Highmark's Weekly Capitol Hill Report

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Federal Issues

Legislative

Senate Clears Infrastructure Package, Begins Consideration of FY2022 Budget

On August 10, the Senate voted 69-30 to approve a bipartisan infrastructure package that had been under negotiation all summer. The bill largely consists of investments in "hard infrastructure" such as improving roads, investing in the nation's power grid, and improving broadband access. However, it does include several health care pay-fors to offset the cost of the proposal, including:

- A three-year delay of the Trump Administration's rebate rule ($49 billion)
- Extension of the Medicare sequester ($8.7 billion)
  - As currently drafted, 2% sequestration would resume 1/1/22 and is authorized through 2031 if the legislation is signed into law.
  - In the last year (2031), the percentage increases to 4% for the first six months of the year.
- Repurposing funds from the COVID-19 Provider Relief Fund ($205 billion)

Following passage of the infrastructure bill, the Senate agreed on a motion to proceed on the FY2022 Budget Resolution released by Senate Democrats. The resolution passed 50-49 early the next morning. Passing the $3.5 trillion budget resolution is the first step in the reconciliation process, which would allow Congress to pass many of the Administrations "soft infrastructure" priorities, such as extending ACA enhancements, with a simple majority vote. To advance, the House, which is scheduled to be in recess through much of September, must also approve the resolution.

Among the policies the budget resolution includes as priorities are number of health care proposals, including:

- Expanding benefits in traditional Medicare to include dental, vision, and hearing coverage (the resolution also references expanding Medicare eligibility)
- Extending enhanced ACA subsidies in the American Rescue Plan
- Creating a new federal health program for Americans in the "Medicaid gap" (i.e., individuals who would be eligible for Medicaid in states that have chosen to not expand the program)
- Reducing the cost of prescription drugs
- Advancing health equity (maternal, behavioral, and racial equity health investments)
- Additional funding for in home and community-based services (HCBS)
- Investments in primary care, safety net providers and the health care workforce

Next steps: House Speaker Nancy Pelosi (D-CA) has indicated that the House will reconvene next week to take up the infrastructure package and the budget resolution together. The budget resolution sets a goal of September 15th for the committees of jurisdiction to draft formal budget reconciliation language, however, with Congress in recess for much of the interim, that deadline could slip.

Pennsylvania

Regulatory

- **DOH Updates COVID-19 Reporting Order**
- **Insurance Department Releases ACA Plan Offerings and Filed Rates**

Once the final spending package is crafted, the Senate and House will vote on final passage of the budget reconciliation later in the fall or winter. The Democrats' razor thin majorities in both chambers combined with the limits of the reconciliation process will impact which pieces of the reconciliation proposal will ultimately be included in the final package.

President Biden Calls on Congress to Address High Prescription Drug Prices

President Biden hosted a press briefing Thursday where he called on Congress to take action on the high cost of prescription drugs.

Key elements of the President's remarks include:

- **Medicare Negotiation for a Subset of Drugs:** "Medicare should be able to negotiate the price for a subset of expensive drugs that don't face any competition in the market. Medicare negotiators would be provided a framework for what constitutes a fair price for each drug, and there should be powerful incentives to make sure drug companies agree to a reasonable price."

- **Inflation Rebates:** "Drug companies that raise their prices faster than inflation should have to pay a penalty."

- **Out-of-Pocket Cap:** "Furthermore, today, seniors who take expensive drugs can face unlimited exposure to high drug prices. We have to fix this and establish a firm cap on the amount that Medicare beneficiaries have to pay out-of-pocket for drugs each year." Note: it does not specify whether this applies only to Part D.

- **Importation:** "The federal government will be working with states and Tribes to import safe, lower-cost prescription drugs from Canada and accelerating the development and uptake of generic and biosimilar drugs that give patients the same exact clinical benefit but at a fraction of the price."

- **Commercial Market Pricing:** "If Medicare makes the prices it negotiates available to commercial payers, too, costs for employer health insurance would fall – reducing premiums by tens of billions of dollars or more."

Highmark joins AHIP, BCBSA and the AHA in working with the Campaign for Sustainable Rx Pricing (CSRxP), to promote bipartisan, market-based solutions to lower drug prices. The CSRxP issued a statement on President Biden's comments praising his commitment to lower drug prices and urging Congress to act.

Federal Issues

Regulatory

CMS Releases Guidance for Resumption of Normal State Medicaid, CHIP, and Basic Health Program Operations Upon Conclusion of the COVID-19 Emergency

The Centers for Medicare & Medicaid Services (CMS) released a State Health Official (SHO) letter that is intended to assist states in their planning efforts to resume routine Medicaid, CHIP, and BHP operations for the eventual end of the COVID-19 public health emergency (PHE). The SHO letter being released today updates specific eligibility and enrollment guidance initially provided to states in the December 2020 SHO #20-004, "Planning for the Resumption of Normal State Medicaid, CHIP, and BHP Operations Upon Conclusion of the COVID-19 Public Health Emergency."

Specifically, this SHO provides updated guidance that:

- Extends the timeframe for states to complete pending eligibility and enrollment work to up to 12 months after the PHE ends.
- Requires states to complete a redetermination of eligibility after the PHE for all beneficiaries prior to taking any adverse action.

Learn more about this guidance here.

U.S. Chamber of Commerce and PCMA File Lawsuits Challenging Provisions of Transparency in Coverage Rule

The U.S. Chamber of Commerce and PCMA each filed separate lawsuits challenging specific provisions of the Trump Administration's *Transparency in Coverage* final rule requiring group health plans and issuers offering individual market and group coverage to publish negotiated rates in machine-readable files.

Why this matters: The cases, filed in federal district courts in the Eastern District of Texas (U.S. Chamber of Commerce) and the District of Columbia (PCMA), each seek to have those specific provisions of the rule declared unlawful and vacated.

Importantly, neither lawsuit is challenging provisions of the rule that require plans to disclose cost-sharing information to individual enrollees upon request through an internet-based self-service tool. And neither lawsuit – at this point in time – has any immediate impact on the *Transparency in Coverage* rule's requirements or implementation dates.

Both cases allege the tri-agencies responsible for promulgating the rule (the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury) violated the Administrative Procedure Act (APA) when they finalized the rule back in November 2020.

Specifically, both complaints allege that by requiring plans to publicly disclose historic net prices in machine-readable files on a website the agencies:

- Exceeded their authority and acted unlawfully when they finalized provisions that go beyond what relevant statutes permit;
- Failed to provide stakeholders with adequate notice and comment on requirements that were unrelated to what the agency had initially proposed; and
- Acted arbitrarily and capriciously by failing to engage in reasoned decision-making and to account for a variety of issues those provisions raise.

In addition, the U.S. Chamber of Commerce also argues the provisions result in an unconstitutional taking because they require disclosure of historical net price information to competitors and deprive plans of the opportunity to continue to obtain a competitive advantage from their own trade secrets.

2.5 Million Americans Gained Health Coverage During Special Enrollment Period

The Biden Administration announced nationally more than 2.5 million people have enrolled in coverage during the 2021 Marketplace special enrollment period (SEP), which began on April 1 and ended on August 15. Separately, the Centers for Medicare and Medicaid Services (CMS) released new data showing 1.8 million consumers have signed up for coverage in Healthcare.gov states, with 404,000 consumers signing up for coverage in July alone. Consistent with other date recently released, the announcement highlighted the impact of American Rescue Plan subsidies on affordability. On average, the ARP subsidies have lowered premiums by an average of $40 per person per month and over a third of customers have found coverage for $10 or less per month.

This announcement shows a record high of nearly 81.7 million people now receive coverage through Medicaid and the Children's Health Insurance Program as of March 2021.

DC Circuit Reinstates CMS Medicare Advantage Overpayment Rule

The U.S. Court of Appeals for the D.C. Circuit issued a unanimous decision in *UnitedHealthcare v. Becerra* reinstating CMS's 2014 final rule addressing Medicare Advantage (MA) payments.

The rule, which requires MA plans to report, and return as an overpayment, any payments made based on a diagnosis code not supported by an underlying medical record that a MA plan either identified or should have identified through reasonable diligence, had been previously vacated by the U.S. District Court for the District of Columbia in September 2018.

In its earlier decision, the district court had found that the rule violated the statutory mandate of "actuarial equivalence," and "constitutes a departure from prior policy that the government fails adequately to explain." CMS did not appeal (and so today's decision did not impact) the district court's additional finding that CMS had relied on an improper interpretation of the term "identified" when it imposed liability based on a failure to exercise reasonable diligence.

However, in this recent decision the D.C. Circuit ruled "actuarial equivalence does not apply to the overpayment rule or the statutory overpayment-refund obligation under which it was promulgated". As a result, the court went on to reject arguments that the overpayment rule breached an obligation for CMS to use the "same methodology" for prospective payments under Medicare and calculations of overpayment

refunds under Medicare Advantage. The court found such a duty "does not bear on the overpayment-refund obligation."

Finally, the court also rejected arguments CMS had acted arbitrarily and capriciously by applying one type of error-correction method to RADV audits and another under the overpayment rule. Instead, the court found that, in light of its finding that actuarial equivalence does not apply to overpayment-refund obligations, "CMS's one-time intention to apply the adjustment in one context but not the other was reasonable."

The court included the following language in a footnote regarding CMS' proposal not to use a FFS Adjuster in the context of contract-level RADV audits: "We express no opinion on whether the actuarial-equivalence requirement in section 1395w-23(a)(1)(C)(i) of the Medicare statute requires such an adjuster in that context. For current purposes, it suffices that the contexts of contract-level RADV audits and overpayment refunds are plainly distinguishable, such that CMS did not need to further explain, when it issued the Overpayment Rule in 2014, why it then intended to use an adjuster in the former context but not the latter."

We will continue to closely monitor developments in this case, including whether UnitedHealthcare seeks further review *en banc* or review by the U.S. Supreme Court.

COVID-19 Updates

- The FDA updated its emergency-use authorizations for the Pfizer and Moderna COVID-19 vaccines, sanctioning third doses for a small percentage of Americans with compromised immune systems. The broadened EUAs specifically permit solid-organ transplant patients or people with other conditions "that are considered to have an equivalent level of immunocompromise" to access additional doses.

- The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted unanimously to recommend a third dose of the mRNA COVID-19 vaccine for individuals who are immunocompromised.
  - The committee stated attempts should be made to match the additional dose type to the primary series, but that heterologous additional doses are permitted.
  - The committee defined immunocompromised persons as undergoing active treatment for solid tumors and hematologic malignancies, solid-organ transplant recipients, those with moderate or severe primary immunodeficiency, advanced or untreated HIV infection, and those undergoing active treatment with high-dose corticosteroids and other immunosuppressive agents.
  - Additional doses of the Johnson & Johnson vaccine were not discussed.
  - The committee also reviewed current data on COVID-19 vaccination and emerging variants and discussed considerations for additional COVID-19 vaccinations.

  The CDC is expected to adopt the panel's recommendation later this afternoon and will release additional clinical guidance.

- Following FDA authorization, the Centers for Medicare and Medicaid Services (CMS) announced people with Medicare who qualify for a third COVID-19 vaccine dose can receive it with no cost

sharing and Medicare would continue to pay providers a national average amount of $40 to administer the additional dose, which is the same amount as paid for other doses of the COVID-19 vaccine. CMS indicated it will share more information and guidance in the coming days about billing and coding for the additional dose of the COVID-19 vaccine for immunocompromised patients.

- The CDC released new data on the safety of the COVID-19 vaccines in pregnant people and is advising people who are pregnant, breastfeeding or contemplating pregnancy to get vaccinated against COVID-19. A new CDC analysis of current data from the v-safe pregnancy registry assessed vaccination early in pregnancy and did not find an increased risk of miscarriage among nearly 2,500 pregnant women who received an mRNA COVID-19 vaccine before 20 weeks of pregnancy.

State Issues

New York
Regulatory

2022 Premiums Announced

The Department of Financial Services (DFS) released the final 2022 premium rates late last week. DFS announced it was reducing health insurers' 2022 requested rates "despite health care costs increasing to pre-pandemic levels." The average weighted increase for premiums in the individual market was 3.7%, a significant reduction from the average of 11.2% that was requested. In the small group market, DFS approved an average increase of 7.6%, almost half of the requested 14% increase.

In a statement responding to the rates decision, the New York Health Plan (HPA) discussed the major factor driving premium increases — growth in prices charged by hospitals, providers and drug companies. HPA's statement went on to say that the rates health plans submitted in May were reasonable, reflecting those costs as well as increased utilization and higher costs from care that was deferred due to the pandemic, along with government taxes and assessments on insurance. For Highmark Western and Northeastern New York, DFS approved a 6.2% increase for individuals, reduced from 18.1% requested, and an 8.6% increase for small groups, down from 17.6% requested. In a press statement, Highmark representatives stated the rates, which affect about 10% of Highmark's New York membership, "do not accurately account for the anticipated rising cost of medical care based on sound actuarial data, particularly considering the ongoing impact of Covid-19."

Department of Financial Services Superintendent Resigns

Shortly after announcing the 2022 rates, Department of Financial Services (DFS) Superintendent Linda Lacewell revealed she would be resigning her post after two and a half years leading the agency. She made the announcement in a letter to DFS staff that was posted to the Department's website. Her resignation takes effect August 24, coinciding with Governor Cuomo's planned departure.

State Issues

Pennsylvania

Regulatory

DOH Updates COVID-19 Reporting Order

On Friday, the Pennsylvania Department of Health (DOH) released an amendment to the order—"*Requiring Hospitals to Make Daily Reports of Specified Data Regarding Supplies and Equipment*"—dated March 24, 2020, as previously amended on July 10, 2020, and January 27, 2021.

The following paragraphs have been amended to include:

Daily Corvena Reporting

- The number of patients admitted on the previous day that were not fully vaccinated, as defined by the federal Centers for Disease Control and Prevention
- The number of patients admitted on the previous day that were fully vaccinated
- The number of patients admitted on the previous day whose vaccine status is unknown
- Other categories or data fields as may be necessary to support the Department's ongoing efforts to allocate resources and implement mitigation strategies

In addition, all hospitals licensed by DOH are instructed to submit a COVID-19 report to the Pennsylvania National Electronic Disease Surveillance System (listed as PA-NEDSS condition "coronavirus, novel 2019") indicating that a patient was hospitalized, and when the hospitalization is attributed to COVID-19.

For purposes of this section, hospitalizations attributed to COVID-19 shall include hospitalizations where COVID-19 is documented as either the patient's admitting or primary diagnosis or COVID-19 has contributed to the patient's admitting or primary diagnosis.

Hospitalizations where COVID-19 was an incidental finding on an admission screening do not need to be reported pursuant to this section. Hospitalization status shall be entered by the hospital on the PANEDSS Clinician Short Form.

This Amendment is effective August 18, 2021.

Why this matters: This order from DOH adds several critical data elements to the list of information that hospitals must report on a daily basis. This data will be vital to understanding the changing nature of the COVID-19 virus strains and in understanding the effectiveness of the current COVID-19 vaccines.

Insurance Department Releases ACA Plan Offerings and Filed Rates

Insurance Commissioner Jessica Altman announced that Pennsylvania's insurance market expects to offer more options and greater competition based on the proposed health insurance plans for 2022. Eight (8) insurers plan to offer plans in the commonwealth. Multiple insurers will offer plans in all 67 of Pennsylvania's counties.

Altman also announced the 2022 requested rate filings for insurance plans under the Affordable Care Act (ACA). Both individual and small group rate requests would result in a modest statewide average increase.

Insurers offering plans in the individual market filed rates requesting an average statewide increase of 2.0 percent. Insurers that currently sell in Pennsylvania's small group market filed plans requesting an average statewide increase of 4.8 percent.

As currently filed, no county will lose an on-exchange insurer and 25 counties will gain a new insurer offering coverage through Pennie, Pennsylvania's health insurance marketplace. Specifically, 22 counties gained one insurer and three counties gained two insurers. Additionally, there will no longer be any counties with only one insurer offering coverage. Every county in Pennsylvania will have at least two insurers offering coverage. Some counties will for the first time have six (6) insurers offering coverage.

Cigna Health and Life Insurance Company joins the state marketplace for plan year 2022. Cigna has filed products that would provide coverage in five counties; Bucks, Chester, Delaware, Montgomery and Philadelphia. With Cigna, Pennsylvania with have eight (8) insurers offering health coverage plans, the most the commonwealth has seen since the passage of the ACA.

The Commissioner stated that nearly 330,000 Pennsylvanians are enrolled in coverage through Pennie.

Next steps: The Pennsylvania Insurance Department will thoroughly analyze the requested rates to ensure they fulfill the guidelines of the department's mission to meet the needs and standards of not being excessive, inadequate or discriminatory. Following this review, final approved rates will be made public in September.

Further details are available on the Insurance Department's website.

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. Senate and U.S. House are currently in recess.

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/.**

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