

MEMORANDUM

November 13, 2023

TO: Members, Subcommittee on Health
FROM: Committee Majority Staff
RE: Subcommittee on Health Markup

I. INTRODUCTION

On Wednesday, November 15, 2023, at 10:00 a.m. (ET), the Subcommittee on Health will meet in open markup session in 2123 Rayburn House Office Building to consider the following:

- **H.R. 5372, Expanding Seniors' Access to Lower Cost Medicines Act of 2023 (Reps. Joyce and Peters)**
- **H.R. 2880, Protecting Patients Against PBM Abuses Act (Reps. Carter and Blunt Rochester)**
- **H.R. 5393, To amend title XVIII of the Social Security Act to ensure fair assessment of pharmacy performance and quality under Medicare part D, and for other purposes (Reps. Griffith and Carter)**
- **H.R. 5385, Medicare PBM Accountability Act (Reps. Landsman and Harshbarger)**
- **H.R. 5386, Cutting Copays Act (Reps. McGarvey and Bilirakis)**
- **H.R. 4881, To amend title XVIII of the Social Security Act to limit cost sharing for drugs under the Medicare program. (Reps. Malliotakis and Wenstrup)**
- **H.R. 5389, National Coverage Determination Transparency Act (Reps. Guthrie and Kelly)**
- **H.R. 133, Mandating Exclusive Review of Individual Treatments (MERIT) Act (Reps. Buchanan and Barragan)**
- **H.R. 5396, Coverage Determination Clarity Act of 2023 (Rep. Bucshon)**
- **H.R. 5371, Choices for Increased Mobility Act of 2023 (Reps. Joyce and Phillips)**
- **H.R. 5388, Supporting Innovation for Seniors Act (Reps. Balderson and Buchanan)**
- **H.R. 5380, To amend title XVIII of the Social Security Act to increase data transparency for supplemental benefits under Medicare Advantage (Rep. Sarbanes)**
- **H.R. 3842, Expanding Access to Diabetes Self-Management Training Act of 2023 (Reps. Schrier, Bilirakis, and Bucshon)**
- **H.R. 5397, Joe Fiandra Access to Home Infusion Act of 2023 (Reps. Fitzpatrick, Dunn and Soto)**
- **H.R. 6366, To amend title XVIII of the Social Security Act with respect to the work geographic index for physician payments under the Medicare program, and to revise the phase-in of clinical laboratory test payment changes under such program (Rep. Hudson)**
- **H.R. 6369, To amend title XVIII of the Social Security Act to extend incentive payments for participation in eligible alternative payment models (Reps. Schrier and Dunn)**

- **H.R. 5555, DMEPOS Relief Act of 2023 (Reps. Miller-Meeks and Tonko)**
- **H.R. 6371, Provider Reimbursement Stability Act of 2023 (Reps. Murphy, Burgess, Kelly, Wenstrup, Buschon, Van Drew, Miller-Meeks, Harris, Babin, Joyce, Jackson, McCormick, Ferguson, Dunn, and Carter)**
- **H.R. 6364, Medicare Telehealth Privacy Act of 2023 (Reps. Balderson, Dunn, Schweikert, and Carey)**
- **H.R. 1352, Increasing Access to Biosimilars Act of 2023 (Rep. Hudson)**
- **H.R. 1691, Ensuring Patient Access to Critical Breakthrough Products Act of 2023 (Reps. Wenstrup, Cardenas, and Eshoo)**

In keeping with Chair Rodgers' announced policy, Members must submit any amendments they may have two hours before they are offered during this markup. Members may submit amendments by email to EandCdocs@mail.house.gov. Any information with respect to an amendment's parliamentary standing (e.g., its germaneness) should be submitted at this time.

II. EXPLANATION OF LEGISLATION

H.R. 5372, Expanding Seniors' Access to Lower Cost Medicines Act of 2023 (Reps. Joyce and Peters)

This legislation 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.

H.R. 2880, Protecting Patients Against PBM Abuses Act (Reps. Carter and Blunt Rochester)

This legislation would establish new requirements for pharmacy benefit managers (PBMs) under Medicare Part D, including a policy to de-link PBM compensation from the cost of medications, while also prohibiting the use of spread pricing in which a PBM charges a sponsor a different amount for the drug's ingredient cost or dispensing fee than the amount the PBM reimburses the pharmacy for such ingredient cost or dispensing fee. The legislation also prohibits PBMs from compensating a network pharmacy less than affiliated pharmacies and includes transparency provisions related to the PBM rebates and administrative fees.

H.R. 5393, To amend title XVIII of the Social Security Act to ensure fair assessment of pharmacy performance and quality under Medicare part D, and for other purposes (Reps. Griffith and Carter)

This legislation would standardize pharmacy performance measures in the Medicare Part D program that assess network pharmacy performance by requiring that prescription drug plans (PDPs) only use pharmacy performance measures that are established by the Secretary of the Department of Health and Human Services (HHS) and are relevant to a particular pharmacy. The legislation would require an HHS Office of the Inspector General (OIG) report studying the implementation of these performance measures. The legislation would also establish a process by which PDPs provide their network pharmacies with comprehensive information about pricing prescription drug claims.

H.R. 5385, Medicare PBM Accountability Act (Reps. Landsman and Harshbarger)

This legislation would create enhanced PBM reporting requirements, including 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. The information submitted would not be publicly disclosed except in limited circumstances. The legislation would stipulate an audits and enforcement process by which PDPs can audit their PBM for compliance.

H.R. 5386, Cutting Copays Act (Reps. McGarvey and Bilirakis)

This legislation would clarify Medicare Part D cost-sharing for generic drugs for low-income patients in the Low-Income Subsidy (LIS) program by setting generic drug co-pays at \$0.

H.R. 4881, To amend title XVIII of the Social Security Act to limit cost sharing for drugs under the Medicare program. (Reps. Malliotakis and Wenstrup)

This legislation would limit patient cost-sharing for drugs under Medicare Part D starting in 2027 by providing that patients would not be required to pay more than the insurance company is paying for highly rebated drugs once all the discounts are accounted for.

H.R. 5389, National Coverage Determination Transparency Act (Reps. Guthrie and Kelly)

This legislation would require the Secretary of HHS to determine whether a request for a National Coverage Determination (NCD) is complete within 30 days of receiving the request. The bill would also allow the Secretary to work directly with the entity who submitted the request to update and resubmit the request if the Secretary finds that the application is incomplete. Additionally, the Secretary would be required to make all complete NCD applications publicly available on Centers for Medicare and Medicaid Services' (CMS's) website. Finally, the bill would clarify that the timeline for making a NCD begins on the date the Secretary receives an NCD application.

H.R. 133, Mandating Exclusive Review of Individual Treatments (MERIT) Act (Reps. Buchanan and Barragan)

This legislation would clarify that national coverage determinations for drugs and biologics under the Medicare program must be made with respect to each drug or biologic, not with respect to a class of drugs or of biologics.

H.R. 5396, Coverage Determination Clarity Act of 2023 (Rep. Bucshon)

This legislation would prohibit Local Coverage Determinations (LCDs) from being more restrictive than existing NCDs and require the Secretary of HHS to review LCDs annually to ensure they are consistent with existing NCDs.

H.R. 5371, Choices for Increased Mobility Act of 2023 (Reps. Joyce and Phillips)

This legislation would clarify payment rules for manual wheelchairs under Medicare Part B to specify that coverage of manual wheelchairs does not include expenses associated with the use of titanium or carbon fiber materials to construct the base of a wheelchair, allowing patients with Medicare Part B to pay out-of-pocket for wheelchair upgrades if they so choose.

H.R. 5388, Supporting Innovation for Seniors Act (Reps. Balderson and Buchanan)

This legislation would expand a flexibility offered through the Medicare Advantage Value-Based Insurance Design (VBID) Model to allow all Medicare Advantage plans to increase access to innovative medical devices and technologies using their existing supplemental benefit funds.

H.R. 5380, To amend title XVIII of the Social Security Act to increase data transparency for supplemental benefits under Medicare Advantage (Rep. Sarbanes)

This legislation would require enrollee-level utilization reporting of supplemental benefits by Medicare Advantage plans.

H.R. 3842, Expanding Access to Diabetes Self-Management Training Act of 2023 (Reps. Schrier, Bilirakis, and Bucshon)

This legislation would expand coverage for diabetes outpatient self-management training services and remove patient cost-sharing and deductible requirements under Medicare Part B. The legislation would also require the Center for Medicare and Medicaid Innovation (CMMI) to test a model covering virtual diabetes outpatient self-management training services.

H.R. 5397, Joe Fiandra Access to Home Infusion Act of 2023 (Reps. Fitzpatrick and Soto)

This legislation would codify a proposed CMS durable medical equipment (DME) policy that clarifies coverage of an external infusion pump under the Medicare DME benefit by clarifying the definition of external infusion pumps as “appropriate for use in the home” for individuals who are unable to self-administer drugs that meet certain criteria.

H.R. 6366, To amend title XVIII of the Social Security Act with respect to the work geographic index for physician payments under the Medicare program and to revise the phase-in of clinical laboratory test payment changes under such program (Rep. Hudson)

This discussion draft 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, which is otherwise set to expire January 1, 2024. The legislation also delays cuts and reporting under the clinical lab fee schedule.

H.R. 6369, To amend title XVIII of the Social Security Act to extend incentive payments for participation in eligible alternative payment models (Reps. Schrier and Dunn)

This discussion draft would extend incentive payments for participation in eligible alternative payment models for one year and tiers the size of the bonus according to how long a provider has participated in an APM to better account for increased up-front costs of APM participation.

H.R. 5555, DMEPOS Relief Act of 2023 (Reps. Miller-Meeks and Tonko)

This legislation would require the Secretary of HHS to provide certain adjustments to Medicare payment for items of durable medical equipment that were formerly included in round 2021 of the Durable Medical Equipment, Prosthetics/Orthotics and Supplies (DMEPOS) competitive bidding program.

H.R. 6371, Provider Reimbursement Stability Act of 2023 (Reps. Murphy, Burgess, Kelly,

Wenstrup, Buschon, Van Drew, Miller-Meeks, Harris, Babin, Joyce, Jackson, McCormick, Ferguson, Dunn, and Carter)

This discussion draft would increase the Physician Fee Schedule (PFS) budget neutrality threshold and provide for a lookback period to reconcile overestimates and underestimates of pricing adjustments for individual services. The draft also requires that the Secretary update prices and rates for direct cost inputs for practice expense relative value units no less than every 5 years. Finally, the draft sets a limitation on year-to-year conversion factor (CF) variance.

H.R. 6364, Medicare Telehealth Privacy Act of 2023 (Reps. Balderson, Dunn, Schweikert, and Carey)

This discussion draft would prohibit the Secretary of HHS from making a physician's or practitioner's address of residence publicly available if they elect to provide telehealth services from that address.

H.R. 1352, Increasing Access to Biosimilars Act of 2023 (Rep. Hudson)

This legislation would create a new pilot program to evaluate the benefits of providing additional shared savings payments to providers of biosimilars under Medicare.

H.R. 1691, Ensuring Patient Access to Critical Breakthrough Products Act of 2023 (Reps. Wenstrup, DelBene, Bilirakis, Cardenas, Moore, Sewell, Guthrie, and Eshoo)

This legislation would provide temporary or transitional Medicare coverage of medical breakthrough devices for four years while CMS works to make a permanent coverage determination. The legislation also enables a process whereby the Secretary would assign coding for approved products in a timely manner.

III. STAFF CONTACTS

If you have any questions regarding this markup, please contact Jolie Brochin with the Committee Staff at (202) 225-3641.