

Federal Issues

Legislative

Infrastructure Agreement Includes Some Health Offsets but Avoids Provider Relief Fund

After months of talks, a bipartisan group of senators this week announced an agreement on an [infrastructure package](#) that would make new investments in the nation's physical infrastructure programs. In a 67-32 vote on Wednesday evening, lawmakers voted to begin consideration of the bill in the Senate. The agreement announced Wednesday includes new investments in physical infrastructure, such as roads, bridges, water infrastructure and broadband internet access.

The infrastructure package includes some healthcare offsets but avoids tapping unused Provider Relief Funds (PRF) to pay for the package, though it does extend the Medicare sequester for one additional year, through Fiscal Year 2031. Advocates for hospitals and other providers advocated strongly against this move, particularly given concerns about increases in COVID-19 cases and the impact this resurgence may have on providers. Several provisions align with hospitals' and health systems' priorities, including funding for broadband internet deployment, equity and affordability, as well as investments to improve federal

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coordination and assistance with response and recovery from significant cybersecurity incidents.

The agreement does include nearly \$50 billion in savings by delaying to January 2026 changes to the Medicare Part D rebate program. These changes, contained in a rule finalized last November, would eliminate the current rebate safe harbor and transition to a model that allows rebates to consumers at the point of sale. The agreement notably does not include a prohibition on the use of spread pricing by pharmacy benefit managers (PBMs). A ban on spread pricing has been in prior pieces of legislation and had been on the list of anticipated offsets earlier in the week. While the bill avoids rescinding unused PRF monies, it does rescind unused funds in a number of other programs created to blunt the impact of the pandemic.

Next steps: Majority Leader Chuck Schumer (D-NY) is hopeful that the chamber can complete work on the bill as well as on a fiscal year 2022 budget resolution this week so the Senate can move to its summer recess. If passed, the package will still need to be taken up by the House, which has recessed until September 20. It is unclear whether Speaker Pelosi will consider bringing the House back in to session prior to that to pass the infrastructure bill.

The budget resolution would contain reconciliation instructions and be necessary to move forward the much larger infrastructure measure championed by the Biden administration and most Congressional Democrats, but is not expected to draw any bipartisan support.

Pennsylvania

Regulatory

- **Pennsylvania 1332 Waiver Reinsurance Program Update**

Senate Panel Advances Bills Seeking to Speed Access to Generic Therapies

As concerns about drug costs and pricing continue to draw attention, the Senate Judiciary Committee on Thursday unanimously advanced a slate of bipartisan bills that seek to curb activities that have impeded bringing generic medications to market.

- One of the bills, the Preserving Access to Affordable Generics and Biosimilars, would prevent “pay for delay” arrangements in which brand name companies enter into agreements with generic or biosimilar manufacturers to delay a product’s entry to the market.
- Another bill, the Stop STALLING Act, seeks to crack down on the use of FDA citizen petitions that impede marketing of generics and biosimilars. The other measures would allow the Federal Trade Commission to examine PBM actions and would address “product hopping” that involves the switching of patients onto new formulations of drugs to prevent them from moving to a generic product.

The diverse bipartisan backing of the bills is a positive indicator of potential resolution though the political divide on the overarching issue of drug pricing.

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New IRS Guidance on COBRA Premium Assistance

The Internal Revenue Service (IRS) published [Notice 2021-46](#) to provide additional guidance on the application of COBRA premium assistance tax credit enacted as part of the American Rescue Plan Act. The IRS had previously addressed technical issues related to the COBRA premium assistance credits in [Notice 2021-31](#) and [Notice 2021-23 IRB 1173](#). This notice includes 11 Questions & Answers addressing extended coverage periods, the application of the end of the premium assistance period to dental and vision coverage, comparable state continuation coverage, and information for the entity claiming the tax credit.

CMS Publishes Rules on Fee-for-Service Medicare

The Centers for Medicare and Medicaid Services (CMS) issued the following rules pertaining to fee-for-service Medicare:

- FY 2022 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation Updates, Hospice and Home Health Quality Reporting Program Requirements ([PDF](#))
- FY 2022 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates ([PDF](#))
- Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2022 and Updates to the IRF Quality Reporting Program; Payment for Complex Rehabilitative Wheelchairs and Related Accessories (Including Seating Systems) and Seat and Back Cushions Furnished in Connection with Such Wheelchairs ([PDF](#))

- Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2022; and Technical Correction to Long-Term Care Facilities Physical Environment Requirements ([PDF](#))
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GAO: Medicare Beneficiaries Leave MA Plans in Last Year Life

A report from the Government Accountability Office (GAO) found that Medicare beneficiaries are more than twice as likely to leave Medicare Advantage (MA) health plans in their final year of life than in healthier prior years. The GAO's findings confirm prior studies that reached the same conclusion but serve to further raise the profile of the issue.

The GAO speculates that the high switch rate could be "because of potential limitations accessing specialized care." However, the GAO report examines disenrollment figures without deeply exploring the root cause of final-year coverage switching.

Concurrent with the release of the report, Senators Bill Cassidy (R-LA) and Debbie Stabenow (D-MI) released a preliminary plan to draft legislation that would require MA plans to cover 90 days of Medicare claims after the member returns to Original Medicare.

NAIC to Review Leads Generators in Health Insurance with Feds

Last week, [the Market Regulation and Consumer Affairs \(D\) Committee](#) of the National Association of Insurance Commissioners (NAIC) adopted revised charges for the Antifraud Task Force that would create the Improper Marketing of Health Insurance (D) Working Group. NAIC is the standards-setting organization of all states and territories that provides expertise, data, and analysis for state insurance regulators.

The new working group will: coordinate with state and federal regulators to assist in monitoring the improper marketing of health plans; coordinate enforcement actions as needed; and review existing NAIC models and guidelines that address the use of lead generators and determine if updates are needed.

Targeted television advertising and calls to seniors and increased use of technology in insurance sales and use of automated dialing systems have caused insurance regulators at the federal and state levels to be more interested in leads generators. In general, leads generators obtain a consumer's contact information and consent to make referrals to agents and brokers to fulfill insurance sales, but some consumers have claimed to be victims of plan switching that they did not approve or fully understand but may generate a commission for the agent or broker.

In a Federal Communications Commission [statement](#) regarding the agency's record-breaking \$225 million fine in March against a telemarketer, the FCC reported seeing an increase in consumer complaints and robocall traffic related to health insurance beginning in 2018.

COVID-19 Updates

- The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Justice (DOJ) issued new [guidance](#) categorizing “long COVID” as a condition that can be a disability under the *Americans with Disabilities Act* (ADA). Under the guidance, individuals with long COVID that qualifies as a disability are entitled to protections from discrimination under the ADA, Section 504 of the *Rehabilitation Act of 1973* and Section 1557 of the *Affordable Care Act*.
- The U.S. Department of Health and Human Services (HHS) [announced](#) it was providing \$121 million in funds from the American Rescue Plan to support the work of community-based efforts to increase COVID-19 vaccinations in underserved communities. According to HHS, the funds will be used to “establish, expand and sustain community-based efforts to mobilize community outreach workers, community health workers, patient navigators, social support specialists and others to increase vaccinations.”
- The Centers for Disease Control and Prevention (CDC) updated [guidance](#) that recommends fully vaccinated individuals wear masks in indoor, public settings if they are in parts of the U.S. with substantial to high transmission to maximize protection from the Delta variant and prevent possibly spreading it to others.
- President Biden announced a series of actions to encourage COVID-19 vaccinations and slow the spread of the Delta variant. These actions include:
 - Requiring every federal government employee and onsite contractor to disclose their vaccination status.
 - Encouraging the Department of Defense to add COVID-19 vaccination to the list of required vaccinations for members of the military.
 - Expanding paid family leave for small- and medium-sized businesses.
 - Directing states, territories, and local governments to do more to incentivize vaccination, including offering \$100 to those who get vaccinated.
 - Encouraging school districts nationwide to host at least one pop-up vaccination clinic over the coming weeks.

For more information on the Administration’s actions, please see this [fact sheet](#).

State Issues

New York

Legislative

Coronavirus Update

Governor Cuomo said that beginning this month, state workers must be vaccinated or subject to weekly COVID-19 testing. The Legislature and state judiciary followed suit and said they will be implementing a vaccination or testing mandate as well. The Governor likewise said that all patient-facing health care workers in New York's state-run hospitals must get vaccinated against COVID-19. With the number of cases again on the rise, Governor Cuomo also called on private businesses — including bars and restaurants — to only admit vaccinated people into their establishments.

Regulatory

Regulatory Update

Alternative Funding Survey -- Last month, the Department of Financial Services (DFS) sent plans a 308 Request for information about plans' "Alternative Funding Arrangements." The broadly drafted letter raised numerous questions as to the scope of the request and the expectations of the Department. Last week, the NY Health Plan Association (HPA) counsel sent DFS a letter outlining concerns and seeking clarification. The most significant concern is that the information request does not provide a definition of "Alternative Funding Arrangements" or the listed examples (i.e., minimum premium arrangements, retrospective premium arrangements, partial self-funding arrangements, etc.). Additionally, because the request was sent to health plans that only participate in public programs — Medicaid, Medicare, Essential Plan, Child Health Plus and qualified health plans — where these arrangements do not exist, HPA's letter requested that the Department clarify that that the request is entirely focused on large group arrangements.

Behavioral Health Cost Survey – NY Department of Health (DOH) issued a survey to mainstream Medicaid managed care plans to help determine the cost of changes to behavioral health utilization management criteria required by the Office of Mental Health. HPA requested an extension from the original due date of the survey from July 30 to August 16 to give plans adequate time to accurately project costs – even though OMH has not approved final criteria, making it difficult to project final cost increases. DOH granted the extension, noting that it could delay future rate revisions for the current fiscal year.

Disaster Preparedness — DFS recently issued [Insurance Circular Letter No. 7 \(2021\)](#), which sets forth standards for health insurance providers and other regulated entities regarding "planning and preparing for, and responding to, disasters occurring anywhere in the world, including New York State, that could affect an addressee's ability to continue doing business and servicing the people of New York State." This circular letter repeals and replaces Circular Letter No. 6 (2019). According to the letter, health insurers are required to:

- Annually perform “a business impact analysis” and prescribes minimum considerations for such analyses to predict the consequences of a disaster (operational and financial impacts), along with potential recovery strategies.
- Use the results of the analysis to establish, maintain, and update as necessary a business continuity plan.
- At least annually perform a risk-based analysis of its capacity to assist customers in New York affected by a disaster occurring anywhere in the world to be used to establish, maintain, and update as necessary, a disaster response plan. This plan is a separate document from the business continuity plan.

Plans must submit their disaster response plan, a response to the disaster response plan questionnaire, and a response to the business continuity plan questionnaire to DFS by October 8, 2021.

State Issues

Pennsylvania

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Pennsylvania 1332 Waiver Reinsurance Program Update

The Pennsylvania Insurance Department issued Notice 2021-09 with a reminder that on July 24, 2020, the Centers for Medicare & Medicaid Services approved the Insurance Department's 1332 Waiver Application. The approval is effective for a waiver period from January 1, 2021, through December 31, 2025, with a provision for a possible extension at the end of the initial term.

Additionally, the Notice explains that the reinsurance program is a claims-based, attachment point reinsurance program that will reimburse health insurers for claims costs of qualifying Affordable Care Act-compliant individual enrollees, where a percentage of the claims costs exceeding a specified threshold (attachment point) and up to a specified ceiling (reinsurance cap) will be reimbursed.

The Notice goes on to state that beginning January 1, 2022, and slightly adjusted from the preliminary parameters in Notice 2021-06 published at 51 Pa.B. 3073 (May 29, 2021), the program-adopted parameters are an attachment point of \$60,000, a cap of \$100,000 and a coinsurance rate of 45% as opposed to 40% coinsurance rate which initially was projected in Notice 2021-06. The Department did acknowledge in its previous Notice that the projections might change in light of the unique challenges of the various Federal legislative responses to the pandemic, higher enrollment projections and possible additional developments, before rates were finalized for the fall open enrollment period.

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 is in session August 2-6.

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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