

Federal Issues

Legislative

House Votes to Extend Moratorium on Medicare Sequester; Senate Action Uncertain

The House on Friday passed [legislation](#) to extend the moratorium on the mandatory 2% Medicare sequestration cuts through the end of the year. The bill also exempts the budgetary effects of the action, as well as the recently passed American Rescue Plan Act of 2021, from the Statutory Pay-As-You-Go Act of 2010 (PAYGO), which would stave off \$36 billion in mandatory payment cuts.

The bill passed by a vote of 246 to 175, but there appears to be less momentum in the Senate, which adjourns for spring break after this week. There is a good chance the issue will be unresolved before the current moratorium ends on March 31.

Last week, two senators - Jeanne Shaheen (D-NH) and Susan Collins (R-ME) - [introduced](#) the [Medicare Sequester Relief Act](#), which would extend relief from the sequester through the public health emergency, but does not contain the PAYGO provisions, which have drawn GOP opposition.

Insurer and provider groups continue to urge Congress to pass legislation that would ensure the nation's

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health care providers and systems can continue to provide quality care and prevent Medicare cuts that will take place on April 1, 2021.

- **Gov. Justice Makes Vaccinations Available to all West Virginians age 16 and older**

HHS Secretary-Designate Becerra Confirmed by Senate

On Thursday, the Senate voted to confirm Xavier Becerra as Secretary of the Department of Health and Human Services (HHS) in a 50-49 vote. Sen. Susan Collins (R-ME) joined Democrats to secure Becerra's confirmation.

Secretary Becerra will serve as a key member of President Biden's health care team. A former member of Congress representing Los Angeles and chair of the Democratic Congressional Campaign Committee, Secretary Becerra most recently served as the Attorney General of California. In that role, Secretary Becerra led a coalition of states defending the Affordable Care Act in a lawsuit before the U.S. Supreme Court.

BCBSA President and CEO Kim Keck [congratulated](#) Becerra on his confirmation and pledged to work with him "to address longstanding racial health inequities, combat the COVID-19 pandemic and make health care work better for everyone."

AHIP president and CEO Matt Eyles [said](#) the industry looks forward to helping "protect and build upon the Affordable Care Act to expand health coverage for all Americans, address the underlying cost of health care, and eliminate racial and ethnic disparities in medical care."

Elsewhere on the Hill

- Reps. Pramila Jayapal (D-WA) and Debbie Dingell (D-MI), [reintroduced](#) their Medicare-for-All proposal, citing the COVID-19 pandemic's devastating impact as a motivating factor. Although the bill is nearly identical to the version introduced in the last Congress, a new provision in the legislation would create an Office of Health Equity at the Department of Health and Human Services (HHS), which would work to address racial disparities in health care. The current bill is supported by more than 100 House Democrats, including Energy and Commerce Committee Chair Frank Pallone, Jr. (D-NJ), who has pledged to hold a hearing on the legislation.
- The House Energy and Commerce Subcommittee on Oversight and Investigations held a [hearing](#) titled "Leading the Way Forward: Biden Administration Actions to Increase COVID-19 Vaccinations." Committee members heard testimony from the nation's top public health officials on a wide variety of topics pertaining to the pandemic, including the ongoing COVID-19 vaccination effort and the threats posed by emerging variants of the SARS-CoV-2 virus. Witnesses also testified about social distancing guidelines and school re-openings, as well as research on the AstraZeneca vaccine and future pandemic preparedness.

- The Senate Health, Education, Labor and Pensions (HELP) Committee held a [hearing](#) on “Examining Our COVID-19 Response: An Update from Federal Officials.” The hearing focused on immediate challenges in the COVID-19 pandemic, including the scaling up of vaccine production and administration amid the discovery of new coronavirus variants. Health equity also emerged as a key theme during the hearing as senators and witnesses alike mentioned the importance of addressing racial health disparities in outcomes and vaccine administration.
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Federal Issues

Regulatory

Medicare Increases Reimbursement for COVID-19 Vaccine Administration

Effective March 15, the Centers for Medicare & Medicaid Services (CMS) [announced](#) increased Medicare fee for service [payment rates](#) for COVID-19 vaccine administration:

- Single-dose vaccines will be \$40 to administer (increased from \$28.39).
- If a series of two or more doses, both dose(s) will have a payment rate of \$40. Previously the initial dose administration payment rate was \$16.94 and \$28.39 for the final dose in the series.

Why this matters: As Medicare payment can heavily influence the prevailing market rate in many areas, it is expected that several other payers like commercial payers and state Medicaid programs could follow Medicare’s lead. HRSA also announced that it would align reimbursement to providers who participate in the “COVID-19 Uninsured Program” with the Medicare rates. Providers can be reimbursed for treating, testing, and vaccinating the uninsured through a fund established within the HHS-administered Provider Relief Fund.

This change follows the January 21 [National Strategy](#) for COVID-19 Response and Preparedness, which indicated CMS was considering whether current payment rates for vaccine administration were appropriate or whether a higher rate may more accurately compensate providers. This rate reflects updated information about the costs involved in administering the COVID-19 vaccine for different types of providers and suppliers and the additional resources necessary to ensure the vaccine is administered safely and appropriately. The rate will be geographically adjusted based on where the service is furnished.

As part of the increased administration fee, CMS reminded the public that as a condition of receiving free COVID-19 vaccines from the federal government, providers are prohibited from charging patients any amount for administration of the vaccine ([CMS toolkits](#)):

- **Medicare FFS**—Vaccine at no cost to patient, no copayment, coinsurance, or deductible.
- **Medicare Advantage**—For CY 2020-2021, Medicare will pay providers directly for the COVID-19 vaccine and its administration for MA beneficiaries; no patient cost-sharing.
- **Medicaid**—Vaccine administration provided by State Medicaid and CHIP agencies with no cost sharing for nearly all beneficiaries during the public health emergency (PHE) and at least one year after it ends; more information will be provided in updates to the [Medicaid toolkit](#).
- **Commercial Market**—Existing regulations require most private health plans and issuers cover in- and out-of-network vaccine and administration with no cost sharing during the PHE; rates are expected to be reasonable, in comparison to Medicare payment rates.

- **Uninsured**—Providers may submit reimbursement claims for COVID-19 vaccine administration to uninsured individuals through the Provider Relief Fund.
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HHS Delays Effective Date of Three Final Regulations, including Part D Rebate Rule

Ongoing litigation, COVID-19, and a January executive order continue to impact agency actions regarding several major regulations finalized in the last several months of the Trump administration.

The Department of Health and Human Services (HHS) delayed the effective dates for the following three final rules under legal challenges:

- 1) [Executive Order on Access to Affordable Life-saving Medications Final Rule](#),
- 2) The [Prescription Drug Rebate Safe Harbor Final Rule](#), and
- 3) The [Securing Updated and Necessary Statutory Evaluations Timely](#) (SUNSET) final rule.

Why this matters

The Access to Affordable Life-Saving Medications rule's new effective date is July 20, 2021, “to ensure that implementation of the rule does not impede HHS’s and health centers’ immediate priority work, on a nationwide basis, of responding to and mitigating the spread of COVID-19, while considering how to address administrative/implementation issues raised by commenters and further address comments regarding the impact of the rule.”

- This rule requires HRSA-funded community health centers to pass through rebates for insulin and epinephrine to patients.

The Prescription Drug Rebate Safe Harbor rule is now delayed until January 1, 2023. This delay reflects an order issued by the U.S. District Court for the District of Columbia on March 15 postponing until January 1, 2023 all provisions of the final rebate rule that were scheduled to take effect on March 22 (*PCMA v HHS et al.*). **Insurer and PBM groups opposed the rule and have urged for it to be fully withdrawn.**

- Matt Eyles, president and CEO of America’s Health Insurance Plans (AHIP), issued this statement earlier this year: “The rebate rule is a misguided proposal from the prior Administration, which would hurt some of our most vulnerable populations—seniors and people with disabilities—through increased premiums. It would cost America’s taxpayers billions of dollars while transferring billions into drug makers’ coffers. Most important, the rebate rule does nothing to lower prescription drug prices.”

Finally, the SUNSET rule’s effective date has been postponed pending judicial review. HHS explains that the delay will allow them to review the rule in light of a lawsuit filed March 9 by a diverse set of stakeholders alleging the rule is contrary to law, arbitrary and capricious, and in violation of the APA’s notice-and-comment requirements. HHS indicates the potential automatic expiration of regulatory programs could create uncertainty and unpredictability regarding large swathes of the rules governing health care, including regulations impacting health insurance providers.

Coronavirus Updates

- Moderna [announced](#) the first participants have received a vaccine dose in a Phase II/III trial testing the COVID-19 vaccine in children ages six months to less than 12 years old.
- The Department of Health and Human Services (HHS) [announced](#) it will invest \$10 billion from the American Rescue Plan to ramp up screening testing to help schools reopen, \$2.25 billion to scale up testing in underserved populations, and provided new [guidance](#) on asymptomatic screening testing in schools, workplaces, and congregate settings. The CDC and state and local health departments will provide technical assistance to schools to help set up and implement the new screening programs in schools.
- HHS also [announced](#) it is investing \$150 million to increase access to COVID-19 monoclonal antibody therapeutic treatments for patients in vulnerable communities across the country.
- White House press secretary Jen Psaki confirmed that the Biden administration was finalizing plans to share the U.S. supply of AstraZeneca's coronavirus vaccine with the governments of Canada and Mexico.
- CMS updated the [Toolkit on COVID-19 Vaccine—Health Insurance Issuers and Medicare Advantage Plans](#). CMS issued this toolkit to help health insurance issuers and Medicare Advantage plans identify issues to consider and address when providing coverage and reimbursement for COVID-19 vaccine administration. Specific changes/additions to the toolkit include:
 - Updated information about the EUA for the Janssen COVID-19 Vaccine for use for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.
 - Updated information on Pharmacy & Provider Agreements related to retail sites.
 - Updates to reflect the [February 26 FAQs](#) indicating that HHS will not take enforcement action against any issuer that does not provide at least 60 days' advance notice of a material modification regarding the addition of coverage for qualifying coronavirus preventive services.
 - Updates to reflect February 26 FAQs that if an individual is denied a vaccine because an individual is not within a category prioritized for vaccination is not an adverse benefit determination made by a health plan or health insurance issuer.

State Issues

Delaware Regulatory

Delaware Expands COVID-19 Vaccination Program

Governor John Carney and the Delaware Division on Public Health [announced](#) an expansion of Delaware's COVID-19 vaccination program.

Beginning March 17, 2021:

- Pharmacies in Delaware may begin vaccinating Delawareans aged 50+.

- Health care providers and hospital systems may vaccinate patients 16+ with **high and moderate risk medical conditions**.
- Non-paid caregivers of Delawareans with **high and moderate-risk medical conditions** may also qualify for vaccination through medical providers.

Beginning March 23, 2021:

- State of Delaware will open the COVID-19 vaccination waiting list to any Delawarean 50+.

Ongoing:

- Vaccinating 65+ Delawareans who are registered on the state's waiting list.
- Partnering with employers to vaccinate frontline and other essential workers.
- Distributing the vaccine in a way that's fast and fair.

Governor John Carney formally extended the [State of Emergency declaration](#) another 30 days to confront community spread of COVID-19

State Issues

West Virginia

Legislative

Legislature Looks to Expand PBM Requirements and Therapy Mandate; Tax Reform Discussions Continue

The 2021 Regular Session of the West Virginia Legislature passed the two-thirds point of completion of the 60-day term, leaving the next critical milestone in the session the 50th day—March 31—when a bill must be passed by at least one house to be considered over the final ten days.

PBM Legislation

HB 2263, proposing new regulations on PBMs and health plans regarding pharmaceutical rebates and dispensing fees, was passed by the Senate last week. However, a Senate provision to allow for health plans to pass through pharmaceutical rebates to members through annual premium adjustments is under intense assault from the House of Delegates.

On Friday, the House voted to amend the Senate's version of the PBM bill to restore the original requirement that the rebates be passed through to the plan member at the point of sale of a prescription.

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.

Expanded Alternative Opioid Therapy Mandate

HB 2634 proposes to clarify current law to require that up to 20 alternative therapy treatments for physical therapy, occupational therapy, chiropractic and a range of other therapy modalities can be stacked and

maximized at 20 visits for each therapy type rather than a simple total of 20 visits for all types of alternative opioid treatment.

This legislation was referred to the House Finance Committee for review, but it is unknown whether this bill will emerge from the Finance Committee this week.

Hospital Price Transparency/Surprise Billing

HB 2005 remains lodged in the Senate Health Committee. This bill proposes to require hospitals to fully disclose their prices on a granular basis and provide estimates for procedures in advance, as well as provisions exceeding the scope of recent federal action in the field of surprise billing and new requirements for health plan network disclosures that go beyond those changes adopted just last year.

Expanded Diabetes Coverage Mandate

HB 2708, proposes a significant expansion of the insulin coverage mandate enacted in 2020 by creating a new required treatment model based the law enacted by Connecticut in 2020.

Other Issues

- HB 2965, proposing a **coverage mandate for PANS/PANDA** cases was endorsed by the House Health Committee and is now under the jurisdiction of the House Finance Committee.

Tax Reform

Discussions about Governor Justice's proposed plan to initially repeal 60% of the state's personal income tax and replacing the revenues with a very wide variety of tax shifts and budget cuts continued to be Topic A at the State Capitol. Business groups continued expressing concerns with the plan and the House Finance Committee Chairman outlined a tax plan dramatically different than the Governor's that would be phased in over a decade rather than the next three years of Governor Justice's second and final term, as the governor had desired.

Regulatory

Gov. Justice Makes Vaccinations Available to all West Virginians age 16 and older

Governor Jim Justice announced that West Virginia will start offering COVID-19 vaccines to all state residents age 16 and older, beginning immediately.

West Virginia becomes one of the few states in the nation to lift virtually all eligibility requirements for COVID-19 vaccines, well ahead of President Biden's May 1 goal to open eligibility to all adults in the U.S. The state previously was allowing shots for all residents 50 and over, essential workers of any age, and individuals 16 and over who had underlying medical conditions.

West Virginians who are age 65 and older will continue to be prioritized first until all state residents in that age range who desire to receive the vaccine have been vaccinated. Gov. Justice noted new data that showed 70 percent of seniors age 65 or older in the state have received at least one dose of the vaccine.

Gov. Justice encouraged all West Virginians age 16 and older wishing to be vaccinated to pre-register at vaccinate.wv.gov or by calling the COVID-19 Vaccine Info Line at 1-833-734-0965.

The Pennsylvania General Assembly is in session March 22-24.

The Delaware Legislature is in session March 23-25.

The West Virginia session runs from February 10 through April 10, 2021.

Congress

The U.S. House is in session March 22-25. The U.S. Senate is in session March 22-26.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: <http://legis.delaware.gov/>.

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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