Highmark's Weekly Capitol Hill Report

Issues for the week ending July 23, 2021

Federal Issues

Legislative

Energy and Commerce Committee Advances Health Bills

On Wednesday, the House Energy and Commerce Committee held a full committee markup of 16 health care bills, including legislation on maternal health and vaccines, as well as other proposals related to public health and the opioid epidemic. Lawmakers voted to advance the health care bills — as well as other proposals on cybersecurity and telecommunications — to the full House of Representatives.

Key bills passed include:

- H.R. 951 – the Maternal Vaccination Act, would require existing immunization programs to include outreach efforts to pregnant and postpartum individuals and obstetric care providers, as well as update grant programs to include efforts to improve maternal vaccination rates as an allowable use of funds. The existing vaccine outreach authorization would also be increased each fiscal year (FY) by $2 million, to $17 million. The legislation is also a component of the larger Black Maternal Health "Momnibus"

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package, which BCBSA and the American Hospital Association (AHA) also supports.

- H.R. 4026 – the Social Determinants of Health Data Analysis Act of 2021, would require, among other things, GAO to submit to Congress within two years of enactment a report on the actions taken by the Secretary of Health and Human Services (HHS) to address social determinants of health.

- H.R. 3894 – the Collecting and Analyzing Resources Integral and Necessary for Guidance (CARING) for Social Determinants Act of 2021, would require the Secretary of HHS to provide guidance and technical assistance to states on how to address social determinants of health through Medicaid and CHIP. It would require that the guidance be updated every three years.

A full list of bills passed during the markup is available here.

- **Update: Prompt Payment Complaint Penalties**
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Congressional Social Determinants of Health Caucus Formed

On Wednesday, a bipartisan group of lawmakers announced the formation of a new Congressional Social Determinants of Health (SDOH) Caucus.

- **Why it matters**: the SDOH Caucus will bring together more than 20 bipartisan members of Congress to highlight opportunities for coordination across federal investments in health, public health, food, housing, transportation and other important drivers of health.

  Specifically, the caucus will spotlight the disparate impact of the COVID-19 pandemic on certain populations and communities; convene thought leaders to educate members on the evidence around social determinants; collect stakeholder input on how best to facilitate effective social determinant interventions; discuss bipartisan legislative efforts to address social determinant challenges; and highlight priorities to external stakeholders and the Executive branch. It invites comments from stakeholders through Sept. 21 on challenges and opportunities related to social determinants of health.

Hospital industry position: The AHA supports the caucus as a member of Aligning for Health, a coalition advocating for federal and state solutions to address the social determinants of health.

Insurance industry position: In a press release issued by Aligning for Health, Justine Handelman, senior vice president for the Office of Policy and Representation at BCBSA, commended the news and said, "Social factors — like where we live and work, and our access to healthy food and transportation — play a critical role in shaping Americans' health and the health of our communities. […] We are thrilled to see Congress come together to form the Social Determinants of Health Caucus, whose work will put people and their needs first, allowing them to live longer, healthier lives. Thank you to Reps. Cheri Bustos, G.K. Butterfield, Tom Cole and Markwayne Mullin, as we look forward to working with the caucus to advance health equity."

Federal Issues

Regulatory

CMS Releases Medicare Hospital Outpatient Prospective Payment System Proposed Rule for 2022

The Centers for Medicare & Medicaid Services (CMS) released a proposed rule that revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2022.

Why this matters:

- In the proposed regulation CMS proposes several changes to the Hospital Price Transparency final rule including increasing the penalty for noncompliance by using a scaling factor based on hospital bed count, prohibiting certain conduct that it believes results in barriers to accessing the information, and clarifying the expected output of online price estimator tools that can be offered in lieu of a consumer-friendly "shoppable services" webpage.

- Additionally, CMS issued proposed requirements for online price estimators which can be used in lieu of posting standard charges for 300 shoppable services. Such a tool must factor a patient's insurance information into the estimate.

- CMS also proposes to remove policies that were previously intended to shift services from inpatient hospitals to outpatient departments and ASCs. Specifically, CMS proposes to halt the elimination of the Inpatient Only (IPO) list that restricts coverage of certain services to hospitals and to add back the services removed from the IPO list beginning in CY 2022. Conversely, CMS reinstates the safety criteria for adding a procedure to the ASC Covered Procedure List (CPL) and removes 258 of the 267 procedures that were added to the ASC CPL in CY2021.

- CMS proposes to proceed with changes to the mandatory bundled payment Radiation Oncology Model that had been delayed by the Consolidated Appropriations Act of 2021 including adjusting the pricing methodology, removing brachytherapy from the included modalities, and paying fee-for-service rates when a beneficiary switches from traditional Medicare to Medicare Advantage before treatment is complete.

- In addition, CMS seeks comment on advancing health equity through its quality reporting programs, transitioning to the use of digital quality measures, defining rural emergency hospitals, and

permanently adopting certain flexibilities that were implemented to address the COVID-19 public health emergency.

For more information on the rule, please see this CMS fact sheet. Comments are due September 17, 2021.

Administration Clarifies Insurance Coverage of HIV Prevention Drugs

The Departments of Labor, Health and Human Services (HHS), and Treasury – the Tri-Agencies – released a new FAQ to clarify issues regarding coverage of HIV Preexposure Prophylaxis (PrEP). The new FAQ indicates health plans are required to provide coverage without cost sharing for services that the USPSTF recommends for a participant, enrollee, or beneficiary. In June 2019, the U.S. Preventive Services Task Force recommended clinicians offer PrEP with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.

The required covered services include:

- HIV testing, both at baseline and every 3 months while taking PrEP
- Hepatitis B and C testing
- Creatinine testing and calculated estimated creatine clearance or glomerular filtration rate to assess kidney function, conducted both at baseline and periodically thereafter, consistent with CDC guidelines
- Pregnancy testing, both at baseline and periodically thereafter
- Sexually transmitted infection (STI) screening and counseling
- Adherence counseling
- PrEP medications

Why this matters: Health plans and issuers are required to provide this coverage prior to a patient being prescribed anti-retroviral medication as a determination of whether PreP is appropriate as well as ongoing follow up and monitoring and are required to cover, without cost sharing, office visits associated with each recommended preventive service when the service is not billed separately from an office visit and the primary purpose of the office visit is the delivery of the recommended preventive service. Plans and issuers may use reasonable medical management techniques to determine the frequency, method, treatment, or setting for the provision of a recommended preventive service only to the extent that they are not specified in the applicable recommendation or guideline.

COVID-19 Updates

- The Department of Health and Human Services (HHS) extended the public health emergency (PHE), which was set to expire July 20. This extension will renew the PHE until October 18, 2021, 90 days after its previous expiration date.

- The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) held a meeting to discuss the incidences of Guillain-Barré Syndrome (GBS) associated with the Johnson & Johnson (J&J) COVID-19 vaccine, and data and clinical considerations for additional vaccination doses in immunocompromised patients. Following review of the current data, the committee determined the benefits of receiving the COVID-19 vaccination outweigh the risks and reported incidences of GBS, and deferred any decision regarding recommending additional doses

until more data is provided. CDC and ACIP will continue to monitor any updates to data and regulatory mechanisms regarding any changes to the emergency use authorizations for COVID-19 vaccines.

- The U.S. Department of Health and Human Services (HHS) announced that it would invest over $1.6 billion in funding to support COVID-19 testing and mitigation in vulnerable communities. The funding was made available through the American Rescue Plan. According to HHS, the funding will be used to "expand activities to detect, diagnose, trace, and monitor infections and mitigate the spread of COVID-19 in homeless shelters, treatment and recovery facilities, domestic violence shelters and federal, state and local correctional facilities– some of the hardest hit and highest risk communities across the country."

New AHIP Report Highlights Continued Price Gouging in COVID-19 Tests

New data from AHIP show price gouging on COVID-19 tests by certain providers continues to be a widespread problem, threatening patients' ability to get the testing they need. On average, a COVID-19 test in the commercial market costs $130. The new data demonstrates the share of tests charging 50% to 100% *above* the average costs has doubled (from 18% to 36%) over the course of the pandemic.

Key results from the survey, which conclude in March 2021, include:

- On average, a COVID-19 test in the commercial market costs $130. In contrast, out-of-network test providers charged significantly higher (more than $185) prices for more than half (54%) of COVID-19 tests a 12% increase since the beginning of the pandemic. The share of most egregious charges (more than $390) decreased from 12% to 7% during the same period.

- More than a quarter (27%) of COVID-19 tests administered in March 2021 were administered out-of-network—a 6% increase since the beginning of pandemic.

- The share of COVID-19 tests at high-cost locations (hospitals and emergency departments) has declined from 18% in the first quarter of 2021 to only 5%.

AHIP's recommendations to help stop COVID-19 testing price gouging:

• Congress should eliminate the ability for price gouging to occur by setting a reasonable market-based pricing benchmark for tests delivered out of network.
• Policymakers should accelerate the availability of consumer-friendly, rapid, and accurate tests that lower costs and mitigate the capacity and supply constraints of providers and labs.
• The Administration should ensure that all available COVID-19 tests, both manufacturer-developed and laboratory-developed, meet appropriate standards for accuracy.

CMS Seeks Feedback to Advance AAPI Health and Minority Health Social Vulnerability Index Launches

The Department of Health and Human Services made two moves last week as it advances the Biden administration's health equity initiative. First, the Department announced a Minority Health Social Vulnerability Index (SVI), which was co-developed by the CDC and the HHS Office of Minority Health. The

SVI is often used by stakeholders, including public health officials, to better target interventions like resources to deploy in specific communities during a public health emergency. The Minority Health SVI is intended to enhance existing resources to support the identification of racial and ethnic minority communities at the greatest risk for disproportionate impact and adverse outcomes due to the COVID-19 pandemic.

Second, the CMS Office of Minority Health announced a Request for Information (RFI) seeking feedback for best practices for advancing cultural competency, language access, and sensitivity towards individuals who identify as Asian American & Pacific Islander (AAPI). The RFI also seeks comments on best practices set forth by public health organizations and experts for mitigating racially discriminatory language in describing the COVID-19 pandemic (as many AAPI groups have been the targets of hate crimes during the pandemic).

The deadline to submit RFI comments is August 17.

State Issues

New York

Legislative

Advocates Push for Early Intervention Covered Lives Bill

Early Intervention advocates are publicly urging Governor Cuomo to sign the recently passed legislation that would mandate commercial insurance coverage of EI services through a $40 million increase in the covered lives assessment rather than as a claims-based reimbursement. In a recent article in the Rockland/Westchester Journal News – the newspaper in the sponsors' backyard – and a commentary in the Albany Times Union, advocates say the measure would help families across New York access key EI services for their children. In a letter to the editor in the Times Union, the Health Plan Association pointed out that health plans have been covering medical services related to early intervention, but argued that the state should not increase the state's covered lives assessment to pay for educational and developmental services that are the responsibility of the state and municipalities.

Regulatory

Alternative Funding Arrangements Data Request

The New York Department of Financial Services (DFS) last week sent plans a "308" letter requesting information on any alternative funding arrangements (e.g., minimum premium plans, retrospective premium arrangements, partial self-funding arrangements) in which plans may participate. Information being sought ranges from scope of benefits – including whether state mandated benefits are provided – under such arrangements; numbers of groups and/or individuals covered; structure of arrangements; and other relevant details. Responses are due back to the Department within 15 days of the plan's receipt of the letter.

DFS Adopts Amendments to IDR/Surprise Billing Rule

The New York Department of Financial Services (DFS) adopted amendments to Part 400 of Title 23 NYCRR (Independent Dispute Resolution (IDR) for Emergency Services and Surprise Bills) (see page 8).

The amendments were adopted without change and:

- Expand the applicability of the rule to include emergency services by non-participating hospitals and inpatient services that follow an emergency room visit.
- Clarify which services the assignment of benefits and hold harmless requirements apply.
- Describes which hospitals are exempt.
- Revise the definition of “dispute resolution process” and add a definition of “hospital”.
- Add references to inpatient services that follow an emergency room visit and references to non-participating hospitals.
- Outline the responsibilities of health care plans for disputes involving hospital bills for emergency services, including inpatient services that follow an emergency room visit.
- Expand the responsibilities of health care plans for disputes involving surprise bills.
- Detail the responsibilities of non-participating hospitals for disputes regarding emergency services, including inpatient services that follow an emergency room visit. It also outlines the process for a hospital to submit a dispute to IDR.
- Add references to non-participating hospitals and to the best and final offers of the parties for disputes involving a non-participating hospital that had previously entered into a participating provider agreement with the health care plan.
- Add references to non-participating hospitals and to the best and final offers of the parties regarding disputes involving a non-participating hospital that had previously entered into a participating provider agreement with the health care plan.

The adopted amendments will go into effect August 13, 2021

State Issues

Pennsylvania

Legislative

PHC4 Issues Updated Disaster Emergency Report

The updated Pennsylvania Health Care Cost Containment Council (PHC4) **COVID-19 Disaster Emergency Report** issued this month confirmed the enormous damaging impact that the COVID-19 pandemic has had on the financial health of hospitals.

The first report, issued earlier this year as directed by Act 15 of 2020, found that hospitals reported $4.9 billion in COVID-19-related expenses and revenue losses for the period January–September 2020. This

updated report, which captured data for period October 2020–March 2021, showed an additional $1.4 billion in expenses and revenue losses.

Total COVID-19-related expenses and lost revenue reported by Pennsylvania hospitals and health systems through March 2021, (January 2020–March 2021) were nearly $6.5 billion.

The report also points out that only 91 percent of hospitals and health systems responded for the first three-quarters of 2020, 94 percent responded to fourth quarter 2020 and 71 percent responded to first quarter 2021. As a result, the expenses and revenue loss figures are likely substantially understated.

Specifically, the report shows that hospitals, for the October 2020–March 2021 period:

- Experienced revenue losses of $670 million
- Incurred $146 million in costs related to COVID-19 testing, including costs related to commercial lab services
- Expended $271 million for increased staffing and labor costs to expand services and staff emergency operations centers
- Devoted $175 million to purchase additional supplies and equipment, such as personal protective equipment, computer hardware, and temporary tents
- Incurred $5.8 million in construction costs, including retrofitting facilities to provide separate screening and security areas
- Expended $161 million for other miscellaneous activities, such as providing housing and care for patients who do not require hospitalization, obtaining consulting services to comply with COVID-19-related operations, and other steps to prevent, prepare and respond to the pandemic

Why this matters: Hospitals continue to deal with the financial fallout of COVID-19 as they take extraordinary steps to treat patients suffering from COVID-19 and provide vaccinations to health care workers and other eligible citizens. Hospitals continue to advocate for sufficient financial resources to allow them to fulfill their critical mission.

Industry Trends

Policy / Market Trends

Opioid Distributors, Manufacturer, and State Attorneys General Announce $26 Billion Settlement Deal

A group of state attorneys generals announced that they had reached a $26 billion settlement deal with one manufacturer and three distributors to resolve several lawsuits claiming that the companies fueled the opioid epidemic. Under the proposed agreement, the distributors would be responsible for paying a total of $21 billion over 18 years, and the manufacturer would pay $5 billion over nine years. The deal would also require that the distributors create and fund an opioid dose clearinghouse that would track opioid doses and alert regulators to suspicious orders. At least 48 states and a majority of cities and counties would need to agree to the proposed offer for payments to begin, and each state's total share would increase to the extent the local governments within their state, many of which have also brought their own suits against the defendants, also agree to the deal. If approved, the deal would become the second largest cash settlement ever agreed upon.

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 session July 26-30.

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/.** .