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McDermott+ Check-Up (Special Regulatory Edition): October 11, 2024

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THIS WEEK'S DOSE

- **Congress Continues Election Recess.** Members are on the campaign trail and are scheduled to return for the lame duck session on November 12, 2024.
- **CMS Releases Proposed NBPP for 2026.** The proposed Notice of Benefit and Payment Parameters (NBPP) released by the Centers for Medicare & Medicaid Services (CMS) includes changes to the Health Insurance Marketplaces for the 2026 plan year.
- **CMS Releases Report on Hospital at Home Initiative.** The report examines the Acute Hospital Care at Home initiative, which is set to expire at the end of 2024 without congressional action.
- **GAO Releases Report on Hospital Pricing Data Transparency.** The US Government Accountability Office (GAO) report could reignite congressional interest in enacting additional hospital price transparency requirements.
- **CMS Issues FY 2025 Interim Final Rule on Medicare IPPS Hospital Wage Index.** The interim final rule comes in response to an appellate court decision and will affect hospitals' fiscal year (FY) 2025 wage index in the Medicare Inpatient Prospective Payment System (IPPS).
- **CMS Highlights Efforts to Lower Medicare Drug Costs.** Several recent announcements focus on the agency's implementation of the Inflation Reduction Act and the Lowering Prescription Drug Costs for Americans Executive Order.
- **SCOTUS Schedules November 5 Oral Arguments for Medicare DSH Calculation Case.** The case before the Supreme Court of the United States questions how the US Department of Health and Human Services calculates disproportionate share hospital (DSH) payments.

ADMINISTRATION

CMS Releases Proposed NBPP for 2026. The rule proposes changes to standards that health plans participating in the Marketplaces must comply with, as well as new requirements for Marketplaces themselves and agents, brokers, web-brokers, direct enrollment entities, and assisters that help Marketplace consumers. Key proposals include:

- Enhancing enforcement efforts against agents or brokers who violate Marketplace standards.
- Updating the model consent form that agents, brokers, and web-brokers can use to obtain and document consumer consent.
- Requiring Exchanges to provide notice to consumers and tax filers who have failed to file and reconcile their advanced premium tax credit for two consecutive years.
- Allowing health plans to adopt a fixed-dollar payment threshold of $5 or less, adjusted for inflation, under which plans would not be required to trigger a grace period or terminate enrollment for enrollees who fail to pay the full amount of their portion of premium owed.

CMS seeks comment on codifying "silver loading" policies included in previous guidance and the impact of the "time value of money" on the risk adjustment program. Comments are due to CMS on November 12, 2024. Read the fact sheet here.

CMS Releases Report on Hospital at Home Initiative. The Acute Hospital Care at Home (AHCAH) initiative allows certain Medicare-certified hospitals to treat patients with inpatient-level care at home. The report was mandated by the Consolidated Appropriations Act, 2023, and compares patients in the initiative to brick-and-mortar hospital inpatient groups. The report highlights topics such as beneficiary demographics for those treated under the initiative, beneficiary and caregiver experiences with AHCAH, and a comparison of Medicare spending and utilization for patients who received care in the inpatient setting and through AHCAH.

The AHCAH initiative is set to expire on December 31, 2024. Legislation that passed out of the House Energy & Commerce and Ways & Means Committees would extend the AHCAH initiative for five years, and may be part of an end-of-year legislative package during the upcoming lame duck session. Read the CMS fact sheet on the report here.

GAO Releases Report on Hospital Pricing Data Transparency. The report was requested by House Energy & Commerce Committee Chair McMorris Rodgers (R-WA) and Ranking Member Pallone (D-NJ). The report finds that while recent CMS actions on hospital price transparency requirements are positive steps, the agency does not have assurance that the data hospitals report are complete and accurate, and therefore cannot determine whether enforcement is needed. The GAO recommended that CMS assess whether hospital pricing data are complete, accurate, and usable, and implement any additional enforcement activities as needed. The agency agreed with the recommendation.

GAO's findings and recommendation could strengthen congressional interest in enacting the hospital price transparency provisions of H.R. 5378, the Lower Costs, More Transparency Act, which passed the House in December 2023. Such provisions may also be in play for inclusion in Congress' year-end legislative package.

CMS Issues FY 2025 Interim Final Rule on IPPS Hospital Wage Index. The interim final rule comes in direct response to *Bridgeport Hosp. v. Becerra*, which held that CMS lacked the authority to adopt a low wage index hospital policy that it finalized in the FY 2020 IPPS rule and continued to

apply. In the 2020 IPPS final rule, CMS increased the wage index values for certain hospitals with low wage index values in order to address “wage index disparities.” CMS implemented this increase in a budget-neutral manner through a downward adjustment to the standardized amounts for all hospitals.

In this interim final rule, CMS recalculates the IPPS hospital wage index to remove the low wage index hospital policy for 2025. CMS believes that some hospitals that previously benefitted from the low wage index hospital policy will experience decreases of 5% or more from their FY 2024 wage index to the FY 2025 wage index established in this rule. To mitigate these decreases, CMS created a narrow transitional exception to the calculation of FY 2025 IPPS payments for hospitals that are most affected, setting these hospitals’ FY 2025 wage index at 95% of their FY 2024 wage index.

The interim final rule went into effect on September 30, 2024, and comments are due November 29, 2024.

CMS Highlights Efforts to Lower Medicare Drug Costs. CMS announced that manufacturers of 54 drugs will be subject to rebates in the Medicare Prescription Drug Inflation Rebate Program, which was created by the Inflation Reduction Act (IRA). The program requires drug manufacturers to pay rebates if prices of certain drugs increase faster than the rate of inflation. With those rebates, CMS will lower coinsurance rates in Medicare Part B. In advance of Medicare open enrollment, CMS also highlighted that average premiums for Medicare Advantage plans and Medicare Part D prescription drug plans (PDPs) will decline from 2024 to 2025. The announcement came after CMS created a voluntary and temporary premium stabilization program for PDPs in 2025 as provisions of the IRA take effect.

As passed in the IRA, negotiated prices for the first round of drugs in the Medicare Drug Price Negotiation Program will take effect in 2026. CMS released final guidance for the second round of negotiations, which will occur in 2025 and result in negotiated prices that will take effect in 2027. The guidance outlines processes and requirements for CMS and drug companies during the second round of negotiations.

CMS also issued a request for information (RFI) on the proposed Medicare $2 Drug List Model, which would standardize PDP cost-sharing for low-cost generic drugs at $2 for a month’s supply. The model stems from an executive order issued by President Biden in 2022. The RFI specifically seeks comment on the drug list development process, maximizing plan participation, outreach efforts, assessing the model’s impact, and drug list modifications. In the RFI, CMS lists 101 prescription drugs that could be included in the model. Comments are due by December 9, 2024.

COURTS

SCOTUS Schedules November 5 Oral Arguments for Medicare DSH Calculation Case. The Supreme Court of the United States agreed in June 2024 to hear the case *Advocate Christ Medical Center, et al. v. Becerra* after the US Court of Appeals for the District of Columbia Circuit ruled in favor of the US Department of Health and Human Services (HHS). At issue in the case is how HHS counts individuals eligible for supplemental security income in Medicare DSH payment calculations. The plaintiff hospitals allege that the HHS methodology excludes individuals who are eligible for, but did not receive, supplemental security income cash payments, which they claim does not comply with the statute or previous Supreme Court rulings. Multiple hospital associations filed an *amicus* brief arguing that HHS’s methodology reduces DSH payments and threatens hospitals’ eligibility for other federal programs, such as 340B.

QUICK HITS

- **HHS Declares PHEs During Hurricanes Helene and Milton.** The public health emergencies (PHEs) in Florida, Georgia, North Carolina, Tennessee, and South Carolina in response to Hurricane Helene and in Florida in response to Hurricane Milton offer providers and suppliers flexibility when caring for beneficiaries. CMS will also provide accelerated and advance payments to Medicare fee-for-service providers and suppliers affected by Hurricane Helene.
- **CMS Releases 2021 – 2024 Accomplishments Report.** The report highlights CMS's work in the past four years, focused on its six strategic pillars: advancing equity, expanding access, engaging partners, driving innovation, protecting programs, and fostering excellence.
- **CMS Releases Medical Loss Ratio Toolkit for State Medicaid, CHIP Programs.** The toolkit is designed to help states review, validate, and oversee managed care plans' annual medical loss ratio reporting in Medicaid and the Children's Health Insurance Program (CHIP).
- **CMS Announces 2025 Value-Based Insurance Design Model Participants.** In calendar year 2025, the model will include 62 Medicare Advantage organizations in 48 states, Puerto Rico, and Washington, DC, that will test providing additional supplemental benefits or reduced cost-sharing. The full list of participants can be found here.
- **CMS Announces Medicare Coverage of PrEP.** The national coverage determination will allow Medicare Part B to cover pre-exposure prophylaxis (PrEP), which prevents Human Immunodeficiency Virus (HIV) in individuals at increased risk, along with other related services such as HIV screenings and HIV risk assessments. These services will be covered without cost-sharing. Read more in the fact sheet.
- **ASTP Finalizes Federal Health IT Strategic Plan.** The strategic plan from the Assistant Secretary for Technology Policy (ASTP) includes goals and objectives to ensure that health information technology and electronic health information are used properly, enhance care delivery, accelerate innovation, and connect the health system with health data. The draft plan, released in March 2024, was created in collaboration with more than 25 federal agencies and was open for public comment. Read more in the press release.
- **Senators Send Letters on FTC Actions.** Senate Finance Committee Chair Wyden (D-OR) and Sen. Brown (D-OH) urged the Federal Trade Commission (FTC) to examine pharmacy benefit manager practices. Meanwhile, Senate Health, Education, Labor, and Pensions Committee Ranking Member Cassidy (R-LA) encouraged the US Food and Drug Administration to fulfill its obligation to list patents in the Orange Book, instead of allowing the FTC to do so.
- **NIH Issues Scientific Integrity Policy.** The policy outlines the scientific integrity principles that the National Institutes of Health (NIH) follows in its extramural and intramural research programs. The NIH notes how public input and accountability are integrated in its processes, and the agency plans to re-evaluate the policy every two years.
- **CFPB Issues Advisory Opinion on Unfair Medical Debt Collection.** The Consumer Financial Protection Bureau (CFPB) guidance reminds medical debt collectors of their obligation under federal law to confirm that debts are accurate, valid, and substantiated before initiating collections. The guidance follows a June 2024 CFPB proposed rule that would ban medical bills from most credit reports.
- **SAMHSA Awards $68.5 Million for Behavioral Health Initiatives.** The Substance Abuse and Mental Health Services Administration (SAMHSA) announced grantees in 11 programs that aim to support the behavioral health workforce.
- **250+ Organizations Commit to White House Challenge to Save Lives from Overdose.** The organizations will take actions to improve training on and access to opioid

overdose reversal medications, such as naloxone. The White House press release can be found here, and the full list of organizations can be found here.

- **House Energy & Commerce Democrats Release Report on Louisiana Abortion Medication Law.** The report discusses the implications of the recently implemented law that classifies misoprostol and mifepristone as controlled substances.
- **MedPAC Holds October 2024 Public Meeting.** The Medicare Payment Advisory Commission (MedPAC) agenda included sessions on Medicare beneficiaries in nursing homes, findings from MedPAC's annual beneficiary and provider focus groups, supplemental benefits in Medicare Advantage, changes to the home health prospective payment system, and an overview of home healthcare use among Medicare Advantage enrollees. Slides and a transcript will be posted here.
- **CMS Releases 2025 Medicare Advantage and Part D Star Ratings.** Average Star Ratings for 2025 have declined compared to previous years. The Star Ratings will appear on the Medicare Plan Finder for 2025 open enrollment and will impact 2026 Medicare Advantage quality bonus payments.

NEXT WEEK'S DIAGNOSIS

Congress continues its election recess and is scheduled to return on November 12, 2024, to begin the lame duck session. Barring any breaking news, our *Check-Up* will be on hiatus until early November.

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