Highmark's Weekly Capitol Hill Report

Issues for the week ending April 2, 2021

Federal Issues

Legislative

President Biden Releases Infrastructure Blueprint

President Biden on Wednesday released the first portion of his wide-ranging infrastructure plan named "The American Jobs Plan." The package totals $2.25 trillion in federal spending over eight years, focusing on transportation, caregiving, manufacturing, housing, schools, water, broadband, and the power grid. The package will be paid by a proposed increase in corporate taxes and implementing a minimum tax on profits U.S. companies earn overseas.

From a healthcare perspective, the plan would allocate $400 billion toward home-based services and caregiving by expanding home and community-based services under Medicaid as a mandatory benefit, and would provide $18 billion to upgrade VA hospitals.

Why this matters: Importantly, President Biden plans to release a second package in mid-April that will include more healthcare-related and social policies such as drug price reform and permanent ACA enhanced premium subsidies.

If the president's plan succeeds, this second package will be combined with this first portion and pass

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through Congress through the reconciliation process, the same process Democrats used to pass the American Rescue Plan without Republican support.

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- **DOL Brief Stands by Opposition to Novel Plan Structure**

Senator Bernie Sanders (I-VT), along with some Democrats, are advocating for the inclusion of policies related to expanding health insurance such as lowering the Medicare age or a public option within the second portion.

American Rescue Plan Insurance Subsidies Debut on Exchanges

Effective Thursday, April 1, $30 billion in new subsidies over the next two years are beginning to reach eligible individual market consumers who apply through the Exchanges.

The American Rescue Plan created two major enhancements:

1. Making premium subsidies available to enrollees with household incomes exceeding 400% of the federal poverty level; and
2. Increasing premium subsidies for those who already qualify with incomes between 100-400% of the FPL.

As consumers will need to update their applications or submit an application for these insurance affordability programs for the first time, the Biden administration is also ramping up a marketing campaign for HealthCare.gov. The campaign will also tout the previously-announced COVID public health emergency-driven special enrollment period (SEP), which will extend through August 15. At least $50 million for the outreach effort, which will include mass media advertising, has been announced by HHS.

CMS also announced the additional funding for organizations currently serving as Navigators across Federally-facilitated Exchange (FFE) states. These additional resources have been made available to current Navigator grantee organizations to support the outreach, education, and enrollment efforts around the 2021 SEP. The final list can be found here.

Federal Issues

Regulatory

MedPAC Calls for CMMI Redirection as CMS Delays Another Payment Model

MedPAC, Congress's Medicare advisory board, called for a "more harmonized portfolio" of alternative payment models from the Center for Medicare and Medicaid Innovations (CMMI). Critics of CMMI suggest that Medicare providers are suffering from model fatigue, and that too many models are not delivering savings and quality improvements. According to the MedPAC presentation, only four of 54 models tested in CMMI's 10-year history have met CMS's actuarial standard to be made a permanent part of the Medicare program. In addition, assessing the success of models is complicated by the fact that roughly 20% of Medicare providers participate in more than model.

The Biden administration is showing skepticism toward CMMI models started under the Trump administration. The Biden-run CMMI has already delayed or revised six CMMI models, including announcing the delay of the Community Health Access and Rural Transformation (CHART) Model last week.

Coronavirus Updates

- The Centers for Disease Control and Prevention (CDC) released the findings of a new study that suggests the Pfizer and Moderna vaccines are highly effective in preventing COVID-19 infections under real-world conditions. Consistent with clinical trial data, a two-dose regimen prevented 90% of infections by two weeks after the second shot. One dose prevented 80% of infections by two weeks after vaccination.

- President Biden announced plans to more than double the number of pharmacies offering COVID-19 vaccines in an effort to provide 90% of all Americans access to a vaccine within a five-mile radius of where they live by April 19 – three weeks from today. As part of his broader effort to advance equity within the national COVID-19 response, Biden also directed the Department of Health and Human Services (HHS), through a partnership between the CDC and the Administration for Community Living (ACL), to provide nearly $100 million to help increase vaccinations among older adults and people with disabilities.

- The Centers for Disease Control and Prevention (CDC) updated travel guidelines to state fully vaccinated Americans can resume travel without a negative COVID-19 test or self-quarantine. The updated guidelines also state fully vaccinated travelers should still follow CDC recommendations on traveling safety, including wearing a mask, 6-feet physical distancing, and hand washing.

- Pfizer announced its COVID-19 vaccine, BNT162b2, was 100% effective at preventing systematic infections in children aged 12 to 15 in a clinical trial of 2,260 adolescents. Pfizer plans to submit these data to the Food and Drug Administration (FDA) for Emergency Use Authorization in the coming weeks.

- The National Institutes of Health (NIH) announced that it is enrolling adults in an early-phase clinical trial to evaluate a Moderna vaccine targeting the more contagious South African variant of COVID-19. The trial will enroll approximately 210 healthy adult volunteers, some who have been vaccinated and some who have not, at four clinical research sites in the U.S. The NIH still believes that the preliminary data shows that the COVID-19 vaccines currently available in the U.S. should provide an adequate degree of protection against the variants but want to pursue the trial out of an "abundance of caution."

- The Food and Drug Administration (FDA) announced late Wednesday that is it authorizing several additional rapid COVID-19 tests that are used to repeatedly screen asymptomatic populations. These tests, made by BD, Quidel and Abbott, have been authorized by FDA for emergency use in various settings including workplaces, schools, and at home. Three different versions of Abbott's BinaxNOW test can now be used to repeatedly screen people without COVID-19 symptoms, including an over-the-counter (OTC) at home test. An iteration of Quidel's QuickVue COVID-19 test can now be sold OTC for at-home serial testing. And BD's Veritor System is now authorized for serial use in point-of-care settings with a prescription.

- The Kaiser Family Foundation reported a significant decline in vaccine hesitancy amongst U.S. adults since 2020. According to their findings, the number of Americans who have already been vaccinated or want to be as soon as possible continues to rise (currently 61%). Enthusiasm for getting the COVID-19 vaccine continues to grow among people across racial and ethnic backgrounds, with the largest increase this month among Black adults.

- The World Health Organization (WHO) released a 120-page report summarizing the WHO's investigation into the origins of COVID-19. The report states that the novel coronavirus probably spread to people through an animal, and probably started spreading among humans no more than a month or two before it was noticed in December of 2019. However, the report is inconclusive and recommends additional study.

State Issues

New York

Legislative

State Budget Not Quite Done

The 2021-2022 New York State budget, due on April 1, is now officially late. Budget bills have been printed and lawmakers were expected to begin the work of debating and approving the final spending plan this week.

Outcome of the top issues affecting insurers:

- **Pay and Pursue** –The final budget agreement does not include the hospital-backed proposal that would require hospital claims to be paid before hospitals submit information needed to determine whether the service or treatment was medically necessary.

- **Pharmacy Carve-out** – For months, health centers, clinics, hospitals, community-based organizations, patient advocates, and health plans have voiced concern about the state's plan to carve the Medicaid pharmacy benefit out of managed care. Specifically, adding significant new costs to the Medicaid program and decreasing quality of care for New York's most vulnerable residents. Legislators responded by including a two-year delay in the budget, which will give the coalition opposing the carve-out more time to advocate for a full repeal.

- **Quality Pool Funding** – Funding for the quality pools for Medicaid managed care plans was restored, as called for by both the Senate and Assembly.

- **Expanding the Essential Plan** (NYS' version of the ACA's Basic Health Plan) – The budget includes language to increase access to coverage by expanding the Essential Plan, which was supported by the Executive and the Legislature.

- **COVID-19 Rate "Adjustment" –** The final budget did not restore a $1.5 billion cut to Medicaid managed care rates enacted by the Executive earlier this year.

- **Telehealth Expansion** – The final budget includes some language aimed at expanding telehealth services, however, a Senate proposal to require reimbursement parity for telehealth services, including audio only, was not included.

- **Early Intervention Assessment** – A proposal to shift state and municipal costs for Early Intervention (EI) services onto commercial coverage, to be paid for by a $40 million increase in the state's covered lives assessment, was not included in the final agreement.

- **Medically Fragile Children** – Language that would require coverage and care for medically fragile children, which was a Senate proposal, was not included in the final budget.

- **Medicaid Global Cap** – Although both the Senate and Assembly's proposals called for eliminating the global cap, the final budget agreement maintains the Administration's policy for controlling Medicaid spending growth.

While they may not have been included in the final budget, a number of these issues – i.e., pay and pursue, EI services, telehealth, and medically fragile children – will likely come back in post-budget discussions. The session continues until late June.

New York

Regulatory

State Issues Proposed Guidance on Managing Financial Risks for NY Insurers

The New York Department of Financial Services (DFS) has issued for public comment Proposed Guidance for New York Domestic Insurers on Managing the Financial Risks from Climate Change based on New York Insurance Law and related regulations, as well as the guidance manuals of the National Association of Insurance Commissioners.

The new proposed guidance builds upon Insurance Circular Letter No. 15(2020), which sets out expectations for all New York insurers to start integrating the consideration of the financial risks from climate change with regards to their governance frameworks, risk management processes, and business strategies. It also suggested insurers start developing their approaches to climate-related financial

disclosures and that they consider engaging with the Task Force for Climate-related Financial Disclosures framework as well as other established initiatives.

This proposed guidance covers, among other things, governance, business models and strategy, risk management, scenario analysis, and public disclosures. It issues the following overview of the DFS' supervisory expectations for insurers with respect to managing climate risks. An insurer should:

• Integrate the consideration of climate risks into its governance structure.
• Consider the current and forward-looking impact of climate-related factors on its business environment in the short-, medium-, and long-term.
• Incorporate the climate risks into the insurer's existing financial risk management, which includes considering them in the company's ORSA.
• Use scenario analysis to inform business strategies and risk assessment and identification, which should consider physical and transition risks, multiple carbon emissions and temperature pathways, and short-, medium-, and long-term time horizons.
• Disclose its climate risks and consider the Task Force on Climate-Related Financial Disclosure and other initiatives when developing its disclosure approaches.

The DFS will hold a webinar to provide an overview on the proposed guidance on April 8 and will accept comments through June 23.

State Issues

Pennsylvania
Regulatory

Teleworking Mandate in Pennsylvania Ends
The Telework mandate for businesses in Pennsylvania ended officially on April 4. Businesses, however, are still encouraged to conduct business through telework and occupancy limits are still in place. According to the State's COVID-19 Guidance for Businesses, "All in-person businesses may operate at 75% occupancy, except where noted. Businesses must follow all the worker and building safety requirements for employers. All businesses are strongly encouraged to conduct their operations in whole or in part remotely through individual teleworking of their employees. Remember to check the COVID-19 Guidance and Resources page for more details."

State Issues

West Virginia
Legislative

Bills Impacting PBMs, Telehealth, and Association Health Plans Move Forward

The 2021 regular session of the West Virginia Legislature reached the critical 50-day point of the 60-day session last week—the point at which all bills must be passed by at least one of the two houses to be considered during the final ten days.

PBM Legislation

HB 2263, proposing new regulations on PBMs and health plans regarding pharmaceutical rebates and dispensing fees, among other issues, has now passed in final form and is pending with Governor Justice for his presumed approval and enactment into law this week. The bill largely contains the rebate language sought by the bill's advocates with only a slight modification that was made during the conference committee on the bill. Health insurers' support the value of the rebates being passed through to members on an annualized basis in premium calculations rather than in an inexact and administratively expensive manner at the point of sale (POS) of prescriptions.

In addition to the POS rebates, there are other significant elements to HB 2263, including:

- A mandated dispensing fees of $10.49 per script;
- A mandate that any pharmacy be permitted in a pharmacy network; and
- The extension of the provisions of the bill to ERISA employers based on an interpretation of a recent U.S. Supreme Court decision.

Telehealth Payment Parity

HB 2024, concerning licensure of telehealth providers, has also completed the legislative process, and will soon be pending with Governor Justice for his review and presumed approval. The original version of this bill was significantly amended by the Senate to include telehealth payment parity for patients who have an existing relationship with a provider. Additionally, the bill will also allow prescribers to write prescriptions for Class II drugs to patients with whom they have an existing relationship.

Hospital Price Transparency/Surprise Billing

HB 2005 was significantly amended and reported from the Senate Health Committee. In its rewritten form, the bill simply provides for the Office of the Insurance Commissioner to promulgate rules that mirror the new federal standards for hospital transparency and surprise billing. The original House version of the legislation proposed new legal requirements beyond federal law in these areas, as well as a requirement for health plan network transparency that did not consider legislative action on the same topic in 2020.

It seems unlikely that the House will accept the narrow, rewritten version of HB 2005, so the bill could die for lack of agreement or be placed into a conference committee where the House could try and exert leverage on the Senate to adopt its position.

Prior Authorization for Cancer Staging Screening

SB 39, which effectively proposes the elimination of prior authorization for cancer staging radiologic screenings, remains within the jurisdiction of the House Health Committee with a subsequent second reference to the House Judiciary Committee. The bill can still advance and pass but it faces a fairly long path over the final week of the legislative session.

Association Health Plan Expansion

The House has passed a deeply modified version of HB 2876, proposing to lower the standards in West Virginia for the formation and operation of association health plans. The Insurance Commissioner

intervened in this issue and caused several significant changes to be adopted to the bill concerning risk management and required stop loss coverage in an effort to bolster the consumer and provider protections in the legislation. Should this bill be passed by the Senate, it should have limited adverse effect on the insurance market with the additions requested to the bill by the Office of the Insurance Commissioner.

Industry Trends

Policy / Market Trends

AHIP Files Amicus Brief in 9th Circuit Case Supporting Reversal of ERISA Re-Processing Decision

AHIP filed an amicus brief in *Wit v. United Behavioral Health* (UBH) urging the U.S. Court of Appeals for the Ninth Circuit to reverse a lower court decision involving plan administrators' ability to oversee and manage employer-sponsored plans under ERISA. AHIP's brief highlights for the court of appeals how the lower court's decision risks undermining ERISA's goal of encouraging employers to provide benefits to employees and their families efficiently, effectively, and uniformly across state lines.

Why this matters: In an earlier decision, the lower court found that certain guidelines used by UBH to assess behavioral health claims were flawed. However, rather than require plaintiffs (who filed suit on behalf of a class) to demonstrate that each member of the class was improperly denied benefits, the court instead found that the flawed guidelines themselves were sufficient to certify a class and base a claim under ERISA. The court went on to require the re-processing of nearly 67,000 claims and ordered UBH to apply specific court-imposed behavioral health guidelines for the next 10 years.

AHIP's brief explains how the lower court's decision turns ERISA on its head. AHIP details how the court's reasoning significantly departs from the traditional means of determining what types of injuries are actionable under ERISA, either individually or on behalf of a class. Their brief also emphasizes the court's decision will have a significantly negative impact on how plans are administered and, if allowed to stand, will increase costs not only for employers and small businesses, but also the individuals and families that rely on those plans for coverage.

DOL Brief Stands by Opposition to Novel Health Plan Structure

The Department of Justice last week filed a brief in the Fifth Circuit Court of Appeals arguing the district court "abused its discretion" by enjoining the Department of Labor from refusing to bless a novel health plan arrangement as an ERISA-covered plan. The Department appealed a ruling in September 2020 by federal district court judge Reed O'Connor who overturned the Department's advisory opinion denying single-employer ERISA group health plan status to an arrangement proposed by a general partner and related limited partnership.

The plaintiffs sought single-employer status and treatment of the benefit arrangement as an ERISA-governed plan, but the Department concluded the arrangement lacked an employment relationship, ownership interest, and sufficient employee-to-partner ratio, concluding that the business enterprise is a "sham" created to provide health insurance coverage to the Limited Partners. Notably, the enterprise hires workers (50,000 as of last year) and in turn offers them entry to the plan by requiring them to opt into a

data-sharing partnership wherein they agree to have their internet browsing and social media presence tracked in exchange for compensation for their time.

Why this matters: The case is being watched closely by federal and state regulators and other stakeholders as a potential new option to offer health insurance without complying with the traditional insurance protections under federal law, such as the Affordable Care Act.

The Pennsylvania House of Representatives is in session April 5-7. The Senate of Pennsylvania returns to session April 12.

The Delaware Legislature returns to session April 20.

The New York Legislature was to be off the next two weeks but will remain in session until they pass the budget.

The West Virginia Legislature is in session February 10 through April 10, 2021.

Congress

The U.S. Congress returns to session April 13-16. The U.S. Senate returns to session April 12-16.

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/.**