

McDermott+ Check-Up: September 27, 2024

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THIS WEEK'S DOSE

- **Congress Votes on CR, Health-Related Legislation.** The continuing resolution (CR) prevented a government shut down and will fund the government until December 20, 2024.
- **Senate HELP Committee Examines GLP-1 Prices.** The Senate Health, Education, Labor, and Pensions (HELP) Committee held a hearing to discuss the cost of prescription drugs, focusing on pricing practices of GLP-1 manufacturers.
- **Senate Finance Committee Discusses Abortion Bans.** Members heard from physicians, patients, and legal experts about the state of abortion access.
- **Senate HELP Employment & Workplace Safety Subcommittee Holds Hearing on AI & the Workforce.** Discussion focused on organizations' desire to integrate artificial intelligence (AI) in their workplaces.
- **Democratic Senators Introduce Healthcare Cybersecurity Legislation.** The bill would set minimum cybersecurity standards for healthcare entities.
- **CMS Releases MDRP Final Rule.** The Centers for Medicare & Medicaid Services (CMS) finalized policies for the Medicaid Drug Rebate Program (MDRP) to correct drug misclassifications by manufacturers and to enhance program integrity.
- **CMS Releases Final Rule to Address ACO Financial Calculations.** CMS will adjust Medicare Shared Savings Program (MSSP) Accountable Care Organization (ACO) benchmarks for 2023 to remove payments for specified urinary catheter codes that were deemed suspicious.

CONGRESS

Congress Votes on CR, Health-Related Legislation. After reaching a deal over the weekend, both

chambers passed a CR to avoid a government shutdown and fund the federal government through December 20, 2024. This tees up a push for an end-of-year package in lame duck that could include pharmacy benefit manager (PBM) reform, healthcare price transparency, prescription drug competition policies, and a variety of [extenders](#), including Medicare telehealth flexibilities and the SUPPORT Act. The CR passed with a vote of 341 – 82 in the House and 78 – 18 in the Senate. All no votes came from Republicans. The CR now awaits a signature from President Biden, which will prevent a government shutdown on October 1. Passage of the CR was the last major piece of legislative business on Congress' agenda before adjourning for its pre-election recess.

Several health-related bills were also approved on the House floor this week under suspension of the rules, which is an expedited process for advancing broadly supported legislation. These bills included legislation related to organ transplant discrimination, disease research and treatment programs, and mailing prescription medication under Medicare. The full list of bills and descriptions of each can be found [here](#).

Senate HELP Committee Examines GLP-1 Prices. In the [hearing](#), members asserted that there is a significant disparity in drug pricing between the United States and other countries, highlighting that certain GLP-1s cost \$59 in Germany but \$959 in the United States. Senators discussed how the high cost of drugs disproportionately affects low-income individuals and those without insurance, and emphasized that it is therefore crucial for manufacturers to offer patient assistance programs and lower list prices. The committee also discussed how PBMs, insurance benefit designs, and regulatory barriers contribute to high drug prices. Of note, Chair Sanders (I-VT) shared that three PBMs have committed to covering GLP-1s and lowering prices if the manufacturer reduces its prices.

Senate Finance Committee Discusses Abortion Bans. The purpose of the [hearing](#) was to hear from physicians, patients, and legal experts regarding the current state of abortion access. Democratic senators blamed former President Trump for the bans and focused on how physicians and women have been negatively impacted by abortion restrictions in many states. Republican members discussed the dangers of women taking abortion pills without physician supervision and emphasized the political nature of the hearing.

Senate HELP Employment & Workplace Safety Subcommittee Holds Hearing on AI & the Workforce. In the [hearing](#), members appeared to be generally optimistic about the use of AI in the workplace. Although members and witnesses emphasized that there is uncertainty surrounding AI's impacts, they agreed that organizations are increasingly integrating AI into their work and are looking for skills related to AI in new employees.

Democratic Senators Introduce Healthcare Cybersecurity Legislation. Senate Finance Committee Chair Wyden (D-OR) and Senator Warner (D-VA) introduced the [Health Infrastructure Security and Accountability Act](#), which seeks to strengthen healthcare cybersecurity rules by setting minimum standards, creating enforcement mechanisms, and allocating funding for implementation. The bill would:

- Create minimum cybersecurity standards for healthcare entities.
- Require annual independent cybersecurity audits and stress tests, with exceptions for small providers.
- Require the US Department of Health & Human Services (HHS) to audit data security practices for 20 entities annually.
- Mandate that healthcare executives annually certify compliance with requirements.
- Eliminate statutory caps on HHS's fining authority.

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- Implement a user fee on covered entities based on their share of national health expenditures.
 - Provide \$800 million upfront for rural and urban safety net hospitals and \$500 million after two years to all hospitals for cybersecurity standards adoption.
 - Codify HHS's ability to provide advanced and accelerated Medicare payments during a cybersecurity disruption.

A section-by-section summary of the bill can be found [here](#), and the press release can be found [here](#).

ADMINISTRATION

CMS Releases MDRP Final Rule. The [final rule](#) implements new statutory authorities provided to CMS in the Medicaid Services Investment and Accountability Act of 2019. CMS finalized a process to identify and correct drug manufacturers' incorrect reporting and misclassifications of drugs in the MDRP. The agency also finalized enforcement actions it may take against noncompliant drug manufacturers, including suspending the drug or terminating the manufacturer from the MDRP, excluding the drug from Medicaid payment, and imposing civil monetary penalties. CMS finalized policies to ensure states can obtain rebates and to improve the pharmacy benefit in managed care programs.

CMS Releases Final Rule to Mitigate Impact of Suspicious Billing Activity on MSSP Financial Calculations. In the [final rule](#), CMS noted that it will adjust MSSP ACO benchmarks for calendar year (CY) 2023 to remove payments for specified intermittent urinary catheter codes, which were identified as having suspicious billing concerns. This recalculation will cause a six-week delay in initial determinations and disbursements of earned performance payments for performance year 2023. The final rule effective date is October 15, 2024, and proposals in the CY 2025 Physician Fee Schedule address significant, anomalous and highly suspect billing activity mitigation for CY 2024 onwards.

QUICK HITS

- **HRSA Awards First-Ever Multi-Vendor Contract for OPTN.** The Health Resources and Services Administration (HRSA) announced separate [contracts](#) for the Organ Procurement and Transplantation Network (OPTN) to modernize the network and improve quality and patient safety. This action was required by the Securing the U.S. Organ Procurement and Transplantation Network Act signed by President Biden in September 2023.
- **CMS Awards \$9 Million for Expanding Access to Women's Health.** Grantees will implement programs to improve coverage of and access to reproductive and maternal healthcare to address health disparities. Grantees include 14 states and the District of Columbia. Read more about the grant program [here](#).
- **CMS Requires State Medicaid and CHIP Renewal Compliance.** CMS announced in an [informational bulletin](#) that all states must conduct a compliance assessment and submit a plan to address identified areas of noncompliance with existing Medicaid and Children's Health Insurance Program (CHIP) renewal requirements by the end of 2024. States will be required to achieve compliance with all federal renewal requirements by the end of 2026. House Energy & Commerce Committee Ranking Member Frank Pallone (D-NJ) and Senate Finance Committee Chair Ron Wyden (D-OR) released a [statement](#) commending the CMS action.
- **CMS Awards \$1.4 Million for Minority Research Grant Program.** The [program](#) funds six

minority-serving universities and foundations that are examining and addressing healthcare disparities among minority populations in their communities.

- **CMS Hosts Educational Session on TCET.** CMS provided an overview of the new Transitional Coverage for Emerging Technologies (TCET) pathway, which aims to create more efficient market access for breakthrough technologies. CMS indicated that it aims to publish additional guidance on TCET.
- **HRSA Awards \$240 Million to Integrate Behavioral Healthcare and Primary Care.** The Behavioral Health Service Expansion Awards include more than 400 community health centers that will implement or expand mental health and substance use disorder services to improve access to behavioral healthcare. The press release can be found [here](#), and the full list of grantees is [here](#).
- **HRSA Invests \$74 Million in Rural Healthcare Initiatives.** The funding aims to expand substance use disorder treatment services; improve access to maternal health services in Alabama, Mississippi, and Tennessee; and support rural hospitals. The full list of awards can be found [here](#).
- **ASTP Releases Two Updates on Laboratory Interoperability and FHIR.** The Assistant Secretary for Technology Policy (ASTP) released a [data brief](#) on laboratory interoperability through health information exchange organizations. ASTP also released the 2024 Draft Federal Fast Healthcare Interoperability Resources (FHIR) [Action Plan](#). Comments on the draft action plan are due November 25.
- **Treasury Report Shows 3.3 Million Self-Employed Individuals, Small Business Owners Received Marketplace Coverage in 2022.** They accounted for 28% of all Marketplace enrollment. If they account for the same share of enrollment in 2024, 4.2 million self-employed individuals and small business owners will receive Marketplace coverage. Read more in the [US Department of the Treasury report](#) and [press release](#).
- **HHS Hosts Hispanic Health Summit.** The summit focused on the Biden Administration's work to improve health equity and access to healthcare in the Latino community. Speakers included HHS Secretary Xavier Becerra, Rep. Barragán (D-CA), community leaders, and senior HHS officials.
- **HHS Hosts Briefing on Maternal Health Initiatives.** HHS and other agencies, including CMS, HRSA, and the National Institutes of Health, provided updates on federal maternal health programs and funding initiatives. The recording can be found [here](#).
- **CMS Releases Guidance on EPSDT Requirements.** The [guidance](#), as required by the Bipartisan Safer Communities Act, highlights best practices for state adherence to the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) requirement. CMS plans to provide regular technical assistance webinars for states. Read the press release [here](#).
- **ASPE Releases Report on the Benefits of Expanding Medicaid Eligibility.** The HHS Assistant Secretary for Planning and Evaluation (ASPE) [report](#) examines the impact of Medicaid throughout its six decades and highlights studies that show the importance of Medicaid coverage for low-income children and adults.
- **CMS Will Soon Allow Medicaid Reimbursement for Firearm Safety Counseling.** The Biden Administration's [Executive Order](#) on gun violence notes that, by the end of October, CMS will announce that states can provide Medicaid reimbursement for firearm safety and injury prevention counseling services for parents and caregivers. CMS will also explore how to incorporate Medicaid benefits into violence prevention programs.

NEXT WEEK'S DIAGNOSIS

Congress is in recess until after the election. Both chambers are currently scheduled to return to session on November 12, 2024, to begin the lame duck session. Our *Check-Up* will be on hiatus

during the October recess, with the exception of a mid-month regulatory roundup on October 11, 2024.

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