

McDermottPlus Check-Up: December 8, 2023

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THIS WEEK'S DOSE

- **Senate Hearing on Drug Shortages:** The Senate Finance Committee held a hearing to examine solutions that would address drug shortages.
- **House Markup of 19 Health Bills:** The House Energy & Commerce Committee held a markup that included consideration of 19 healthcare bills addressing issues such as prescription drug price transparency, access to care and physician payments.
- **Senate RFI on Gene Therapies:** Sen. Cassidy (R-LA), Ranking Member of the Senate Health, Education, Labor & Pensions (HELP) Committee, released a request for information (RFI) on gene therapies.
- **Senate Budget Committee Investigation of Private Equity Hospital Ownership:** Budget Committee Chair Whitehouse (D-RI) and Ranking Member Grassley (R-IA) launched a bipartisan investigation into the impacts of private equity ownership on hospitals.
- **Protecting Rural Seniors' Access to Care Act:** Sen. Fischer (R-NE) introduced the Protecting Rural Seniors' Access to Care Act, which would prohibit the US Department of Health and Human Services (HHS) from finalizing a proposed nursing home staffing rule.
- **Medicaid Unwinding Enforcement:** The Centers for Medicare & Medicaid Services (CMS) released an interim final rule on enforcement of federal Medicaid renewal requirements.
- **Draft March-In Rights Guidance:** The National Institute of Standards and Technology (NIST) within the US Department of Commerce released for public comment its Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights.

CONGRESS

Senate Finance Committee Examines Drug Shortages. The [hearing](#) addressed concerns and explored potential solutions related to drug shortages in the United States, particularly focusing on essential medications. The hearing emphasized building a more resilient pharmaceutical supply chain by addressing issues such as the concentration of manufacturing in specific regions, incentivizing domestic production, and implementing measures to ensure a stable and robust supply of critical

medications.

Various policy recommendations were discussed, including the need for regulatory reforms, incentivizing domestic drug manufacturing, revisiting reimbursement mechanisms and exploring pay-for-performance models. Members and witnesses noted that shortages in the pharmaceutical supply chain have significant implications for cancer patients, because shortages can impact physicians' ability to provide optimal and potentially life-saving treatments. The discussion emphasized the urgent need to address these challenges in the context of oncology medications.

House Energy & Commerce Committee Holds Markup. The markup included 19 health bills aimed at addressing access to care, drug price transparency and physician payment issues.

A full list of the bills and amendments can be found [here](#), and more detailed summaries can be found in the markup [memo](#). Highlights include the following:

- **[H.R. 5372](#), the Expanding Seniors' Access to Lower Cost Medicines Act of 2023**, would encourage greater patient access to biosimilar products by allowing for mid-year changes in insurance plan formularies for certain biosimilar products starting in 2025.
 - Advanced by a vote of 48–0.
- **[H.R. 5385](#), the Medicare PBM Accountability Act**, would create enhanced pharmacy benefit manager (PBM) reporting requirements, such as annual reporting of drug pricing and other information to the Secretary of HHS, including information about Part D drugs, drug dispensing, drug costs and pricing, generic and biosimilar formulary placement, PBM affiliates, financial arrangements with consultants and potential PBM conflicts of interest.
 - Advanced by a vote of 44–0.
- **[H.R. 5555](#), the DMEPOS Relief Act of 2023**, would require the Secretary of HHS to provide certain adjustments to Medicare payment for durable medical equipment that were formerly included in the 2021 year of the Durable Medical Equipment, Prosthetics/Orthotics and Supplies (DMEPOS) competitive bidding program.
 - Advanced by a voice vote.
- **[H.R. 6364](#), the Medicare Telehealth Privacy Act of 2023**, would prohibit the Secretary of HHS from making a physician or practitioner's address of residence publicly available if that individual elected to provide telehealth services from that address. This policy is currently in place through 2024 via HHS regulatory action.
 - Advanced by a vote of 44–0.
- **[H.R. 6545](#), the Physician Fee Schedule Update and Improvements Act**, would further patch the Medicare physician fee schedule conversion factor, adding another 1.25% for calendar year 2024 and extending incentive payments for participation in eligible alternative payment models (APMs) for one year. The bill would also tier the size of the bonus according to how long a provider has participated in an APM to better account for increased upfront costs of APM participation. The bill would extend for one year a policy to increase the work geographic index to 1.00 for any locality where the index would be less than 1.00. This policy is otherwise set to expire January 19, 2024.
 - Advanced by a vote of 46–0.

Senate HELP Committee Ranking Member Publishes RFI on Gene Therapies. The RFI seeks feedback on ways to improve and protect access to gene therapies for Americans with ultra-rare diseases. As discussed in the [press release](#), Sen. Cassidy hopes to use the feedback to inform future legislation to modernize and improve the market structure for gene therapies, to ensure that the US commercial health insurance market supports Americans with ultra-rare diseases, and to ensure the

continued development of innovative gene therapies. The deadline for comments is January 22, 2024. Here is the [full RFI](#), which includes 59 questions across a broad range of categories.

Senate Budget Committee Investigates Private Equity Hospital Ownership. This investigation follows the committee's outreach in March 2023, when Sen. Whitehouse and Sen. Grassley wrote letters to four companies with ownership interests in a regional health center. The senators now seek to understand how questionable financial transactions may have impacted quality of care for patients in hospitals under private equity ownership. Their investigation asks for documents and detailed answers about related-party transactions and the degree to which the private equity firms are calling the shots at these hospitals. Read the press release [here](#) to find the letters that were sent as part of the investigation.

Senate Introduces Bipartisan Legislation to Halt Implementation of the Nursing Home Staffing Ratio Regulation. The Protecting Rural Seniors' Access to Care Act ([S. 3410](#)) is cosponsored by eight senators in addition to Sen. Fischer, including John Tester (D-MT), Angus King (I-VT), Joe Manchin (D-WV) and Kyrsten Sinema (I-AZ), and is endorsed by more than 90 organizations. It is presented as protecting rural communities but has a broader application because it would prohibit the HHS Secretary from finalizing a proposed nursing home staffing standards rule. The legislation would also establish an advisory panel on nursing home staffing that includes voices from both urban and rural communities. The panel would submit a report to Congress that analyzes workforce shortages and makes practical recommendations to strengthen the workforce. The House version of this legislation was [introduced](#) by Rep. Fischbach (R-MN) in September. This bill follows submission of more than 46,000 comments to the Administration expressing concern over the requirements outlined in the proposed rule. Next steps from the Administration remain to be seen.

ADMINISTRATION

Administration Releases Draft Guidance for New March-In Rights Framework. NIST released for public comment its [Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights](#), a tool to help agencies evaluate the appropriateness of requiring licensing of a patent developed with federal funding. The draft guidance is intended to help agencies work through a range of policy considerations relevant to a potential march-in decision, including price.

Under the Bayh-Dole Act of 1980, the government retains certain rights on any products produced through a public-private partnership using federal funding. Federal agencies may compel companies that make such products to provide a "nonexclusive, partially exclusive, or exclusive" license to a "responsible applicant." If the company refuses to grant a license for its product, the government has the authority to grant the license itself. These are referred to as march-in rights, because they allow the federal government to "march in" and issue a license for a product on its own. The Administration's draft guidance would allow enforcement of march-in authorities on drug development, for example. This means that if manufacturers refused to make their products reasonably available, the government could give other companies license to produce those drugs at a lower cost.

NIST seeks public comments through February 6, 2024, after which it will review and make publicly available all comments received, before finalizing the guidance. NIST will host a public informational [webinar](#) on December 13 from 1:00–2:00 pm EST to review the framework and explain the type of feedback sought. A press release with additional information can be found [here](#).

In related news, the Administration also released a [fact sheet](#) outlining actions taken to increase

equitable access to lower-cost, taxpayer-funded drugs by promoting competition as well as broader initiatives on healthcare for the coming year, many of which we should also expect to hear on the campaign trail.

CMS Releases Interim Final Rule on Medicaid Unwinding. The [interim final rule](#) implements reporting requirements and enforcement authorities in the Consolidated Appropriations Act (CAA) of 2023. CMS will use the new enforcement authorities as described in the rule if states fail to comply with the reporting requirements added by the CAA, 2023, or with federal Medicaid eligibility redetermination requirements during a timeframe that is generally aligned with the period when states are restoring eligibility and enrollment operations following the end of the Medicaid continuous enrollment condition under the Families First Coronavirus Response Act. The new enforcement authorities include requiring states to submit a corrective action plan, suspending disenrollments from Medicaid for procedural reasons and imposing civil money penalties. They also include reducing the state-specific Federal Medical Assistance Percentage for failure to meet reporting requirements.

The interim final rule was effective December 6, 2023, but is open for comments until February 2, 2024.

Administration Announces Next Steps to Enhance Healthcare Cybersecurity. HHS [released](#) a concept paper that outlines its cybersecurity strategy for the healthcare sector. The paper details four pillars for action, including publishing new voluntary healthcare-specific cybersecurity performance goals, working with Congress to develop supports and incentives for domestic hospitals to improve cybersecurity, increasing accountability and coordination within the healthcare sector, and expanding and maturing a “one-stop shop” cybersecurity support function for the healthcare sector within the Administration of Strategic Preparedness and Response.

QUICK HITS

- **CMS Provides Update on ACA Open Enrollment.** CMS [highlighted](#) that almost 7.3 million people have selected an Affordable Care Act (ACA) Health Insurance Marketplace plan since the 2024 Marketplace Open Enrollment Period began on November 1, 2023. This represents activity through December 2, 2023, for the 32 states using HealthCare.gov and through November 25, 2023, for the District of Columbia and the 18 states with state-based Marketplaces. Read the CMS fact sheet [here](#).
- **MedPAC Holds December Meeting.** The Medicare Payment Advisory Commission [hosted](#) its two-day December meeting, during which it discussed payment adequacy for physician, hospital inpatient and outpatient, hospice, outpatient dialysis, skilled nursing facility, home health and inpatient rehabilitation facility services.
- **Administration Publishes Fall 2023 Unified Agenda.** The unified agenda can be found on the Office of Management and Budget website [here](#). The HHS fall 2023 agency rule list can be found [here](#).
- **Administration Will Publish MA RFI Early Next Year.** CMS reportedly intends to implement a new phase of its efforts to increase MA data transparency, beginning with an RFI early next year to solicit information from the public to strengthen CMS’s data capabilities and MA transparency efforts. We will provide more details once the RFI is published next year.

NEXT WEEK’S DIAGNOSIS

Healthcare may return to the House floor as soon as Monday, when it is expected that [H.R. 5378](#), the Lower Costs, More Transparency Act, will be considered on the House floor under suspension of the

rules. Healthcare activity will also continue at the committee level next week, including a Senate HELP Committee markup of four healthcare bills and a House Energy & Commerce Committee hearing on artificial intelligence. The Office of the National Coordinator for Health Information Technology also will hold its annual meeting.

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National Law Review, Volumess XIII, Number 342

Source URL: <https://natlawreview.com/article/mcdermottplus-check-december-8-2023>