ENERGY & COMMERCE
CHAIR RODGERS

MEMORANDUM

To: Subcommittee on Health Members and Staff
From: Committee on Energy and Commerce Majority Staff
Re: Health Subcommittee Hearing on September 19, 2023

The Subcommittee on Health will hold a hearing on Tuesday, September 19, 2023, at 10:00 a.m. (ET) in 2322 Rayburn House Office Building. The hearing title is "Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices, and Technology."

I. Witnesses

- **Dr. Dora Hughes, MD, MPH,** Acting Director, Center for Clinical Standards and Quality, Acting Chief Medical Officer, U.S. Centers for Medicare and Medicaid Services
- **Mr. John Dicken,** Director, Health Care – Public Health and Private Markets, U.S. Government Accountability Office

II. Background

On July 18, 2023, the Subcommittee on Health held a hearing to examine various Medicare coverage pathways and processes and their impact on patients' access to care. The Subcommittee heard from six witnesses who shared different perspectives on the challenges that patients, caregivers, innovators, and providers face in accessing and delivering innovative medical products and services to patients. Witnesses and Members from both parties raised questions and concerns about the Biden administration's Transitional Coverage for Emerging Technologies (TCET) proposal, and additional concerns were raised over the Centers for Medicare and Medicaid Service's (CMS) National Coverage Determination and corresponding Coverage with Evidence Development (CED) requirements. The discussion also covered the CMS Innovation Center (CMMI) and its track record, the promise and difficulties in harnessing and paying for artificial intelligence tools, prescription digital therapeutics, telehealth, and other technologies.

This hearing is a follow up to that discussion to examine legislative solutions to address problems identified, such as the significant gaps between the FDA approval of innovative medical products, CMS coverage of these products, the need for more predictable coverage pathways for innovative medical products, and accountable timelines for coverage review and determinations.

After the July hearing, the Government Accountability Office (GAO) issued a September 2023 report titled "Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending" and noted that Medicare Part D drug expenditures exceeded $200 billion in 2021 and that private insurance plan sponsors who provide Part D drug

coverage received $48.6 billion in rebates from drug manufacturers. GAO noted that these rebates "do not lower individual beneficiary payments for drugs, as these are based on the gross cost of the drug before accounting for rebates." GAO found that patients paid more than the insurance plans paid, after accounting for rebates, for 79 of the 100 drugs receiving the greatest amount of rebates. Further, GAO noted that Part D plan sponsors "frequently gave preferred formulary placement to highly rebated, relatively higher-gross-cost brand-name drugs on their formularies compared to lower-gross-cost competitor drugs, which generally had lower rebates." GAO also found that generic counterpart drugs for highly rebated brand drugs were less likely to be included or given preferred placement on formularies over these highly rebated brand-name drugs.

In addition to examining legislation with respect to Medicare coverage determinations and patient access, legislation will also be considered that looks at the Part D program and the impact it has on patient access to drugs.

III. Legislation

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

This legislation would provide temporary or transitional Medicare coverage of medical breakthrough devices for four years while the Centers for Medicare and Medicaid Services (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.

H.R. 2408, the Access to Innovative Treatments Act of 2023 (Rep. Barragan)

This legislation would amend the Social Security Act (SSA) to provide for a review process for adverse National Coverage Determinations (NCDs) with respect to drug and biologics coverage. The legislation would also prohibit existing NCDs from denying or limiting coverage to subsequently FDA-approved drugs or biologics, which would effectively prohibit CMS from limiting coverage to an entire class of drugs.

H.R. 133, the 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. 2407, the Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act (Reps. Arrington, Hudson, and Ruiz)

This legislation would allow for Medicare coverage and payment for FDA cleared or approved multi-cancer early detection screening tests.

H.R. 1199, the Facilitating Innovative Nuclear Diagnostics (FIND) Act of 2023 (Reps. Dunn, Peters, Trahan, Blunt Rochester, Miller-Meeks, Tonko, Joyce, Kuster, and Bucshon)

This legislation would change the Medicare reimbursement structure from being bundled with other imaging services by establishing separate payment requirements for diagnostic radiopharmaceuticals under the Medicare prospective payment system for hospital outpatient department services. These requirements would apply to diagnostic radiopharmaceuticals that have an average daily cost of $500 or more in 2024 and as adjusted based on a specified fee schedule factor in each year thereafter.

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

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. 4818, the Treat and Reduce Obesity Act (TROA) of 2023 (Reps. Wenstrup, Ruiz, and Miller-Meeks)

This legislation would expand Medicare Part D coverage of obesity medications and allow additional health care providers to offer the Intensive Behavioral Therapy benefit. Additionally, the bill would require the Secretary of Health and Human Services (HHS) to submit a report to Congress on steps taken to implement the provisions of this Act, along with recommendations to improve Federal coordination to treat, reduce, and prevent obesity.

H.R. 1458, the Access to Prescription Digital Therapeutics Act of 2023 (Reps. Hern, Johnson, and Matsui)

This legislation would provide for Medicare and Medicaid coverage of prescription digital therapeutics.

H.R. 2880, the 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 delink 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. 5074, the Kidney PATIENT Act of 2023 (Reps. Carter and Kuster)

This legislation would delay implementation of the inclusion of oral-only End Stage Renal Disease (ESRD) drugs in the Medicare ESRD Prospective Payment System (PPS).

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

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. 5372, To amend Title XVIII of the Social Security Act to facilitate midyear formulary changes for biosimilars (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. 5376, the Share the Savings with Seniors Act (Reps. Miller-Meeks and Peters)

This legislation would require full rebate pass-through for chronic condition medicines within the deductible, or when patients owe coinsurance.

H.R. 5371, the Choices for Increased Mobility Act of 2023 (Rep. Joyce)

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. 5394, the Expanding Remote Monitoring Access Act (Reps. Balderson and Porter)

This legislation would provide for Medicare coverage of remove monitoring services if such services collect data for a minimum of 2 days over a 30-day period, down from 16 days in current law. The legislation also requires a study of remote monitoring services that will help inform reimbursement and coverage policies of remote monitoring services.

H.R. 5386, the 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. 5393, the Transparency and Fairness for Pharmacies Act (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 HHS Secretary and

relevant to a particular pharmacy. The legislation would require a 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. 5389, the National Coverage Determination Transparency Act (Rep. Guthrie)

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 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. 5395, the Coverage Parity for Medicare Patients Act of 2023 (Rep. Harshbarger)

This legislation would establish a demonstration program for Medicare patients in a number of states or regions to provide for coverage for items and services that are otherwise safe and effective and not experimental or investigational, if commercial insurance plans already cover these items or services for patients. This policy would test commercial coverage parity for Medicare patients to provide that seniors do not lose access to innovative medical products and services by enrolling in the Medicare program.

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

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

H.R. 5392, the Timely Access to Coverage Decisions Act of 2023 (Rep. Dunn)

This legislation would require that LCD requests received by Medicare administrative contractors (MACs) be reviewed and determined whether complete or not within 30 days of a request. In the case of incomplete requests, the MAC must transmit the additional information needed to complete the request within 60 days of the receipt. The legislation would also standardize a 9-month timeline for issuing a coverage decision after a request is determined to be complete.

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

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. 5385, the 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. 5388, the Supporting Innovation for Seniors Act (Rep. Balderson)

This legislation would expand a flexibility offered through the Medicare Advantage Value-Based Insurance Design (VBID) Model to allow all Medicare Advantage plans to offer supplemental benefits for innovative medical devices and technologies.

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 that Medicare Advantage plans submitted to the Secretary of HHS have enrollee-level data on the utilization of supplemental benefits offered by plans de-identified.

IV. Staff Contacts

If you have questions regarding this hearing, please contact Caitlin Wilson or Alec Aramanda of the Committee staff at 202-225-3641.