in New York hospitals and nursing homes must be vaccinated or risk losing their jobs. Governor Hochul last week said that the state stands by the mandate and intends to move forward with it.

According to data from the Department of Health, 84 percent of New York hospital workers had been fully vaccinated as of September 22, while 83 percent of workers at skilled nursing facilities and 85 percent at adult care facilities were vaccinated as of September 22.

Department of Health Commissioner Resigns

New York State Health Commissioner Howard Zucker last week submitted his resignation. Governor Hochul announced the news, praising him as a “dedicated public servant for over seven and a half years” and saying he agreed to stay on until the position is filled. While the Governor did not say who is being considered to take over as head of DOH, reports late last week said Dr. Mary Bassett – former New York City Health Commissioner under Mayor de Blasio – has “soared to the top of the state’s shortlist.”

Regulations Extended

- **COVID-19 Vaccinations —** The emergency regulation waiving cost sharing for COVID-19 vaccinations, scheduled to expire September 22, has been extended until December 20.

- **Audio-Only Telehealth Services** — The regulation requiring coverage of telehealth services including audio-only services, which had been promulgated on an emergency basis and is set to expire on October 1, is now a proposed regulation. Neither the emergency regulation nor the new proposed regulation prohibit cost sharing for telehealth services.

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/.**