

Combined Document

Description of the Chairman's Mark The Better Mental Health Care, Lower-Cost Drugs, and Extenders Act and Description of Certain Provisions of the Modernizing and Ensuring PBM Accountability (MEPA) Act

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Title 1. Expanding Mental Health Care Workforce and Services Under Medicare and Medicaid.

Section 101. Expanding Eligibility for Incentives Under the Medicare Health Professional Shortage Area Bonus Program to Practitioners Furnishing Mental Health and Substance Use Disorder Services

Current Law

On a quarterly basis, Medicare makes incentive payments to physicians for Part B professional services delivered to Medicare beneficiaries within a Health Resources and Services Administration (HRSA)-designated health professional shortage area (HPSA). The Medicare statute sets these bonus payments at 10% the amount paid by the program to the physician for qualifying services. Under current law, only physicians are eligible for bonuses. Additionally, only psychiatrists can receive bonus payments for professional services furnished within a geographic mental health HPSA that is not also a primary medical care HPSA.

Provision

The provision would extend eligibility for HPSA bonuses to certain mental health and substance use disorder services furnished in mental health HPSAs by applicable non-physician health care professionals, including: (1) physician assistants, nurse practitioners, or clinical nurse specialists; (2) clinical social workers; (3) clinical psychologists; (4) marriage and family therapists; and (5) mental health counselors.

The provision would also increase bonus payments from 10% to 15% for mental health and substance use disorder services furnished in mental health HPSAs by eligible providers. These provisions would apply to services furnished on or after January 1, 2026.

Section 102. Improved Access to Mental Health Services Under the Medicare Program

Current Law

Medicare covers certain behavioral health services, which include mental health and substance use disorder services, furnished by licensed or certified clinical social workers (CSW) for the diagnosis and treatment of mental health illness. CSWs bill for such services under Part B. Medicare does not currently cover health behavior assessment and intervention services provided by CSWs, although CMS included a proposal to enable CSWs and certain other non-physician practitioners to bill the program for these services in the “Calendar Year (CY) 2024 Medicare Physician Fee Schedule Proposed Rule,” published on July 13, 2023.

Medicare pays for eligible skilled nursing facility (SNF) care under Medicare Part A through a prospective payment system (PPS), which excluded psychiatrists’ and psychologists’ services when the SNF PPS methodology was implemented, but did include clinical social worker services. Because of this, SNF patients are unable to receive Medicare-compensated care from CSWs who bill under Medicare Part B. The prohibition of additional payments under Part B is due to potential double-billing from what is paid to SNFs by Medicare in the SNF PPS.

Provision

The provision would, beginning January 1, 2026, modify the definition of clinical social worker services covered under Medicare Part B to include services for health behavior assessment and intervention, identified by specific current and successor Healthcare Common Procedure Coding System (HCPCS) codes, furnished in an outpatient setting. The provision would also exclude clinical social worker services from the Part A Medicare SNF PPS. The provision would ensure that the required payment adjustment in Section 1888(e)(4)(G)(iii) of the SSA applies for the furnished CSW services that are removed from the SNF PPS per diem payment bundle, preventing provider double-billing.

Section 103. Clarifying Coverage of Occupational Therapy Under the Medicare Program

Current Law

No current law.

Provision

Within one year of enactment, the provision would require the Department of Health and Human Services (HHS) Secretary to provide education and outreach to stakeholders about the availability of substance use disorder or mental health disorder services furnished by occupational therapists to Medicare beneficiaries.

Section 104. Medicare Incentives for Behavioral Health Integration with Primary Care

Current Law

Medicare, under Medicare Part B, covers eligible care management for behavioral health conditions (e.g., depression, anxiety, or another mental health condition) and pays health care providers using the Psychiatric Collaborative Care Model, a set of integrated behavioral health services that include care management support such as care planning for behavioral health conditions, ongoing assessment, medication support, counseling, and other treatments.

Provision

Beginning in 2026, this provision would increase the payment amount under the Medicare physician fee schedule (MPFS) for certain behavioral health integration services (identified in the legislation by specific service codes), and then phase down that increase in 2027 and 2028. For 2026, the payment for the codes would be 175% of the MPFS amount; for 2027, the payment would be 150%; and for 2028, it would be 125%. The increase and phase-down in payments under this provision would not be included in the MPFS's budget neutrality calculations.

Section 105. Establishment of Medicare Incident to Modifier for Mental Health Services Furnished through Telehealth

Current Law

During the coronavirus public health emergency (PHE), the Coronavirus Aid, Relief, and Economic Security Act (CARES, P.L. 116-136) gave the HHS Secretary authority to modify or waive many of the

statutory restrictions on Medicare telehealth services. The Secretary used these flexibilities to expand access to behavioral health services (substance use disorder and mental health services) delivered via telehealth, including for services furnished incident to care provided by a physician or non-physician practitioner. Subsequently, the Consolidated Appropriations Act, 2021 (P.L. 116-260) made this new modification permanent.

Provision

This provision would direct the Secretary to establish requirements within two years of enactment of this Act related to the use of a code or modifier identifying claims for certain telehealth services furnished by auxiliary personnel incident to a physician's or non-physician practitioner's services.

Section 106. Guidance on Furnishing Behavioral Health Services via Telehealth to Individuals with Limited English Proficiency under Medicare Program

Current Law

No current law.

Provision

This provision would require the HHS Secretary to issue and disseminate guidance on best practices (1) for providers to work with interpreters to furnish behavioral health services via video-based and audio-only telehealth, when video-based telehealth is not an option; (2) on integrating the use of video platforms that enable multi-person video calls into behavioral health services furnished via telehealth; (3) on teaching patients, especially those with limited English proficiency, to use video-based telehealth platforms; and (4) for providing patient materials, communications, and instructions in multiple languages, including text message appointment reminders and prescription information

Section 107. Ensuring Timely Communication Regarding Telehealth and Interstate Licensure Requirements

Current Law

No current law.

Provision

This provision would require the HHS Secretary to provide information on licensure requirements for furnishing telehealth services under Medicare and Medicaid, including updates to guidance and other information that clarifies the extent to which licenses through the interstate license compact pathway can qualify as valid and full licenses for the purposes of meeting licensure requirements under Titles XVIII and XIX of the Social Security Act.

Section 108. Facilitating Accessibility for Behavioral Health Services Furnished through Telehealth

Current Law

No current law.

Provision

This provision would require the HHS Secretary to provide updates to guidance to facilitate the accessibility of behavioral health services furnished through telehealth for the visually and hearing impaired.

Section 109. Requiring Enhanced & Accurate Lists of (REAL) Health Providers Act

Current Law

Section 1852(c)(1)(C) requires Medicare Advantage (MA) Organizations to disclose in a clear, accurate, and standardized form the number, mix, and distribution of plan providers. Under its statutory authority, CMS requires MA organizations to provide enrollees with plan directories by October 15th each year, within 10 days of enrollment, and at the request of an enrollee. MA organizations are required to include printable and searchable copies of plan directories listing providers on plan websites and maintain a publicly accessible standards-based Application Programming Interface that must provide a complete and accurate directory of the MA plan's network of contracted providers. CMS guidelines state that MA plans should contact contracted providers on a quarterly basis to update provider directory information including the ability to accept new patients, street address, phone number, and any other changes that affect availability to patients. Directories must be updated within 30 days of the plan receiving information requiring update.

MA plans vary with respect to whether, or the extent to which, they cover out-of-network care. When out-of-network care is covered, the enrollee is generally required to pay higher cost sharing for going out-of-network.

Provision

Starting in plan year (PY) 2026, the provision would require each network-based MA plan to verify provider directory information at least every 90 days; the HHS Secretary can allow plans to verify hospital and other facility information less frequently than 90 days, as long as that information is verified at least annually. MA plans would be required to note in the directory providers whose information could not be verified and to remove providers listed in a directory within 5 business days if the organization determines the provider is no longer participating in the network. Provider directories would be required to include information that the enrollee may need to access covered benefits from a contracted provider. If an enrollee received care from an out-of-network provider that was listed when the appointment was made as an in-network provider in the plan's directory, the MA organization would be required to cover that out of network care, as long as it was a covered item or service, and ensure that the enrollee was only responsible for in-network cost sharing.

Beginning in PY2026, MA contracts would be required to conduct and submit to the HHS Secretary annual reports of their provider directory accuracy, including provider specialties with high inaccuracy rates (such as providers specializing in mental health) as determined by the HHS Secretary for each plan. The HHS Secretary, in implementing this provision, would be required to consider various data sources as well as the administrative burden on plans and providers, and the relative importance of certain directory information on access to care. Beginning in PY 2027, the HHS Secretary would be required to post on the CMS website the provider directory accuracy scores, in a machine-readable format and plans would be required to disclose the accuracy scores on its plan directory. The HHS Secretary would be required to implement provider directory accuracy analyses through the rulemaking process and would be permitted to waive these requirements for certain low enrollment MA plans. The provision would provide that, in addition to amounts otherwise available, there would be appropriated to CMS Program Management Account, out of the General Fund of the Treasury, \$1,000,000 to remain available until expended.

By not later than January 15, 2031, the Comptroller General of the United States would be required to submit a study of the implementation of: (1) the requirement that in-network cost sharing amounts apply to care furnished by an out-of-network provider if the provider choice was based on incorrect directory information, (2) provider response rates to plan outreach methods; and (3) the requirement that MA organizations conduct and submit provider directory accuracy analyses (both overall and among providers specializing in mental health or substance disorder treatment).

The HHS Secretary would be required to hold a public stakeholder meeting on best practices for maintaining accurate provider directories, issue guidance to MA Organizations on best practices, and issue guidance to providers on when to update their information in the National Plan and Provider Enumeration System.

Section 110. Guidance to States on Strategies Under Medicaid and CHIP to Increase Mental Health and Substance Use Disorder Care Provider Capacity

Current Law

In general, Medicaid state plans must allow program enrollees to obtain services from any willing and qualified provider that chooses to offer such services. States are generally responsible for determining which providers meet program qualification criteria including licensed clinicians and non-licensed providers such as peer support specialists. Providers who meet these federal and state requirements may enter into agreements with state Medicaid agencies to provide Medicaid-coverable services to individuals enrolled in the Medicaid program.

Section 1003 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act; P.L. 115-271) established a time-limited competitive demonstration project to increase the treatment capacity of Medicaid substance use disorder (SUD) providers and inform best practices through specified activities, including improved reimbursement, recruitment, training, and technical assistance.

Provision

This provision would require the HHS Secretary to issue state guidance within 18 months of the enactment of this Act on strategies to increase the capacity of MH and SUD providers under Medicaid and CHIP, with a focus on improving MH/SUD provider capacity in rural and underserved areas.

Section 111. Guidance to States on Supporting Mental Health Services and Substance Use Disorder Care for Children and Youth

Current Law

Early and Periodic, Screening, Diagnostic, and Treatment (EPSDT) services are a required benefit for nearly all children (under age 21) who are enrolled in Medicaid, and for targeted low-income children under the State Children's Health Insurance Program (CHIP) Medicaid expansion programs.¹ EPSDT covers comprehensive health screenings, including assessments of children's physical and mental health development, and all federally allowable, medically necessary treatment to correct problems identified through screenings (including services to treat any identified MH and/or SUD condition), even if the specific treatment needed is not otherwise covered under a given state's Medicaid plan.

¹ While EPSDT is not a required benefit for separate CHIP programs, many states also offer this benefit under their separate CHIP plans.

While MH and SUD services are not specifically defined categories of Medicaid benefits, the program covers many MH/SUD benefits under other service categories, and states have the flexibility to cover MH/SUD services under several different statutory authorities (e.g., state plan, waiver authorities, and other authorities for Medicaid payment). For separate CHIP programs, Title XXI of the Social Security Act requires states to cover a wide-array of MH/SUD services necessary to prevent, diagnose, and treat mental health conditions and substance use disorders.

Provision

Within one year after enactment of this Act, the provision would require the HHS Secretary, in consultation with (1) the CMS Administrator, (2) the Assistant Secretary for the Administration for Children and Families (ACF), (3) the Assistant Secretary for Mental Health and Substance Use, and (4) the Director of the Office of National Drug Control Policy to release state guidance regarding opportunities to improve the design, implementation, screening for and access to a continuum of culturally competent, developmentally appropriate, and trauma-informed Medicaid and CHIP MH/SUD services for at-risk children and youth, as defined, as well as other special populations such as youth in foster care and those with intellectual or developmental disabilities.

Section 112. Recurring Analysis and Publication of Medicaid Health Care Data Related to Mental Health Services

Current Law

The SUPPORT for Patients and Communities Act (SUPPORT Act, P.L. 115-271) requires the HHS Secretary to publish a report on the prevalence of substance use disorders (SUDs) and the SUD treatment services provided to Medicaid enrollees based on federally required state submissions of Transformed Medicaid Statistical Information System (T-MSIS) data. CMS is required to issue annual updates that include certain specified information not later than January 1 for each calendar year through 2024.

Provision

The provision would require the HHS Secretary to publish to a publicly available website with specified information on the prevalence of mental health (MH) conditions and MH treatment services provided to Medicaid enrollees, based on federally-required state submissions of Transformed Medicaid Statistical Information System (T-MSIS) (or a successor system) data. The first publication of Medicaid MH data would be required to be made available within 18 months of this Act's enactment, and biennially thereafter. The provision would also require CMS to permanently continue to issue annual updates of the SUPPORT Act SUD Databook.

Section 113. Guidance to States on Supporting Mental Health Services or Substance Use Disorder Care Integration with Primary Care in Medicaid and CHIP

Current Law

The Centers for Medicare & Medicaid Services (CMS) has issued guidance to encourage states to adopt strategies that promote the integration of physical and mental health (MH) or substance use disorder (SUD) care delivery under existing Medicaid and CHIP authorities, payment methodologies, and

integrated care models. This approach is being undertaken in an attempt to more effectively identify enrollee health care needs and connect enrollees with appropriate treatment.²

Provision

The provision would require the HHS Secretary to conduct an analysis of Medicaid and CHIP clinical outcomes associated with various integrated care models and payment methodologies, within 18 months of the enactment of this Act. Within 12 months of completing this analysis, the HHS Secretary would be required to issue state guidance on supporting the integration of Medicaid and CHIP MH care or SUD care with primary care that meets specified requirements.

Section 114. Medicaid State Option Relating to Inmates with a Substance Use Disorder Pending Disposition of Charges

Current Law

The federal Medicaid statute includes the inmate payment exclusion which generally prohibits the use of federal Medicaid funds to pay for the health care of an inmate of a public institution. CMS sub-regulatory guidance clarifies that Medicaid's definition of an inmate of a public institution does not distinguish between individuals who are detained in a public institution pending disposition of charges and those who are incarcerated post-sentencing.

Section 5122 of the Consolidated Appropriations Act, 2023 (CAA 2023; P.L. 117-328) permits states to receive federal payment for certain specified Medicaid services provided to “eligible juveniles” during the period in which such enrollees are inmates of a public institution pending disposition of charges, beginning January 1, 2025.

Provision

The provision would modify the Medicaid statute, as amended in CAA 2023, to permit states to receive federal payment, for a period not to exceed 7 days, for medical assistance for individuals with an SUD who are inmates of a public institution pending disposition of charges, who were assessed to confirm an SUD diagnosis while incarcerated, and whose eligibility for medical assistance is suspended by the state during the period the individual is an inmate of such a public institution. The provision would be effective beginning January 1, 2026.

Title 2. Reducing Prescription Drug Costs under Medicare and Medicaid.

Section 201. Assuring Pharmacy Access and Choice for Medicare Beneficiaries

Current Law

Under Social Security Act (SSA) 1860D-4(b) ((42 U.S.C. 1395w-104(b)), Part D plans must contract with an adequate network of brick-and-mortar pharmacies each year in order to provide easy access for

² CMCS Informational Bulletin. Leveraging Medicaid, CHIP, and Other Federal Programs in the Delivery of Behavioral Health Services for Children and Youth. August 18, 2022, at <https://www.medicaid.gov/sites/default/files/2022-08/bhccib08182022.pdf>.

plan enrollees. Plan sponsors often contract with pharmacy benefit managers (PBMs) to contract with pharmacies and maintain pharmacy networks on the plan’s behalf. Under 1860D-4(b)(A), plan sponsors must contract with any willing pharmacy that agrees to accept their pharmacy network terms and conditions. Under current regulations and program guidance, such terms and conditions must be reasonable and relevant, including with respect to reimbursement.³ However, pharmacy contract terms and drug reimbursement vary among Part D plans.

Chapter 5 of the Medicare Prescription Drug Benefit Manual indicates that CMS generally defers to the relevant parties to resolve disputes regarding Part D’s any willing pharmacy requirements, although the agency issued program guidance in 2015 highlighting reports from pharmacies raising “several issues” with plan sponsors’ approach to compliance.^{4,5} The guidance did not outline any substantive changes or increases in enforcement with respect to the relevant requirements.

In recent years, CMS has also noted a sharp rise in pharmacy fees and other price concessions that plan sponsors and PBMs extracted from retail pharmacies after the point of sale and reported as Direct and Indirect Remuneration (DIR). Part D pharmacy DIR includes administrative fees, network access fees, and fees for not meeting plan quality metrics. Part D plan sponsors may provide incentive payments to pharmacies for meeting specified goals, but CMS data indicate that extracted fees, or penalties, far outpace additional compensation to pharmacies. According to CMS, pharmacy fees are the fastest-growing category of DIR, accounting for nearly 5% of gross Part D drug costs (\$9.5 billion) in 2020, compared to 0.01% (\$8.9 million) in 2010.⁶ The increase in fees, as well as their post-point of sale nature, have made it difficult for pharmacies to accurately predict their total reimbursement for dispensing a covered drug, with some pharmacies expressing concerns that reimbursement on certain drugs can drop below pharmacy acquisition costs.

In May 2022, CMS issued a final rule, effective in 2024, to help address the uncertainties in pharmacy reimbursement caused by PBM fees. The rule changes the definition of “negotiated price” to include the lowest possible reimbursement that a network pharmacy will receive in total for dispensing a drug.⁷ Some pharmacies have expressed concerns that implementation of this rule could lead to further reductions in overall reimbursement from PBMs working on behalf of Part D plans.⁸

After a plan has developed an adequate network, Part D plan sponsors (except those offering the Part D defined standard benefit) may contract with select pharmacies to create a second, preferred pharmacy network. Part D sponsors may institute lower copayments or coinsurance for enrollee prescriptions filled in preferred pharmacies, but such cost-sharing reductions may not increase Medicare payments to the Part

³ 42 C.F.R. § 423.505; Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50

⁴ *Ibid.*

⁵ CMS, “Compliance with Any Willing Pharmacy (AWP) Requirements,” August 13, 2015.

https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/anywillingpharmacyguidance_166.pdf

⁶ CMS, “Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs,” 87 *Federal Register*, May 2022, p. 1413, <https://www.federalregister.gov/d/2022-09375/p-1413>.

⁷ CMS, “Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs,” 87 *Federal Register*, May 2022.

⁸ Levitt, Jonathan. “A New World Order of Drastically Lower Pharmacy Reimbursement Series—Part 1: Lower Net Pharmacy Reimbursement Following CMS Final Rule on DIR Fees,” Frier Levitt, June 2022.

<https://www.frierlevitt.com/articles/a-new-world-order-of-drastically-lower-pharmacy-reimbursement-series-part-1-lower-net-pharmacy-reimbursement-following-cms-final-rule-on-dir-fees/#:~:text=DIR%20fees%20from%202016%20through,pharmacies%20below%20pharmacy%20acquisition%20cost.>

D plan. CMS does not apply any willing pharmacy requirements to the designation of preferred network pharmacies, and program guidance permits plans to increase cost-sharing for non-preferred network pharmacies in order to meet the requisite actuarial tests while reducing cost-sharing for preferred network pharmacies.⁹ A number of large Part D plans include no independent pharmacies in their preferred networks.¹⁰

Provisions

I. Reasonable & Relevant Codification

These provisions would amend SSA 1860D–4(b)(1) by requiring plan sponsors to contract with any willing pharmacy that meets their standard contract terms and conditions, and by requiring that such contract terms and conditions be reasonable and relevant. No later than January 1, 2025, the HHS Secretary would be required to request information on such contract terms and conditions, as well as contracting practices between pharmacies and Part D plans/PBMs. No later than January 1, 2028, the HHS Secretary would establish standards for reasonable and relevant contract terms and conditions through notice-and-comment rulemaking.

II. Essential Retail Pharmacies

These provisions would also amend 1860D–4(b)(1)(C) (42 U.S.C. 1395w–104(b)(1)(C)), which governs convenient access to Part D pharmacies. Effective starting in 2028, a plan sponsor offering preferred pharmacy networks would be required to contract with at least:

- 80% of essential retail pharmacies in the plan’s service area that are independent community pharmacies, and
- 50% of essential retail pharmacies in such plan’s service area that are not independent community pharmacies.

An independent community pharmacy would be defined as a retail pharmacy with fewer than four locations that is not affiliated with any person or entity other than its owners.

An essential retail pharmacy would be defined as a pharmacy that: (1) is not an affiliate of a PBM or plan sponsor;¹¹ (2) is located in a medically underserved area; and (3) is designated as an essential retail pharmacy by the HHS Secretary for the year. The HHS Secretary would designate essential retail pharmacies each plan year based in part on information submitted by plan sponsors about affiliate pharmacies. The HHS Secretary would issue a list of essential retail pharmacies prior to the start of a plan year. The HHS Secretary could revoke a designation in certain cases, such as when a pharmacy no longer meets the requirements.

Starting in 2028, total reimbursement for a covered drug dispensed by an essential retail pharmacy that is an independent community pharmacy could not be lower than the average National Average Drug

⁹ 42 C.F.R. § 423.505; Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50

¹⁰ Fein, Adam. “Small Pharmacies Walk Away from Medicare Part D’s 2023 Preferred Networks,” Drug Channels, December 2022. <https://www.drugchannels.net/2022/12/small-pharmacies-walk-away-from.html>

¹¹ AFFILIATE.—The term ‘affiliate’ means any entity that is owned by, controlled by, or related under a common ownership structure with a pharmacy benefit manager or PDP sponsor or that acts as a contractor or agent to such pharmacy benefit manager or PDP sponsor, if such contractor or agent performs any of the functions described in item (cc).

Acquisition Cost¹² (aNADAC) for such drug for retail community pharmacies. If there were no NADAC data for retail community pharmacies available, the aNADAC for applicable non-retail pharmacies or the Wholesale Acquisition Cost (WAC) would be used to determine the reimbursement floor for such pharmacies.

III. Allegations of Violations

These provisions would amend SSA 1860D–4(b)(1) (42 U.S.C. 1395w–104(b)(1)) to require the HHS Secretary, no later than January 1, 2028, to establish a process enabling a pharmacy to submit an allegation, via a standardized template, that a plan sponsor was in violation of: (1) standards for reasonable and relevant contract terms and conditions; or (2) protections for essential retail pharmacies that are independent pharmacies. The provisions would allow a pharmacy to submit allegations of violations related to reasonable and relevant standards once per contract per plan year. Essential retail pharmacies that are independent pharmacies would be permitted to submit allegations of reimbursement violations on a quarterly basis.

A plan sponsor accused of such violations would have to provide relevant documents or materials to the HHS Secretary upon request, and could not limit the ability of a pharmacy to submit such information to the HHS Secretary. If the HHS Secretary determined that a pharmacy submitted frivolous allegations on a routine basis, the HHS Secretary could temporarily prohibit such pharmacy from using the allegation process.

Civil penalties would apply for violations of the statute. In addition, a plan sponsor that underpaid a pharmacy would be required to provide full reimbursement.

These provisions would also amend SSA 1860D–12(b) (42 U.S.C. 1395w–112) to require that each contract between a Part D plan and a PBM include a written agreement that the PBM reimburse the sponsor for any amounts related to violations of contract terms and essential retail pharmacy protections that were related to responsibilities such plan delegated to the PBM.

These provisions would provide \$250 million in funding to carry out these provisions, beginning in 2024, to remain available until expended.

Section 202. Ensuring Accurate Payments to Pharmacies Under Medicaid

Current Law

State Medicaid programs reimburse statutorily defined retail community pharmacies (RCPs) for covered outpatient drugs dispensed to Medicaid beneficiaries based on two components: (1) the cost of the medicine (the ingredient cost) and (2) a payment for the cost to the pharmacy of administering and filling a prescription (the professional dispensing fee). State Medicaid programs, subject to CMS approval, determine pharmacy ingredient payment rates, as well as professional dispensing fees.

The Deficit Reduction Act of 2005 (DRA, P.L. 109-171) amended SSA Section 1927 by adding a new subsection (f) that required the HHS Secretary to retain a contractor to survey RCPs. To implement the survey, CMS contracted for the National Average Drug Acquisition Cost (NADAC) survey. NADAC is a monthly survey of RCP acquisition costs paid for most covered outpatient drugs. CMS, through a

¹² The National Average Drug Acquisition Cost (NADAC) is a Medicaid price measure that is based on survey of pharmacy acquisition costs and represents the average acquisition cost.

contractor, surveys a national random sample of RCPs monthly and has been publishing NADAC data since November 2013. RCP participation in NADAC is voluntary, but to provide an accurate national estimate of average acquisition costs, it is important that the sample is representative of all geographic areas and different pharmacy types such as independent and chain pharmacies.

The NADAC survey excludes specialty and mail-order pharmacies, as well as a number of other non-retail community pharmacies. According to a 2020 HHS OIG report, “60 percent of drugs categorized as specialty drugs with Medicaid reimbursement in 2018 did not have NADAC data available,” limiting states’ ability to set accurate payment rates for these products.¹³ OIG recommended that CMS provide states with acquisition cost data for these products, but the agency cited its lack of clear statutory authority to conduct a NADAC-like survey of specialty pharmacies in responding to the recommendation.

As of last year, the three largest specialty pharmacies were all PBM affiliates and accounted for a combined 65 percent of prescription revenue for pharmacy-dispensed specialty drugs.¹⁴ A September 2023 Nephron Research study found that “expansion of specialty pharmacy is now the leading driver of PBM profit growth,” accounting for an estimated 39% of gross profits for PBMs in 2023, up from just 16% in 2012.¹⁵ A number of studies have pointed to vertical integration in the sector as a potential source of substantial markups on otherwise low-cost specialty drugs in Part D.

Provision

This provision would require the Secretary to survey RCPs’ drug prices to determine national average drug acquisition costs. Specifically, the HHS Secretary would be required to conduct a monthly survey to determine NADACs for covered outpatient drugs that represent a nationwide average of consumer purchase prices, net of all discounts and rebates (to the extent discount and rebate information is available). RCPs that receive payment related to the dispensing of covered outpatient drugs to individuals receiving benefits under Medicaid would be required to respond to the survey. The Secretary would be authorized to use a vendor to conduct the survey. Information on national drug acquisition prices obtained through the NADAC survey would be publicly available, as would other specified information on the NADAC survey.

These provisions would also to require the HHS Secretary to survey drug prices at applicable non-retail pharmacies to determine NADAC benchmarks for such pharmacies that are separate from benchmarks used for RCPs. Applicable non-retail pharmacies that receive payment related to the dispensing of covered outpatient drugs to individuals receiving benefits under Medicaid would also be required to respond to the survey.

An “applicable non-retail pharmacy” would be a state-licensed pharmacy that is not an RCP, including mail order and specialty pharmacies. The following pharmacies would not be considered applicable non-retail pharmacies: nursing home, long-term care facility, hospital, clinic, charitable or not-for-profit, government, and low-dispensing (defined by the HHS Secretary) pharmacies. By January 1, 2025, the

¹³ Murrin, Suzanne. “States Could Do More To Oversee Spending and Contain Medicaid Costs for Specialty Drugs.” *HHS OIG*, December 2020. <https://oig.hhs.gov/oei/reports/OEI-03-17-00430.pdf>

¹⁴ Fein, Adam. “DCI’s Top 15 Specialty Pharmacies of 2022: Five Key Trends About Today’s Marketplace,” *Drug Channels*, April 2023. <https://www.drugchannels.net/2023/04/dcis-top-15-specialty-pharmacies-of.html#:~:text=PBMs%20still%20dominate.,that%20also%20own%20a%20PBM.>

¹⁵ Percher, Eric. “Trends in Profitability and Compensation of PBMs & PBM Contracting Entities,” *Nephron Research*, September 2023. https://nephronresearch.bluematrix.com/sellside/AttachmentViewer.action?encrypt=1c65fc0e-f558-4f1d-891f-21c196a9f1ad&fileId=7276_04a77b17-d298-48a2-bd15-1c5ed22a6984&isPdf=false

HHS Secretary, would be required to consult with appropriate stakeholders and issue guidance defining applicable non-retail pharmacies. In addition, under the guidance promulgated to define non-retail pharmacies, the HHS Secretary would be required to establish pharmacy type indicators to distinguish between different non-retail pharmacies, such as mail order and specialty pharmacies. Applicable non-retail pharmacies may be identified by multiple pharmacy type indicators.

To receive federal financial participation on prescription drugs, state Medicaid programs must require pharmacies in the state to respond to the monthly NADAC surveys. States would be prohibited from using survey data from applicable non-retail pharmacy prices to develop or inform reimbursement rates for RCPs.

National drug acquisition prices would be made publicly available as well as other information on the survey such as the monthly response rate, identification of noncompliant pharmacies, the sampling frame and the number of pharmacies sampled monthly. In addition, price concessions to pharmacies including discounts, rebates, and other price concessions would be made public, if that information may be released publicly, and to the extent the HHS Secretary has collected the information through the NADAC survey during the survey period.

The HHS Secretary in consultation with the Department of Health and Human Services Office of the Inspector General (OIG), would be required to enforce pharmacy compliance with the NADAC survey through establishing appropriate civil monetary penalties (CMPs). CMPs may be assessed for each violation or survey non-response and on each non-compliant pharmacy until compliance is completed.

OIG would be required to conduct appropriate periodic studies of the NADAC survey data, including substantial variations in acquisition costs or other applicable costs, as well as how internal transfer prices and related party transactions may influence costs reported by pharmacies. As appropriate, OIG would be required to update Congress periodically on the results of these studies without disclosing trade secrets and other proprietary information.

OIG would receive an appropriation of \$5 million for FY2024 that would be available until expended to carry out oversight of the NADAC survey. The HHS Secretary would receive a \$9 million appropriation for FY2024 and for each fiscal year thereafter to conduct the NADAC survey.

These provisions would be effective on the first day of the first quarter 18 months after this provision's enactment date.

Section 203. Protecting Seniors from Excessive Cost-Sharing for Certain Medicines

Current Law

Under Part D's standard benefit, enrollees incur 100% of covered drug costs during the deductible phase, after which point they incur 25% cost-sharing until reaching the out-of-pocket threshold. Currently, beneficiaries face 5% cost-sharing beyond the out-of-pocket threshold, but this obligation will sunset after plan year 2023. Plans participating in the program can opt to provide either the standard benefit, an actuarially equivalent benefit, or an enhanced benefit.

Most Part D plans charge a mix of flat copayments and coinsurance (cost-sharing calculated as a percentage of a drug's price), although adoption of the latter has grown in recent years. Cost-sharing levels tend to vary across formulary tiers. For specialty-tier drugs, for instance, all plans charge coinsurance (between 25% and 33%), and a sizable share of plans apply coinsurance to medications on

their non-preferred tiers (charging up to 50%), whereas all plans adopt flat copays for generic and preferred generic tiers.¹⁶

While the Part D statute requires plans to provide enrollees with “access to negotiated prices” for covered drugs, “tak[ing] into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations,” most plans choose not to include manufacturer rebates in calculating these prices, which typically form the basis for beneficiary cost-sharing.¹⁷ As summarized by the Government Accountability Office (GAO), “[R]ebates do not lower individual beneficiary payments for drugs, as these are based on the gross cost of the drug before accounting for rebates.”¹⁸ CMS has finalized regulations, effective beginning next year, that will require plan sponsors to incorporate price concessions from pharmacies into the Part D negotiated price, thus reducing beneficiary cost-sharing at the point of sale, but this rule does not extend to rebates furnished by manufacturers.

Manufacturer rebates refer to post-sale price concessions paid by drugmakers to plans, often through their PBMs. According to a GAO analysis of CMS data, for 2021, manufacturers paid \$48.6 billion in rebates, compared with \$16.8 billion in 2014, representing a 189% increase.^{19, 20} A recent MedPAC analysis of 2020 data suggests manufacturers rebate approximately 22% of Part D spending back to plan sponsors and PBMs, in addition to the mandatory discounts that the statute requires drugmakers to provide on branded drugs and biosimilars.²¹ That said, rebate volume varies significantly across therapeutic classes.

Rebate growth has a range of implications for beneficiaries, plan sponsors, and other stakeholders across the prescription drug supply chain. With respect to cost-sharing, MedPAC noted in its June 2023 report to Congress that “the subset of enrollees who use rebated drugs may pay disproportionately high cost sharing relative to the net benefit cost of their medicines,” and that “for about 8% of gross spending aggregated across all phases of the Part D benefit (9% of brand spending), the cost-sharing amounts set by plan sponsors exceeded net drug costs after deducting rebates.”²² GAO found that for 79 of the 100 most highly rebated Part D drugs, beneficiaries paid more, on net, than their plan sponsors.²³ A JAMA analysis concluded that rebate growth was associated with a \$13 average increase in Medicare beneficiary cost-sharing per prescription between 2014 and 2018.²⁴

¹⁶ Cubanski, Juliette and Anthony Damico, “Key Facts About Medicare Part D Enrollment and Costs in 2023,” Kaiser Family Foundation, July 2023. [https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-and-costs-in-2023/#:~:text=most%20MA%20DPD%20enrollees%20\(91%25\)%20are%20in%20plans%20that%20charge%20copayments%20while%20virtually%20all%20PDP%20enrollees%20are%20in%20plans%20that%20charge%20coinsurance](https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-and-costs-in-2023/#:~:text=most%20MA%20DPD%20enrollees%20(91%25)%20are%20in%20plans%20that%20charge%20copayments%20while%20virtually%20all%20PDP%20enrollees%20are%20in%20plans%20that%20charge%20coinsurance)

¹⁷ 42 U.S.C. § 1395w-102(d)(1)

¹⁸ GAO, “Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending,” *Government Accountability Office*, September 2023. <https://www.gao.gov/assets/gao-23-105270.pdf>

¹⁹ *Ibid.*

²⁰ <https://www.46brooklyn.com/research/2020/1/21/2018-medicare-part-d-data-review-sxnf7>

²¹ Hayes, Tara, Shinobu Suzuki, and Rachel Schmidt. “Analysis of Part D data on drug rebates and discounts.” *MedPAC*. September 2022. <https://www.medpac.gov/wp-content/uploads/2021/10/DIR-Slides-MedPAC-29-Sept-2022.pdf>.

²² MedPAC, “June 2023 Report to Congress,” *MedPAC*, June 2023. https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch2_MedPAC_Report_To_Congress_SEC.pdf

²³ GAO, “Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending,” *Government Accountability Office*, September 2023. <https://www.gao.gov/assets/gao-23-105270.pdf>

²⁴ Yeung, Kai, Stacie Dusetzina, and Anirban Basu. “Association of Branded Prescription Drug Rebate Size and Patient Out-of-Pocket Costs in a Nationally Representative Sample, 2007-2018.” *JAMA Open Network*. June 2021. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780950>

Manufacturer rebates also influence formulary design and coverage decisions, often to the advantage of products with higher list prices, as more than 92% of rebate volume in Part D is provided “for providing manufacturers with formulary access and tier placement.” GAO’s analysis indicates frequent use of rebate agreements as a means of blocking coverage or preferential placement for biosimilars and other products with lower list prices. Plan sponsors generally direct the majority of rebate revenue to reduce premiums for enrollees and premium subsidies for the program, although MedPAC notes in its June 2023 report that data from the 2020 Medicare Current Beneficiary Survey indicate that more beneficiaries report out-of-pocket costs as the most important factor in choosing a plan than any other feature, including premiums.

Provision

Starting in 2028, these provisions would amend SSA 1860D–2(b) to base post-deductible enrollee coinsurance for certain covered Part D drugs (“discount-eligible drugs”) on their net prices, inclusive of projected manufacturer rebates, rather than their Part D negotiated prices or other list price derivatives. The HHS Secretary would publish a list of discount-eligible drugs in advance of the relevant plan year.

“Discount-eligible drugs” would be defined as Part D drugs that are on a plan’s formulary, are subject to a coinsurance amount (other than recommended vaccines or insulin), and:

1. Are in the following categories and classes: anti-inflammatories that are inhaled corticosteroids; bronchodilators, anticholinergic agents; bronchodilators, sympathomimetic agents; respiratory tract agents; anticoagulants; cardiovascular agents; and
2. For which aggregate manufacturer price concessions to Part D plan sponsors/PBMs, in aggregate, are equal to or exceed 50% of aggregate Part D gross costs.

The “net price” would be defined as the Part D negotiated price, net of all approximate price concessions that were not already reflected in the negotiated price for a plan year. “Approximate price concessions” would be defined as the amount of price concessions that Part D sponsors prospectively expect to receive from manufacturers for a plan year. Each year, plan sponsors would provide the HHS Secretary with: (1) approximate price concessions and net prices for each discount-eligible drug; and (2) a written explanation of the methodology used to calculate such approximate price concessions and net prices.

Plans would be compliant with rules under these provisions when net price calculations are consistent with:

1. A “drug-specific threshold” (set at 20% for 2028 through 2032), which would be the maximum percentage by which approximate price concessions *for a specific discount-eligible drug* could vary from the actual price concessions a plan received for such a drug, according to DIR reporting for the applicable plan year; and
2. An “aggregate threshold” (set at 15% for 2028 through 2032), which would be the maximum percentage by which *total* approximate price concessions for all discount-eligible drugs could vary from the actual price concessions for all such discount-eligible drugs, in the aggregate, according to DIR reporting for the applicable plan year.

Beginning in 2033, the HHS Secretary could adjust these thresholds, taking into account historical variations in expected and actual drug price concessions, factors that could result in price concession uncertainty or variation in a given plan year, sponsor behavioral responses, effects of precise price concession disclosures, beneficiary out-of-pocket costs, expenditures under Part D, and other factors. The HHS Secretary would be required to publish any threshold adjustments prior to the start of the applicable plan year.

The HHS Secretary would perform audits, as determined appropriate, in order to monitor compliance. A plan sponsor that violated the requirements could be subject to civil monetary penalties.

Additionally, beginning in 2028, Part D plans would be required to limit post-deductible enrollee cost-sharing for any covered Part D drug included in their formulary to the net price for such drug, inclusive of manufacturer rebates. Enforcement would occur retroactively, as needed, based on a comparison between cost-sharing amounts for covered Part D drugs under a plan and the net prices for such drugs under said plan, as evidenced through DIR reporting. Plans found to be in violation of this requirement could face civil penalties.

Title 3. Medicaid Expiring Provisions.

Section 301. Delaying Certain Disproportionate Share Hospital Payment Reductions Under the Medicaid Program

Current Law

Social Security Act (SSA) Section 1923 requires states to make Medicaid disproportionate share hospital (DSH) payments to hospitals treating large numbers of low-income patients.²⁵ Each state receives an annual DSH allotment, which is the maximum amount of federal matching funds that each state is permitted to claim for Medicaid DSH payments. The ACA included a provision directing the HHS Secretary to make aggregate reductions in Medicaid DSH allotments for FY 2014 through FY 2020, but subsequent laws have amended the Medicaid DSH reductions by eliminating the reductions or delaying them. Under current law, the aggregate reductions to the Medicaid DSH allotments equal \$8.0 billion for part of FY 2024 (i.e., November 18, 2023 through September 30, 2024) and \$8.0 billion for each fiscal year from FY 2025 through FY 2027, which totals \$32.0 billion.²⁶ In FY 2028, DSH allotments are to rebound to the pre-reduced levels, with annual inflation adjustments for FY 2024 to FY 2027.

Provision

The provision would further amend the Medicaid DSH reductions under SSA Section 1923(f)(7) (42 U.S.C. 1396r-4(f)(7)(A)) by eliminating the reductions for FY 2024 and FY 2025. The reductions for FY 2026 and FY 2027 would be unchanged. The aggregate reduction amount from FY 2024 to FY 2027 would decrease from \$32.0 billion under current law to \$16.0 billion.

Section 302. Extension of State Option to Provide Medical Assistance for Certain Individuals Who Are Patients in Certain Institutions for Mental Diseases

Current Law

Medicaid's institutions for mental diseases (IMD) exclusion limits the circumstances under which federal Medicaid funding to states is available for inpatient behavioral health care.²⁷ In addition to the other authorities available to states to allow Medicaid coverage for a period of time for eligible individuals who are patients in an eligible IMD, Section 5052 of the Substance Use-Disorder Prevention That Promotes

²⁵ For more information about Medicaid disproportionate share hospital (DSH) payments, see CRS Report R42865, [Medicaid Disproportionate Share Hospital Payments](#).

²⁶ For more information about the ACA Medicaid DSH reductions, see CRS In Focus IF10422, [Medicaid Disproportionate Share Hospital \(DSH\) Reductions](#).

²⁷ For more information about the IMD exclusion, see CRS In Focus IF10222, [Medicaid's Institution for Mental Diseases \(IMD\) Exclusion](#).

Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act; P.L. 115-271) added a new Section 1915(l) of the Social Security Act (SSA). Section 1915(l) provided a new state option to make Medicaid coverage available to eligible individuals who were patients in an eligible IMD. This coverage was authorized from October 1, 2019 through September 30, 2023 and available to patients for no more than a 30-day period (whether or not consecutive days) during any 12-month period.²⁸ To participate in the state option, states were required to comply with a maintenance of effort (MOE) requirement and requirements regarding coverage of certain services and transitions of care, among others. Only two states were participating in this state option as of September 30, 2023: South Dakota and Tennessee.

Provision

The provision would amend SSA Section 1915(l)(1) to remove the September 30, 2023, expiration date of the state option to make the state option permanent. The provision would also amend the MOE requirement to broaden the type of expenditures relevant to the MOE standard, among other things. In addition, the provision would add a requirement that states commence an assessment of the availability of treatment at each level of care for Medicaid enrollees.

Title 4. Medicare Expiring Provisions and Provider Payment Changes.

Section 401: Extension of Funding for Quality Measure Endorsement, Input, and Selection

Current Law

Under Social Security Act (SSA) Section 1890, the HHS Secretary is required to have a contract with a consensus-based entity (CBE) to carry out specified duties related to health care performance measurement. These duties include, among others, convening multi-stakeholder groups to provide input on the selection of measures, making recommendations on a national strategy for health care performance measurement, endorsing new health care performance measures, maintaining existing health care performance measures, and submitting annual reports to Congress.

SSA Section 1890A requires the HHS Secretary establish a pre-rulemaking process to select quality measures for use in the Medicare program. As part of this process, the Secretary makes available to the public measures under consideration for use in Medicare quality programs and broadly disseminates the quality measures that are selected to be used. Simultaneously, the CBE gathers input from multiple stakeholders and annually transmits that input to the Secretary. Until recently, the National Quality Forum (NQF) held this contract and fulfilled this requirement through its Measure Applications Partnership (MAP), an entity that convened multi-stakeholder groups to provide input into the selection of quality measures for use in Medicare and other federal programs. The MAP published annual reports with recommendations for selection of quality measures in February of each calendar year, with the first report published in February of 2012. On February 8, 2023, CMS awarded the CBE contract to Battelle Memorial Institute, which carries out this work under its Partnership for Quality Measurement (PQM).

The Consolidated Appropriations Act, 2021 (P.L. 116-260) most recently extended mandatory funding for quality measure endorsement, input, and selection through September 30, 2023. The law appropriated \$26 million for fiscal year (FY) 2021, \$20 million for FY 2022, and \$20 million for FY 2023.

²⁸ For more information about the SUPPORT Act state option, see CRS Insight IN12212, [Expiration of 1915\(l\) Medicaid State Plan Option](#).

Provision

The provision would amend Section 1890(d)(2) of the SSA (42 U.S.C. 1395aaa(d)(2)) to provide for the transfer of \$20 million for FY 2024 from the Medicare Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) Trust Funds, to carry out Section 1890 and Section 1890A activities. Amounts transferred shall remain available until expended.

Section 402. Extension of Funding Outreach and Assistance for Low-Income Programs

Current Law

Beginning in fiscal year (FY) 2009, Section 119 of the Medicare Improvements for Patients and Providers Act (MIPPA; P.L. 110-275) provided mandatory funding for outreach and assistance to low-income Medicare beneficiaries through State Health Insurance Assistance Programs (SHIPs), Area Agencies on Aging (AAAs), and Aging and Disability Resource Centers (ADRCs). This funding includes assistance to those who may be eligible for the Low-Income Subsidy program, Medicare Savings Program, and the Medicare Part D Prescription Drug Program. This funding is in addition to annual discretionary funding for SHIPs, AAAs, and ADRCs. MIPPA also provided mandatory funding to an entity to help inform older Americans about benefits available under Federal and State Programs. The funds are awarded through a competitive process. The grant is currently awarded to the National Council on Aging, which operates the National Center for Benefits and Outreach Enrollment. The National Center for Benefits and Outreach Enrollment assists organizations to enroll older adults and individuals with disabilities into benefit programs that they may be eligible for, such as Medicare, Medicaid, the Supplemental Security Income program, and the Supplemental Nutrition Assistance Program, among others. MIPPA funding was extended multiple times, most recently in the Consolidated Appropriations Act, 2021 (P.L. 116-260) through FY2023. The HHS Secretary is required to transfer specified amounts for MIPPA program activities from the Medicare HI and SMI Trust Funds to the Centers for Medicare & Medicaid Services (CMS).

Provision

The provision would amend specified subsections of MIPPA Section 119 (42 U.S.C. §1395b-3 note) to extend authority for these programs through September 30, 2024. For FY 2024, it would provide the same funding levels as FY 2023, for a total of \$50 million annually to be transferred from the Medicare HI and SMI Trust Funds in the following amounts: SHIPs, \$15 million; AAAs, \$15 million; ADRCs, \$5 million; and grant funding to coordinate efforts to inform older Americans about benefits available under Federal and State programs, \$15 million.

Section 403. Extension of the Work Geographic Index Floor Under the Medicare Program

Current Law

Medicare payments for services of physicians and certain nonphysician practitioners are made on the basis of a fee schedule (SSA §1848(e)(1)(E), U.S.C. §1395w-4(e)(1)(E)). The Medicare physician fee schedule (MPFS) is adjusted geographically for three categories of inputs to reflect differences in the cost of resources needed to produce physician services: physician work, practice expense, and medical malpractice insurance. The geographic adjustments are indices—known as Geographic Practice Cost Indices (GPCIs)—that reflect how each area compares to the national average in a "market basket" of

goods. A value of 1.0 represents the average across all areas. These indices are used to calculate the payment rate under the MPFS.

Since January 1, 2004, several laws have established a “floor” on the physician work GPCI where the index has been increased to 1.0 for all geographic regions in which the calculation of the GPCI would have been less than 1.0. The current authority is scheduled to expire on December 31, 2023.

Provision

The provision would extend the floor value of 1.0 for the physician work geographic index used in the calculation of payments under the Medicare physician fee schedule through December 31, 2024.

Section 404. Extension of Medicare APM Payment Incentives

Current Law

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA; P.L. 114-10) introduced a new merit-based incentive payment system (MIPS) based on fee-for-service payments and put in place processes for developing, evaluating, and adopting alternative payment models (APMs) designed to incentivize improvements in the quality and efficiency of care. Advanced Alternative Payment Models (AAPMs), APMs that include certain features related to quality measures and financial risk, provide a number of incentives for clinicians who meet the requisite payment- or patient-based thresholds to become Qualifying APM Participants (QPs).

Specifically, under amendments included in the Consolidated Appropriations Act, 2023 (CAA 23), for performance year 2023, an eligible professional must either receive at least 50 percent of Medicare Part B payments through an AAPM entity or see at least 35 percent of Medicare patients through such an entity in order to become a QP. Meeting these thresholds for performance year 2023 qualifies a QP for an APM Incentive Payment, to be paid out in payment year 2025, as a lump-sum amount equal to 3.5% of the estimated aggregate payment amounts for covered professional services furnished by the clinician during the preceding year.

Under current law, QPs will not receive an APM Incentive Payment in payment year 2026 on the basis of performance year 2024, although beginning in 2026, the statute provides for an annual MPFS conversion factor update of 0.75% for QPs. Additionally, starting with performance year 2024, the relevant thresholds for QP eligibility will increase, requiring a larger share of Part B payments or patients through AAPM entities in order to qualify as a QP.

Provision

This provision would provide for a 1.75% APM Incentive Payment for QPs for payment year 2026 (based on performance year 2024) and would extend the QP payment and patient thresholds in place with respect to payment year 2025 through payment year 2026 (based on performance year 2024).

Section 405. Payment Rates for Durable Medical Equipment Under the Medicare Program

Current Law

Medicare pays for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) either through (a) statutorily defined fee schedules, (b) competitive bidding in selected urban areas, or (c) adjustments to the fee schedule amounts based on data from competitive bidding; the adjustment decreases the payments relative to unadjusted payments. The Coronavirus Aid, Relief, and Economic

Security Act (CARES Act, P.L. 116-136) temporarily increased the adjusted DME fee schedule amounts for certain geographic areas (areas other than rural or noncontiguous areas), basing them on a blend of (higher) unadjusted fee schedule amounts and (lower) amounts adjusted by competitive bidding data; prior to the CARES Act, the payments for areas other than rural or noncontiguous areas were based entirely on the lower amounts adjusted by competitive bidding data. The CARES Act specified a weighting scheme calling for the payments to be based 25% on the higher unadjusted rates, and 75% on the lower adjusted rates (hereafter, referred to as the 25/75 blend), through the duration of the COVID-19 public health emergency. The Consolidated Appropriations Act, 2023 (P.L. 117-328) extended the 25/75 blend through December 31, 2023.

Provision

The provision would extend by one year (through December 31, 2024) the 25/75 blend payment that applies to areas other than rural or noncontiguous areas. The provision prohibits the HHS Secretary from applying the pre-CARES act payment (i.e., the lower payment based entirely on the fee schedule amounts adjusted by competitive bidding data) in areas other than rural or noncontiguous areas prior January 1, 2025. The HHS Secretary may implement the provision through program instructions or otherwise.

Section 406: Extending the Independence at Home Medical Practice Demonstration Program Under the Medicare Program

Current Law

The Affordable Care Act [Public Law (P.L.) 111-148] created the Independence at Home (IAH) demonstration under the Medicare program to test a payment incentive and service delivery model that uses home-based primary care teams and is designed to reduce expenditures and improve health outcomes in the care of certain chronically ill Medicare beneficiaries. Qualifying IAH medical practices are legal entities comprised of an individual physician or nurse practitioner, or group of physicians and nurse practitioners, that use a team-based approach to carry out care plans that are tailored to individual beneficiaries' chronic conditions. Such teams could include physicians, nurses, physician assistants, pharmacists, and other health and social services staff, as appropriate. Practice staff are to have experience providing home-based primary care services to applicable beneficiaries. The practice staff is required to make in-home visits and to be available 24 hours per day, 7 days per week to implement care plans. Subject to meeting performance standards on quality measures, qualifying IAH medical practices may be eligible for sharing savings, based on the extent to which actual expenditures for a year for the applicable beneficiaries enrolled by an IAH practice are less than the estimated annual spending target and the resulting incentive payment.

The Centers for Medicare & Medicaid Services (CMS) Innovation Center (CMMI) initially selected a total of 15 individual practices to launch the IAH demonstration in 2012; however, the number of participating practices with IAH agreements has varied over the years. The demonstration was originally scheduled to end on September 30, 2017, but has been extended twice (Bipartisan Budget Act of 2018, P.L. 115-123, Section 50301, and the Consolidated Appropriations Act of 2021, P.L. 116-260, Division CC, Section 105), such that agreements with IAH medical practices under the demonstration program are set to end no later than December 31, 2023.

For purposes of administering and carrying out the demonstration program, the Consolidated Appropriations Act of 2021 provided \$9.0 million to CMS from the Medicare Hospital Insurance (HI) Trust Fund and the Medicare Supplemental Medical Insurance (SMI) Trust Fund, in proportions determined appropriate by the HHS Secretary. The funding was made available for fiscal year (FY)2021, and available until expended.

Provision

The provision would extend the IAH demonstration program through December 31, 2025. Further, for purposes of administering and carrying out the demonstration program, the provision would provide \$3.0 million from the Medicare HI and SMI Trust Funds (in proportions determined appropriate by the HHS Secretary) for FY2024, to be available until expended.

Section 407. Increase in Support for Physicians and Other Professionals in Adjusting to Medicare Payment Changes

Current Law

In 2020, payments to physicians and non-physician practitioners under the Medicare physician fee schedule (MPFS) were subject to many changes due to a combination of statutory, technical, and circumstantial factors including the impact of questions about the application of sequestration and PAYGO requirements, the redefinition of certain medical codes, and the uncertainty of the impact of the COVID-19 pandemic on health care professionals. The Consolidated Appropriations Act, 2021 (P.L. 116-260) established a 3.75% increase in MPFS payments to support physicians and other professionals for services furnished in 2021. The Protecting Medicare and American Farmers from Sequester Cuts Act (P.L. 117-71) extended the increase through 2022 at the reduced level of 3.0%. The Consolidated Appropriations Act, 2023 (P.L. 117-328) extended the increase through 2023 at 2.5% and through 2024 at 1.25%.

Provision

The provision would replace the statutory increase of 1.25% for MPFS services furnished in 2024 with 2.50% for that year.

Section 408. Revised Phase-In of Medicare Clinical Laboratory Test Payment Changes

Current Law

Payments for outpatient clinical laboratory services are paid under the Medicare Clinical Laboratory Fee Schedule (CLFS). The Protecting Access to Medicare Act of 2014 (PAMA, P.L. 113-93) mandated a different method for determining clinical laboratory payments based on reported private insurance payment amounts and required the Centers for Medicare & Medicaid Services (CMS) to phase-in CLFS payments during the transition. Prior to the passage of PAMA, private insurance CLFS payment rates had generally been lower than Medicare payments. The applicable reporting period used to calculate the new rates and the date of implementation of the phase-in payments have been modified several times since PAMA was enacted.

Current law establishes that (1) “no reporting is required for clinical laboratory payments during the period beginning January 1, 2020, and ending December 31, 2023”; (2) “reporting is required during the period beginning January 1, 2024, and ending March 31, 2024”; and (3) reporting is required every three years thereafter. Correspondingly, reductions in CLFS payments based on the phase-in of the new methodology are to be limited; for 2023, there are no reductions in payments compared to those received in the previous year, while reductions are limited to 15 percent for each Medicare clinical laboratory payment in 2024 through 2026.

Provision

The provision would continue to limit reductions in CLFS payments by extending the moratorium on the reporting and collecting of private insurance payments for clinical laboratory services through December 31, 2024 and by extending the zero-percent cap on payment reductions through 2024. Reductions in CLFS payments in 2025 through 2027 would be limited to 15 percent.

Section 409. Extension of Adjustment to Calculation of Hospice Cap Amount Under Medicare

Current Law

The Medicare hospice benefit covers a broad set of palliative care services in the management of a terminal illness. These services are furnished to Medicare beneficiaries with a life expectancy of six months or less, as determined by a physician. For conditions unrelated to a terminal illness, Medicare continues to cover items and services outside of the hospice benefit.

Payment for hospice care is based on one of four prospectively determined rates (which correspond to four different levels of care) for each day a beneficiary is under the care of a Medicare-certified hospice agency. The four rate categories are routine home care, continuous home care, inpatient respite care, and general inpatient care. Payment rates are adjusted to reflect differences in area wage levels, using the hospital wage index. Annual payments to a hospice agency are limited by two caps. The first limits the number of days of inpatient care a hospice agency may provide to not more than 20% of total patient care days in a single year (42 Code of Federal Regulations (C.F.R.) §418.108(d)). The second, as required under law (Social Security Act (SSA) §1814(i)(2)(B)), limits a hospice agency's average annual payment per beneficiary. The latter cap is currently, for Fiscal Year (FY) 2024, set at \$33,494.01. If a hospice agency's total payments exceed its total number of Medicare patients, multiplied by the FY 2024 absolute dollar limit, then the hospice must repay the difference.

Unlike the daily base payment rates, the hospice aggregate cap is not adjusted for geographic differences in costs. The average annual payment cap amount is adjusted for increases or decreases in medical care expenditures. As required by Section 1814(i)(2)(B) of the SSA, the average annual payment cap, through FY 2032, is indexed to the general hospice base payment update, rather than using the Consumer Price Index for all urban consumers (CPI-U) for medical care expenditures. The CPI-U is published by the U.S. Bureau of Labor Statistics. Federal law mandates that the average annual hospice payment cap after FY 2032 be adjusted to reflect the percentage increase or decrease in the medical care expenditure category of the CPI-U. This policy allows the hospice payment rate and the aggregate hospice cap to grow using a common inflationary index.

Provision

The provision would amend Section 1814 of the SSA, extending the update of the Medicare hospice average annual payment cap using the general hospice base payment update (rather than indexing it to the CPI-U) through FY 2033.

Title 5. Offsets.

Section 501: Medicaid Improvement Fund

Current Law

Section 7002(b) of the Supplemental Appropriations Act of 2008 (P.L. 110-252) added Social Security Act (SSA) Section 1941, requiring the HHS Secretary to establish the Medicaid Improvement Fund (MIF). SSA Section 1941 authorized the HHS Secretary to use the MIF “to improve the management of the Medicaid program by the Centers for Medicare & Medicaid Services, including oversight of contracts and contractors and evaluation of demonstration projects.” P.L. 110-252 authorized \$100 million to be available for expenditures in FY 2014 and \$150 million for FY 2015 through FY 2018.

Multiple pieces of legislation have amended SSA Section 1941 to adjust the amount of money available to the MIF. P.L. 118-15

Provision

This provision would amend SSA Section 1941 (42 U.S.C. §1396w-1(b)(3)(A)) by reducing funding available to the MIF for FY 2028 and thereafter from \$6,357,117,810 to \$561,000,000.

Section 502: Medicare Improvement Fund

Current Law

The Medicare Improvements for Patient and Providers Act (P.L. 110-275) added Social Security Act (SSA) Section 1898 (42 U.S.C 1395iii), which authorized the HHS Secretary to establish the Medicare Improvement Fund. The amounts in the Medicare Improvement Fund are available to the HHS Secretary "to make improvements under the original Medicare fee-for-service program under parts A and B ... including adjustments to payments for items and services furnished by providers of services and suppliers under such original Medicare fee-for-service program." Funding for the Medicare Improvement Fund is made available from the Hospital Insurance Trust Fund and the Supplementary Medical Insurance Trust Fund in the amount determined appropriate by the HHS Secretary. Many subsequent laws have modified the amount in the fund, but to date, none of the monies have been expended. Most recently, the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) modified Section 1898 to make \$180,000,000 available in the Medicare Improvement Fund during and after fiscal year 2022.

Provision

This provision would change the amount available in the Medicare Improvement Fund for services furnished “during and after fiscal year 2022, \$180 million” to “during and after fiscal year 2022, \$936,000,000.”

Title 6. Certain Provisions from the Modernizing and Ensuring PBM Accountability Act.

Section 601. Arrangements with Pharmacy Benefit Managers with Respect to Prescription Drug Plans and MA-PD Plans

Current Law

Medicare Part D is a voluntary outpatient prescription drug benefit, enacted in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173), effective January 1, 2006. Congress designed Part D as a market-based program. Private insurers submit annual contract bids to

CMS to provide outpatient prescription coverage to Medicare beneficiaries. Medicare beneficiaries can choose a stand-alone Part D plan (PDP) or obtain drug coverage through a Medicare Advantage (Part C) plan with a Part D component (MA-PD plan). All Part D plans must provide coverage that meets or exceeds the minimum standard benefit that defines the range of drugs covered by Medicare Part D and maximum enrollee cost-sharing, including deductibles and prescription co-insurance or copayments. Enrollee premiums are based on each plan's annual cost for offering Part D benefits. Part D plan sponsors may augment plan benefits as long as their plans meet the standard benefit specified at Social Security Act (SSA) Section 1860D-2(b).

Part D plan sponsors often contract with pharmacy benefit managers (PBMs) to design and administer Part D benefits. Since the program's inception, Congress expected that PBMs, already in use in the commercial insurance market, would play a role in Part D to help control prices and costs. PBMs also perform a variety of other core functions for Part D plan sponsors, including developing formularies (covered drug lists), contracting with pharmacies to establish networks, negotiating price concessions from pharmaceutical manufacturers, operating mail order and specialty drug pharmacies, and administering electronic payment for prescription drug claims. Initially, most plans contracted with independent PBMs, however, recently, many insurers that offer Part D plans have merged or affiliated with PBMs.

Federal statutes and regulations govern annual CMS contracting with Part D plan sponsors.²⁹ PBM contract terms and service agreements with Part D plan sponsors vary from sponsor to sponsor, including with regard to the level and type of compensation (i.e., flat fees or retention of volume-based rebates), whether a contract includes PBM performance incentives, whether a contract includes Part D plan drug price guarantees and the specifications of such guarantees, and definitional terms. Neither statute or regulation govern the forms of compensation PBMs can generate from plan sponsors and entities in the supply chain related to prescription drugs dispensed under Part D. Further, PBM revenue streams have evolved considerably since 2003, when the MMA was enacted.

Under current law, Part D plans and their PBMs must report all price concessions that affect the price of Part D drugs to CMS via two main mechanisms:

1. Prescription Drug Event (PDE): A PDE report is generated each time a beneficiary fills a prescription at a network pharmacy. The PDE includes information on the negotiated price, including the amount paid to the pharmacy for the drug, the quantity dispensed, the out-of-pocket spending by the beneficiary, and any coverage by qualified third parties, such as other insurers.
2. Direct and Indirect Remuneration (DIR): DIR reporting applies to price concessions that are not passed on to enrollees at the point of sale. DIR includes discounts, rebates, pharmacy fees, and other price concessions or similar benefits from manufacturers, pharmacies, or similar entities that are obtained by an intermediary organization, such as a PBM, with which the Part D plan sponsor has contracted.³⁰

Provisions

These provisions would require that, beginning in plan year 2026, each Part D plan sponsor must have a written agreement with any PBM acting on its behalf under which the PBM agrees to meet the requirements outlined below. All of these requirements would apply to MA-PD plans, as well as PDPs.

²⁹ Part D contract regulations are at 42 CFR § 423.505.

³⁰42 CFR §423.308.

These provisions also would define “pharmacy benefit manager” as any entity that acts as a price negotiator or group purchaser, manages prescription drug benefits, processes and pays prescription drug claims, performs drug utilization reviews, processes prior authorization requests, adjudicates drug plan appeals or grievances, contracts with network pharmacies, controls the cost of covered Part D drugs, or provides related services on behalf of a Part D plan. These provisions would define an “affiliate” as any entity owned by, controlled by, or related under a common ownership structure with a PBM.

I. Bona Fide Service Fees

This provision would require that a PBM and any affiliate of a PBM may not derive remuneration for services provided in connection with the use of Part D covered drugs, except in the form of bona fide service fees. The provision would define a “bona fide service fee” as a fee that reflects the fair market value for a bona fide, itemized service. A bona fide service fee would be required to be a flat dollar amount not based on the drug’s price or other related drug price benchmarks and factors. Remuneration would be subject to audit, including by the Department of Health and Human Services (HHS) Office of the Inspector General (OIG), to ensure compliance with these requirements.

Part D plan sponsors could continue to collect rebates, discounts, or price concessions that lower net costs for covered part D drugs. Nothing in this provision would be construed as prohibiting a PBM from reimbursing entities that acquire prescription drugs for the ingredient cost of the products.³¹

II. Transparency Regarding Guarantees and Cost Performance Evaluations

This provision would institute transparency standards for written agreements between Part D plan sponsors and PBMs. Specifically, the provision would require PBMs to define and apply drug and drug pricing terms in written agreements with plan sponsors in a transparent and consistent manner for the purposes of calculating or evaluating PBM performance against pricing guarantees or similar cost performance measurements. PBMs would also have to identify any exceptions to such guarantees and provide a calculation of such guarantees using either the WAC or an equivalent, in addition to any other benchmarks used.

III. PBM Data Reporting Requirements

This provision would set out new requirements for PBMs to annually report drug price and other information to Part D plans and to HHS. PBMs would be required to include several categories of information in their reports, including the following:

- Lists of all drugs covered;
- Information about dispensing of such drugs;
- Information about enrollee cost-sharing and access to generics and biosimilars, including the relative formulary tier placement of such generics and biosimilars, if a plan covers the brand-name drugs or biologic reference products;
- Information on financial relationships between the PBM and other entities in the drug pricing supply chain;
- Information related to net and gross prices and total drug spending; and
- Information about the PBM’s affiliates.

PBMs that are affiliated with a pharmacy must also report the following categories of information:

³¹ In general, the ingredient cost is the amount paid by the pharmacy or wholesaler for the drug. It does not include pharmacy dispensing fees.

- Information related to dispensing and drug costs by affiliate pharmacies;
- Information related to drug acquisition costs; and
- Information related to drugs subject to 340B arrangements.

This provision would also require PBMs or their affiliates to provide Part D plans with a written explanation of contracts or arrangements with a drug manufacturer (or affiliate) that makes rebates, discounts, payments, or other financial incentives related the drug manufacturer’s drug(s) contingent upon coverage, formulary placement, or utilization management conditions on other prescription drugs. The PBM would be required to provide this information shortly after the contract or arrangement with the drug manufacturer is finalized. The written agreement must be certified and would include information about the manufacturers and drugs subject to such arrangement.

IV. Confidentiality

This provision would bar the HHS Secretary from publicly disclosing information obtained from a Part D sponsor or PBM under the required agreements and reports that is not otherwise publicly available, except in limited circumstances, including:

- By the HHS Secretary to carry out this part;
- To the GAO, the Congressional Budget Office (CBO), the HHS OIG, and the Medicare Payment Advisory Commission (MedPAC); and
- To permit oversight and enforcement by government agencies.

These agencies would not be permitted to report on or disclose the information in a way that would identify a specific supply chain stakeholder or prices for specific drugs.

V. Audit Rights

This provision would permit audits, by an auditor of the Part D plan sponsor’s choice, of a PBM, no less than once a year, if requested by a Part D sponsor, including to ensure the accuracy of drug price information reported under these provisions. The PBM would be required to provide information to the auditor necessary to perform the audit and confirm the accuracy of PBM reporting, including information owned or held by a PBM’s affiliate, in a timely manner. The HHS Secretary would be allowed to include reasonable restrictions on how the information is reported to prevent redisclosure.

VI. Enforcement

This provision would require a PBM to:

- Disgorge remuneration received by the PBM, or an affiliate of such PBM, in violation of the bona fide service fee requirements;
- Reimburse the Part D sponsor for any civil money penalty imposed on the sponsor due to the failure of the PBM to meet the requirements of these provisions; and
- Be subject to punitive remedies for breach of contract for failing to comply with the requirements of these provisions.

This provision would also require each Part D sponsor to provide the HHS Secretary an annual certification of compliance with the provisions outlined above, as well as such additional information as the Secretary determines necessary to carry out this subsection.

VII. Funding

This provision would provide \$20 million to CMS for FY 2026 and \$5 million to the HHS OIG to carry out the provision. The funds would remain available until expended.

VIII. GAO Report on Certain Pricing Requirements

This provision would require GAO to conduct a study of federal and state reporting requirements for health plans and PBMs regarding the transparency of prescription drug costs and prices. Study results would be required to include recommendations for legislation and administrative actions to streamline and reduce burden with respect to the reporting requirements for health plans and PBMs.

IX. MedPAC Reports on PBM-Reported Information

This provision would require MedPAC to issue two reports and related recommendations to Congress on the information being reported by PBMs under this section, including: (1) an initial analysis of information reported by PBMs during the early years of implementation; and (2) a second analysis several years later analyzing changes in trends revealed in the information reported over time.

Section 602. Ensuring Fair Assessment of Pharmacy Performance and Quality under Medicare Part D

Current Law

Part D plan sponsors and PBMs create contracted networks of retail pharmacies that dispense covered drugs at negotiated reimbursement rates. Part D regulations³² require plan sponsors to have standard pharmacy contracts with reasonable and relevant terms and conditions of participation, and to allow any willing pharmacy to participate in their basic pharmacy network. Actual contract terms vary across Part D plans, however, meaning that retail pharmacies, which often contract with multiple Part D plans, may have to navigate differing plan contracts, payment rates, and other terms.

Many plans and PBMs use quality measures to evaluate pharmacy performance in various areas, such as medication adherence and generic dispensing. In recent years, however, pharmacies have reported that the quality measures imposed by plans and PBMs are unpredictable, assessing items outside the scope of the pharmacy practice, and/or measuring outcomes over which pharmacies have limited control.³³

Provision

This provision would require the HHS Secretary to institute standard Part D measures for assessing network pharmacy performance, beginning in 2025. Under the provision, a Part D sponsor that wanted to institute fees, price concessions, or incentive payments based on network pharmacy performance would only be able to do so if the plan sponsor/PBM used performance measures that were: (1) established or adopted by the HHS Secretary; and (2) relevant to the pharmacy, as determined by pharmacy type.

³² 42 CFR §423.505.

³³ Frier Levitt and the National Association of Specialty Pharmacy. ““Performance” Based DIR Fees: A Rigged System with Disparate Effect on Specialty Pharmacies, Medicare Part D Beneficiaries and the U.S. Healthcare System.” March 20, 2017. <https://communityoncology.org/research-publications/studies/performance-based-dir-fees-a-rigged-system-with-disparate-effect-on-specialty-pharmacies-medicare-part-d-beneficiaries-and-the-us-healthcare-system/>.

The HHS Secretary would be required to establish or adopt standardized pharmacy performance measures that were: (1) evidence-based and reasonable; and (2) focused on pharmacy performance related to patient health outcomes and other areas that pharmacies can reasonably impact, as determined by the Secretary. The Secretary’s determination may be based on data and information from relevant stakeholders.

Rather than establishing some or all of the required performance measures, the Secretary may adopt measures endorsed by a multi-stakeholder consensus organization (such as the Pharmacy Quality Alliance), that has participation from pharmacies, health plans, PBMs, and CMS. The performance measure list would be subject to periodic evaluation and revision by the Secretary.

This provision would provide \$4 million to CMS in FY 2025 to carry out the provision. The funds would remain available until expended.

Section 603. Promoting Transparency for Pharmacies under Medicare Part D

Current Law

Just as drug pricing and formulary coverage vary among Part D plans, Part D plan reimbursements to pharmacies also differ according to formulary requirements, plan specifications, and a plan’s negotiated price for a covered drug. Pharmacies dispense billions of Part D drugs each year, and payments from Part D plan sponsors are processed in real time at the point of sale through electronic systems that aggregate plan-specific data, including the drug ingredient cost, dispensing fees, cost-sharing requirements, and other third-party sources of payment.

In recent years, CMS has noted a sharp rise in pharmacy fees and other price concessions that plan sponsors and PBMs extracted from retail pharmacies after the point of sale and reported as DIR. Part D pharmacy DIR includes administrative fees, network access fees, and fees for not meeting plan quality metrics. Part D plan sponsors may provide incentive payments to pharmacies for meeting specified goals, but CMS data indicate that extracted fees, or penalties, far outpace additional compensation to pharmacies. According to CMS, pharmacy fees are the fastest-growing category of DIR, accounting for nearly 5% of gross Part D drug costs (\$9.5 billion) in 2020, compared to 0.01% (\$8.9 million) in 2010. The increase in fees, as well as their post-point of sale nature, have made it difficult for pharmacies to accurately predict their total reimbursement for dispensing a covered drug.³⁴ Differences in reporting of negotiated prices among Part D plans can also affect beneficiary cost sharing, CMS payments to plans, and, according to CMS, can even diminish competition between Part D plans.

In May 2022, CMS issued a final rule, effective in 2024, to help address the uncertainties in pharmacy reimbursement caused by PBM fees. The rule changes the definition of “negotiated price” to include the lowest possible reimbursement that a network pharmacy will receive in total for dispensing a drug.³⁵ Part D plan sponsors are required to take the rule change into account when submitting 2024 contract bids.

Provision

This provision would establish a process by which Part D plan sponsors provide their network pharmacies

³⁴ CMS, “Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs,” 87 *Federal Register*, May 2022, p. 1413, <https://www.federalregister.gov/d/2022-09375/p-1413>.

³⁵ CMS, “Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs,” 87 *Federal Register*, May 2022.

with comprehensive information about the pricing of prescription drug claims. The new system would be required to take effect in 2025.

This provision would provide \$2 million for FY 2025 to CMS to carry out the provision. The funds would remain available until expended.

Section 604. Preventing the Use of Abusive Spread Pricing in Medicaid

Current Law

State Medicaid programs reimburse statutorily defined retail community pharmacies for covered outpatient drugs (CODs) dispensed to Medicaid beneficiaries. The payment to retail community pharmacies has two components: (1) an amount to cover the cost of acquiring the drug (ingredient cost); and (2) an amount for the pharmacist's professional services in filling a prescription (dispensing fee).

The Patient Protection and Affordable Care Act (ACA, P.L. 111-148) required drug manufacturers that participate in the Medicaid Drug Rebate Program to provide rebates on CODs that are dispensed to beneficiaries covered under a managed care organization (MCO) that contracts with the state Medicaid program. Most MCOs and other entities that provide Medicaid prescription drug benefits contract with PBMs to manage and administer their drug benefits. Generally, MCOs pay PBMs for drugs supplied to Medicaid beneficiaries based on a published price, such as a percentage of the average wholesale price (AWP), while PBMs separately determine pharmacy reimbursement. Although the difference (spread) between the MCO payments to PBMs and the PBM payments to pharmacies may be small for each individual drug, it can be substantial when aggregated across all drugs dispensed by an MCO.

Contracts between Medicaid MCOs and PBMs are sometimes based on the margin (spread) between the amount charged to the MCO for a COD and the amount paid by a PBM to the pharmacy provider.³⁶ Effective April 2017, the Centers for Medicare & Medicaid Services required prescription drug benefits under fee-for-service (FFS) Medicaid programs to use a drug pass-through pricing model, but this requirement does not apply to Medicaid MCOs. Under pass-through pricing PBMs charge their MCO clients the actual amount it reimburses the pharmacy for CODs, then passes back all the rebates from manufacturers, and only collects explicit administrative fees as income. Although CMS has issued spread pricing guidance,³⁷ federal statute does not prohibit the use of spread pricing in contracts between Medicaid MCOs and PBM or other entities.³⁸

Provision

This provision would require a pass-through pricing model for CODs reimbursed under Medicaid, including when services are provided under contract with MCOs. This section would require payment for PBM services to be limited to the ingredient cost and a professional dispensing fee equivalent to no less than the professional dispensing fee paid under FFS through a state plan or waiver and passed through in

³⁶ Centers for Medicare & Medicaid Services (CMS), Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, 88 *Federal Register* 34249, May 26, 2023.

³⁷ CMS, Center for Medicaid and CHIP Services Informational Bulletin, Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors, May 19, 2019.

³⁸ CMS, Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, 88 *Federal Register* 34250, May 26, 2023.

its entirety to the dispensing pharmacy. The provision would allow an exception to the pass-through payment requirement for drugs purchased by 340B covered entities.

Payments to PBMs for administrative services would be limited to the fair market value of those services. PBMs and other entities would be required to make available to state Medicaid programs, and the Secretary upon request, all specified costs and payments related to CODs and accompanying administrative services.

This provision would also prohibit any form of spread pricing that exceeds the amount paid to pharmacies or providers on behalf of the state for purpose of claiming federal Medicaid matching payments. State Medicaid programs would be prohibited from making payments to certain specified health plans unless the contract between the state and the entity met the Medicaid Drug Rebate Program and other prescription drug requirements.

This provision would apply to state Medicaid program contracts between MCOs, other specified entities, and PBMs with an effective date that begins 18 months after this law's enactment date.

Section 605. HHS OIG Study and Report on Drug Price Mark-Ups in Medicare Part D

Current Law

The past several decades have seen rapid consolidation in the health care sector, including among PBMs. The early 2000s saw horizontal integration as freestanding PBMs merged. More recently, there has been vertical integration, with major PBMs now owned by, or affiliated with, retail pharmacy chains, insurers, and health care providers such as hospitals. As a result of the consolidation, the three largest PBMs were expected to account for nearly 80% of prescription claims processed in 2022.³⁹ In addition, some PBMs have entered into strategic agreements with insurers and retail pharmacies to provide certain services to insurers and retail pharmacies.

It can be difficult to determine the pricing structure and flow of funds within these vertically integrated entities. MedPAC's June 2023 report, however, included an analysis that suggested vertically integrated organizations, such as PBMs affiliated with a health plan and at least one pharmacy channel, appear to be paying their affiliate pharmacies more than other pharmacies. Specifically, in comparing Part D payments between plan-sponsor-affiliated (vertically integrated) pharmacies and non-affiliated (non-vertically integrated) pharmacies, MedPAC found that in 71 percent of cases, plans incurred the highest average net drug costs for transactions with their pharmacy affiliates.⁴⁰ Other recent studies have found that Part D may be overpaying for certain medicines relative to purchases made by entities such as Costco or the Mark Cuban Cost Plus Drug Company, potentially by billions of dollars.⁴¹

³⁹ Adam J. Fein, "The Top Pharmacy Benefit Managers of 2022: Market Share and Trends for the Biggest Companies," *Drug Channels*, May 23, 2023, <https://www.drugchannels.net/2023/05/the-top-pharmacy-benefit-managers-of.html>.

⁴⁰ MedPAC June 2023 Report: https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf

⁴¹ Lalani, H. et al. (July 2022). "Potential Medicare Part D Savings on Generic Drugs From the Mark Cuban Cost Plus Drug Company." *Annals of Internal Medicine*. Available at: <https://pubmed.ncbi.nlm.nih.gov/35724381/>; Trish, E. et al. (July 2021) "Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members." *JAMA*. Available at: <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2781810?guestAccessKey=89d9de51-fc11-4451-97aa-90b352b7867b>

Provision

This provision would require the HHS OIG to study how vertical integration between Part D plans, PBMs, and pharmacies affects Part D plan negotiated prices (i.e., the prices Part D plans charge the Medicare program for drugs dispensed to Part D enrollees). The study would include an analysis of the following:

- Affiliate acquisition costs within vertically integrated entities;
- Transfer pricing and margin created between affiliates;
- The impact of such transactions on Part D; and
- Other issues determined to be relevant and appropriate by the Inspector General.

The Inspector General would submit the study under a specified timeframe to the Senate Finance and House Energy and Commerce and Ways and Means Committees. The provision would provide \$5.2 million to the HHS OIG for FY 2024 to carry out the provision, to remain available until expended.

Section 606. P&T Committee Conflicts of Interest

Current Law

Under the Part D statute, CMS-approved pharmacy and therapeutic (P&T) committees must develop and review formularies of covered drugs for prescription drug plans. CMS requires that P&T committees “must review for clinical appropriateness the practices and policies for formulary management activities, such as prior authorizations, step therapies, quantity limitations, generic substitutions, and other drug utilization activities that affect enrollee access.” However, P&T committee recommendations regarding these activities are advisory only and not binding on the Part D sponsors.

A majority of the committee members must be practicing physicians or practicing pharmacists. Committees are to base decisions on the strength of scientific evidence and standards of practice when developing and reviewing formularies. At least one practicing pharmacist and at least one practicing physician on every such P&T committee must be free of conflicts of interest with respect to the PDP sponsor, but neither statute nor regulations and guidance extend these limitations to PBMs explicitly.

Provision

This provision would amend Section 1860D-4 of the Social Security Act (SSA) to require that at least one practicing physician and one practicing pharmacist is independent and free of conflict with respect to any PBM.

Section 607. Enhancing PBM Transparency Requirements

Current Law

SSA section 1150A includes a set of reporting requirements for PBMs, including with respect to generic dispensing rates (including by pharmacy dispensing channel), rebates and price concessions received from drug manufacturers (and the amount of such concessions passed along), and prescription volume, among other data elements). The information is considered confidential and may not be disclosed except

in a form that does not disclose the name of the PBM, plan or the prices charged for drugs, and only in limited circumstances.

These reporting requirements currently exclude transparency regarding service fees collected and retained by PBMs. Additionally, the codification of these requirements largely predated the establishment and, in some cases, acquisition of certain downstream PBM affiliates that serve as rebate negotiators and aggregators for a growing share of the PBM market.

Provision

These provisions would amend SSA 1150A by requiring additional entities to provide information to the HHS Secretary and, for some entities, to the health benefits plan with which the entity is under contract. The reporting entities would include:

- A health benefits plan;
- Any entity that provides PBM services on behalf of a health benefits plan that manages prescription drug coverage under a contract with: (1) a Part D sponsor or (2) a qualified health benefits plan offered through an exchange; and
- Any affiliate of an entity described above that acts as a price negotiator or group purchaser on behalf of such PBM, PDP sponsor, MA organization, or qualified health benefits plan.

The term ‘affiliate’ would be defined as any entity owned by, controlled by, or related under a common ownership structure with a PBM (including an entity owned or controlled by Part D sponsor, or a qualified health benefits plan for which such entity is acting as a price negotiator or group purchaser).

These provisions would add reporting requirements on the amount (in the aggregate and disaggregated by type) of all fees a PBM or an affiliate of a PBM receives from all drug manufacturers in connection with patient utilization under a plan, and the amount and percentage (in the aggregate and disaggregated by type) of such fees that are passed through to the plan sponsor or issuer.

The HHS Secretary would be required to make publicly available on the CMS website an annual report that summarizes the trends observed with respect to data reported section 1150A.

The changes would apply to plan or contract years beginning on or after January 1, 2027.

Section 608. Facilitating Midyear Formulary Changes for Biosimilars

Current Law

Part D plans may alter their formularies from year to year. Plans are also allowed, in limited circumstances, to make changes to their formularies within a plan year. Plans generally may not change therapeutic categories and classes of drugs within a plan year, except to account for new therapeutic uses or to add newly approved Part D drugs. If Part D plans remove drugs from their formularies during a plan year (or change cost-sharing or access requirements), they must provide timely notice to CMS, affected enrollees, physicians, pharmacies, and pharmacists.

Part D sponsors may immediately remove brand-name drugs from a formulary (or change the cost-sharing tier) during a plan year if they replace the brand-name product with a therapeutically equivalent generic that is placed on the same or lower cost-sharing tier and if the generic is subject to the same or less restrictive utilization criteria than the brand-name drug. To qualify for substitution, the new generic must

have been released to the market after the initial formulary was submitted. These rules do not apply in the same manner with respect to biologic medicines. A number of reports from HHS OIG, MedPAC, and other entities suggest that greater biosimilar uptake and adoption under Part D would produce both gross and net savings for beneficiaries and the Medicare program.

Provision

These provisions would amend Social Security Act Section 1860D–4(b) (42 U.S.C. 1395w–104(b)) to allow mid-year formulary changes for biosimilar and biologic products. Starting in 2025, after the first 60 days of the plan year a Part D sponsor would be allowed to change the cost-sharing status of a reference biologic if the sponsor adds a biosimilar: (1) at the same or a higher preferred tier status; or (2) to the same or lower cost-sharing tier, as the reference biological product. Prior to making the change the plan sponsor must submit a request to the HHS Secretary. If the HHS Secretary approves the request or has not provided a decision within 30 days, the sponsor may make the change.

Section 609. Strengthening Pharmacy Access for Seniors

Current Law

Pursuant to the Part D Manual, Part D plans may designate certain pharmacies as specialty pharmacies for the distribution of drugs where: (1) the FDA has restricted distribution of the drug to certain facilities or physicians; or (2) appropriate dispensing requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy. Part D plans may not require enrollees to use a specialty pharmacy to fill a prescription solely because a drug has been placed on a Part D plan specialty drug tier.⁴²

Provision

These provisions would amend SSA Section 1860D–4(b)(1) (42 U.S.C. 1395w–104(b)(1)) to specify that plan sponsors, beginning in 2026: (1) could not restrict or limit access to any covered drug to a subset of plan network pharmacies, other than a ‘limited access drug’; and (2) would be required to document the reason that a drug meets the definition of a limited access drug, if the sponsor restricts or limits access. A limited access drug would a covered part D drug that met at least one of the following conditions:

- The FDA has restricted distribution of the drug to certain facilities or physicians; or
- The drug dispensing requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy.

Starting for plan year 2026, all Part D sponsors would be required submit to the HHS Secretary an annual list of all drugs that the sponsor designated as limited access drugs; a written rationale for why each drug met the definition of a limited access drug; a summary of requirements imposed on network pharmacies (including accreditation requirements, if any) to ensure appropriate handling and dispensing of each listed drug; the percentages of each list drug dispensed through retail pharmacies, specialty pharmacies, mail order pharmacies, or other dispensing channels as defined by the sponsor; the annual percentage of each drug dispensed through a pharmacy that is affiliated with the plan or is an affiliate of a PBM acting on behalf of the plan sponsor; and other information required by the HHS Secretary.

⁴² Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.3

Starting for plan year 2026, a plan sponsor must, within 14 days of receiving a request, provide any requesting pharmacy with the list of limited access drugs, their associated rationale for designation, and a summary of the imposed requirements on network pharmacies for handling these products.

By December 31, 2028, and each year thereafter, the HHS Secretary would be required to submit a report to Congress on Part D sponsor compliance. The reports would include:

- A description of the patterns, trends, variations, and rationales for the designation of certain drugs as limited access drugs, and the implications of such designations on beneficiary access;
- A description of the information that plan sponsors are required to submit to the Secretary; and
- Any other information determined appropriate by the HHS Secretary.

Section 610. Initiating Meaningful Patient Review of Various Existing Part D Regulations

Current Law

The Medicare Part D statute includes a number of beneficiary protections with respect, for instance, to prescription drug plan disclosures, utilization management requirements, and appeals processes. Beneficiary experience, however, varies on these fronts, as well as on navigation of comparison tools and other resources provided by CMS or by PDP sponsors.

Provision

This provision would amend Social Security Act Section 1860D–42 (42 U.S.C. 1395w–152) to require the HHS Secretary to hold at least one beneficiary-focused listening session by the end of 2024 to receive input on potential improvements in Part D plan management and transparency. Any beneficiary-focused listening session would be open to the public. The listening sessions may include an opportunity for the public to provide input to the Secretary on potential improvements to:

- the information made available by prescription drug plans to individuals;
- tools and mechanisms to assist enrollees in navigating plan complaint systems, as well as the efficiency and effectiveness of such systems;
- tools and mechanisms to assist beneficiaries in selecting a prescription drug plan;
- tools and mechanisms to assist enrollees in navigating utilization management requirements of such plans, such as step therapy and prior authorization;
- access to, and effectiveness and utilization of, electronic real-time benefit tools;
- formulary management and oversight by prescription drug plans; and
- other subjects, as determined appropriate by the HHS Secretary.

Section 611. Reporting on Enforcement and Oversight of Pharmacy Access Requirements

Current Law

The Part D statute includes a number of requirements related to ensuring pharmacy access for beneficiaries. The ‘any willing pharmacy’ provision, for instance, specifies that a PDP sponsor must

permit any pharmacy willing to meet its terms and conditions into its network, and regulations further stipulate that these terms must be reasonable and relevant, including with respect to reasonable reimbursement.

Provision

This provision would require the HHS Secretary to publish biennial reports on enforcement actions and oversight activities undertaken by the Department with respect to the pharmacy access requirements under section 1860D-4(b)(1) of the Social Security Act.

Section 612. Study on Price-Linked Compensation Across the Supply Chain

Current Law

As numerous government oversight reports in the past have illustrated, a wide range of stakeholders included in the outpatient prescription drug supply chain engage in compensation arrangements tied to drug prices or other related benchmarks.

Provision

This provision would require GAO to complete a study, no later than two years after enactment, of compensation and payment structures related to the prescription drug pricing in the retail prescription drug supply chain. The study is to look at different types of pricing used by intermediaries such as wholesalers, pharmacies and pharmacy service organizations, markups along the supply chain, different business models and potential conflicts of interest, and potential effects on federal health care programs.

Section 613. Reports on Inappropriate Pharmacy Rejections

Current Law

Medicare prescription drug plan sponsors employ a number of cost-containment measures, including utilization management tools (i.e. prior authorization, step therapy, quantity limits). Under current law, CMS must approve the use of these mechanisms. In practice, however, oversight agencies, including HHS OIG, have found that inappropriate pharmacy rejections and coverage denials sometimes prevent beneficiaries from accessing covered part D drugs, sometimes as a result of the use of unapproved utilization management tools. Moreover, a number of data collection efforts and other initiatives intended to identify such practices have lapsed in recent years.

Provision

This provision would require the Secretary to publicly post a biennial report related to preventing, identifying, or addressing inappropriate pharmacy rejections and inappropriate coverage denials under Part D.

Section 614. Study on Drug Shortages

Current Law

According to the American Society of Health-System Pharmacists (ASHP), active drug shortages had risen to 301 at the end of the first quarter of 2023, up from 271 at the close of Q1 2021.^{43, 44} ASHP reports that “[o]ngoing and active shortages are the highest since 2014.”⁴⁵ A March 2023 majority staff report from the Senate Homeland Security and Government Affairs Committee (HSGAC) found that new medication shortages increased by close to 30 percent between 2021 and 2022.⁴⁶ While some shortages conclude fairly quickly, others persist for years. With some exceptions, federal health care programs generally do not include comprehensive provisions explicitly related to drug shortages, although a range of agencies and experts have cited economic dynamics and factors as playing a role in such shortages.

Provision

This provision would require GAO to complete a study of factors across the outpatient prescription drug supply chain that influence prescription drug shortages.

Section 615. Report on Biosimilar and Generic Access Under Part D

Current Law

Medicare Part D has generally offered high generic dispensing rates, while the retail outpatient biosimilar market has only begun to emerge in recent years. A number of agencies, including HHS OIG, have found that biosimilar uptake and adoption in Part D plans has remained relatively low, particularly with respect to low-wholesale acquisition cost (WAC) options that would translate into lower cost-sharing for beneficiaries.

Provision

This provision would direct HHS OIG to conduct a study and generate a report on biosimilar and generic drug access under Part D, including with respect to Part D plan features that discourage or encourage low-priced biosimilar and generic drug adoption and utilization under the program, along with trends in such adoption and utilization.

⁴³ <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>

⁴⁴ Note: FDA also maintains a list of drug shortages, although the agency’s criteria differ. <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

⁴⁵ <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>

⁴⁶ <https://www.hsgac.senate.gov/wp-content/uploads/Drug-Shortages-HSGAC-Majority-Staff-Report-2023-03-22.pdf>