Calendar No. 265

118TH CONGRESS, 1st Session | SENATE | REPORT 118–121

THE BETTER MENTAL HEALTH CARE, LOWER-COST DRUGS, AND EXTENDERS ACT

DECEMBER 7, 2023.—Ordered to be printed

Mr. WYDEN, from the Committee on Finance, submitted the following

R E P O R T

[To accompany S. 3430]

The Committee on Finance, having considered an original bill (S. 3430) to amend titles XVIII and XIX of the Social Security Act to expand the mental health care workforce and services, reduce prescription drug costs, and extend certain expiring provisions under Medicare and Medicaid, and for other purposes, reports favorably thereon without amendment and recommends that the bill do pass.

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I. LEGISLATIVE BACKGROUND

The Committee on Finance, having considered S. 3430, a bill to amend titles XVIII and XIX of the Social Security Act to expand mental health care workforce and services, reduce prescription drug costs, and extend certain expiring provisions under Medicare and Medicaid, and for other purposes, reports favorably thereon that the bill as modified by the Committee do pass.

Background on Medicare and Medicaid Mental Health Care and Prescription Drug Coverage

Medicare is a federal program that provides health insurance coverage for individuals aged 65 and older, certain individuals under the age of 65 who have disabilities, and those with end-stage renal disease (ESRD). Medicare also pays for certain services for individuals dually eligible for both Medicare and Medicaid. Medicare consists of four parts: Part A covers inpatient hospital and other facility-based services; Part B covers physician visits and other outpatient-based care, including physician-administered prescription drugs; Part C, or Medicare Advantage (MA), covers the same Part A and Part B services (and some supplemental services) through private insurance companies; and Part D covers prescription drugs through private prescription drug plan sponsors. Medicare pays for health care services and items that are "reasonable and necessary."

Traditional Medicare covers certain mental health services delivered in inpatient and outpatient settings. Medicare Part A covers inpatient mental health services furnished in a distinct psychiatric unit of a general hospital. Medicare Part A also allows a beneficiary to receive up to 190 days of mental health care services furnished in a psychiatric hospital during their lifetime. Medicare Part B covers a range of outpatient mental health services that can be provided in different settings, including a physician's office, hospital outpatient department, or community mental health center. These services include psychotherapy, family counseling, annual depression screening, psychiatric evaluation, medication management, partial hospitalization, outpatient substance use disorder services, among other services. Part B covers mental health services provided by psychiatrists and other physicians, clinical psychologists, clinical social workers, clinical nurse specialists, nurse practitioners, and physician assistants. Starting on January 1, 2024, Medicare Part B will also cover mental health services delivered by marriage and family therapists and mental health counselors. Medicare Advantage plans are required to cover the same set of mental health services covered under traditional Medicare.

Medicare provides a voluntary outpatient prescription drug benefit, known as the Part D program, in which beneficiaries can receive covered, medically necessary outpatient drugs prescribed by a physician or other qualified clinician. The Part D program uses private insurers offering prescription drug plans (PDPs) to provide prescription drug benefits to beneficiaries. Insurers bear risk for enrollees' drug spending and, in general, the federal government subsidizes about 75% of total premium costs. Insurers manage costs, typically through contracts with pharmacy benefit managers (PBMs) that use formularies to negotiate rebates from drug manufacturers, pay pharmacies for dispensing drugs to beneficiaries, and develop networks of preferred pharmacies.

Medicaid is a joint federal-state program that finances the delivery of primary and acute medical services, as well as long-term services and supports, for a diverse low-income population. Each state has a Medicaid state plan that describes how the state will administer its program. The benefits covered under Medicaid include both mandatory and optional services. Mandatory services include inpatient hospital services, outpatient hospital services, and

a range of services for infants and children under the early and periodic screening, diagnostic, and treatment (EPSDT) benefit. Optional services include certain non-mandatory categories of services, which may include certain types of residential treatment, therapy, and counseling services as well as prescription drugs.

State Medicaid programs are required to cover medically necessary mental health services for adults provided in hospitals, rural health clinics, nursing homes, home health settings, and physician offices. Medicaid programs have the option of covering additional mental health services for adults, including prescription drugs; medication management; case management; occupational, physical, or speech therapies; clinic services; licensed clinical social worker services; and peer support services. Medicaid programs also have the option to cover services delivered in institutions for mental diseases (IMD) for specific subpopulations for specific lengths of time, as well as health services in school-based settings, including services provided by mental health counselors. Infants and children covered under Medicaid access mental health services necessary to correct or ameliorate a mental health condition under the mandatory EPSDT benefit.

Every state Medicaid program offers an outpatient prescription drug benefit. State Medicaid programs receive federal funding for drugs manufactured by companies that participate in the Medicaid Drug Rebate Program. Covered outpatient drugs are generally dispensed at the pharmacy counter, though they may also include physician-administered drugs. State Medicaid programs reimburse statutorily defined retail community pharmacies for covered outpatient drugs 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).

Background on the Need to Expand Mental Health Care and Address Pharmacy Benefit Manager Practices under Medicare and Medicaid

Nearly one in four U.S. adults, or 59.3 million people, live with a mental illness.[1] Nearly 22 million adults with a substance use disorder (SUD) also had a co-occurring mental health condition.[2] While private insurance and Medicare covers the majority of adults, more Medicaid beneficiaries experience mental illness (30%) than people with private health insurance (21%) or those who are uninsured (20%).[3] About one in five adult Medicaid beneficiaries have a substance use disorder, compared to 16% of adults with private health insurance.[4] Young Americans are experiencing signifi-

[1] Highlights for the 2022 National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration, November 2023, available at https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-main-highlights.pdf.

[2] *Id.*

[3] Demographics and Health Insurance Coverage of Nonelderly Adults with Mental Illness and Substance Use Disorder in 2020, Heather Saunders and Robin Rudowitz, Kaiser Family Foundation, June 2022, available at https://www.kff.org/mental-health/issue-brief/demographics-and-health-insurance-coverage-of-nonelderly-adults-with-mental-illness-and-substance-use-disorders-in-2020/.

[4] *Id.*

cant mental health challenges, with one in three teenage girls reporting
having seriously contemplated suicide in 2021.[5] Mental health conditions have been exacerbated by the COVID–19 pandemic, which contributed to increased isolation and loneliness, grief, and financial insecurity. At the same time, behavioral health providers have reported increasing demand with decreasing staff sizes.

Despite the prevalence of behavioral health conditions in the U.S., nearly half of adults with mental illness do not receive treatment, often due to barriers to comprehensive and affordable mental health care.[6]

In addition, delayed access to mental health care can be exacerbated by inaccurate provider directories published by health plans. Health plan provider directories serve two purposes: (1) to assist consumers who are choosing a plan; and (2) to assist consumers who are seeking specific health care providers. Currently, MA organizations are required by regulation to maintain accurate provider directories. However, CMS audits have found that MA provider directories were inaccurate about 50% of the time.[7]

Escalating costs of prescription drugs are placing pressure on federal health care programs and the individuals they serve. The Office of the Inspector General of the Department of Health and Human Services (HHS) finds that Medicare and Medicaid account for 41% of total national spending on prescription drugs.[8] Between 2018 and 2021, gross Medicare Part D spending on prescription drugs increased from $166 billion to $216 billion, with spending on the top 10 drugs increasing from $22 billion to $48 billion.[9] Medicaid has also experienced increases in prescription drug spending net of rebates over the same time frame.[10]

Finance Committee investigations as well as other research have found that entities within the prescription drug supply chain may be contributing to price increases for federal health programs and patients at the pharmacy counter through a complex network of financial relationships.[11] [12] Middlemen like PBMs negotiate discounts on behalf of payers, like the federal government, states, and PDP and MA plans, as well as on behalf of patients, yet PBM dis-

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[5] U.S. Teen Girls Experiencing Increased Sadness and Violence, Centers for Disease Control and Prevention, February 2023, available at https://www.cdc.gov/media/releases/2023/p0213-yrbs.html.

[6] Highlights for the 2022 National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration, November 2023, available at https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-main-highlights.pdf.

[7] Online Provider Directory Review Report, Round 3, 2018, Online Provider Directory Review Report, Round 2, 2018, Online Provider Directory Review Report, Round 1, 2017, Centers for Medicare and Medicaid Services (CMS).

[8] Drug Spending, U.S. Department of Health and Human Services Office of the Inspector General, November 2023, available at https://oig.hhs.gov/reports-and-publications/featured-topics/drug-spending/index.asp.

[9] A Small Number of Drugs Account for a Large Share of Medicare Part D Spending, Juliette Cubanski and Tricia Neuman, Kaiser Family Foundation, July 2023, available at https://www.kff.org/medicare/issue-brief/a-small-number-of-drugs-account-for-a-large-share-of-medicare-part-d-spending/.

[10] Trends in Medicaid Drug Spending and Rebates, available at https://www.macpac.gov/publication/trends-in-medicaid-drug-spending-and-rebates/#:~:text=In%20FY%202021%2C%20Medicaid%20spent,percent%20of%20Medicaid%20benefit%20spending.

[11] A Tangled Web: An Examination of the Drug Supply and Payment Chains, Minority Staff of the U.S. Senate Committee on Finance, June 2018, available at https://www.finance.senate.gov/imo/media/doc/A%20Tangled%20Web.pdf.

[12] A Tangled Web: An Examination of the Drug Supply and Payment Chains, Minority Staff of the U.S. Senate Committee on Finance, June 2018, available at https://www.finance.senate.gov/imo/media/doc/A%20Tangled%20Web.pdf.

counts are not always passed on to payers or patients at the pharmacy counter. In Medicare, seniors' cost sharing is often based on an amount that more closely approximates the list price of a drug, not the PBM's net price that includes discounts. Several state Medicaid programs have found some PBMs mark up the price of drugs paid by Medicaid—costing one state more than $200 million a year.[13]

Experts have noted that payments from drug manufacturers to PBMs may create conflicts of interest between PBMs and their health plan clients. Furthermore, linking PBM payment to a drug's list price could create incentives for PBMs to drive utilization of higher-priced drugs, rather than lower-priced, clinically equivalent alternatives, to achieve higher rebates and higher administrative fees.[14] [15]

Evidence suggests that some PBMs also engage in a practice known as "spread pricing," which occurs when PBMs charge their health plan clients a higher amount than what the PBM actually reimburses the pharmacy for the same dispensed drug—with the PBM retaining the difference.[16] Across markets, PBM clients often lack line of sight into the extent of such spreads. Spread pricing has been widely documented in Medicaid. For example, a 2018 audit of Ohio's Medicaid program found that PBMs were charging the state an average 9% spread across all drugs, with some spreads in excess of 30% for certain generics.[17] Similar behavior has been documented in other state Medicaid programs, prompting several state lawmakers and regulators to intervene.[18] Spread pricing is less common in Medicare Part D.[19]

Senate Finance Committee's Work to Improve Access to Mental Health Care and Address Pharmacy Benefit Manager Practices under Medicare and Medicaid

In 2021, Finance Committee Chairman Ron Wyden and Ranking Member Mike Crapo launched a bipartisan process to examine behavioral health care needs and assess factors contributing to gaps in mental health care. Chairman Wyden and Ranking Member Crapo sent a letter to all Committee members asking for data-driven policy proposals designed to improve access to behavioral health care services for individuals enrolled in Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Affordable

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[13] Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs, Joanna Shepherd, *The Yale Law and Policy Review*, January 2019, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3313828.

[14] Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills, Robin Feldman, *Harvard Journal on Legislation,* 2020, available at https://repository.uchastings.edu/cgi/viewcontent.cgi?article=2773&context=faculty_scholarship.

[15] Pharmacy Benefit Tactics Drive Up Drug Prices, Limit Access, Contribute to Health Risks, Purchaser Business Group on Health, December 2022, available at https://www.pbgh.org/wp-content/uploads/2022/12/Pharmacy-Benefit-Tactics-Drive-Up-Drug-Prices-Limit-Access-Contribute-to-Health-Risks.pdf.

[16] Costs and Savings under Federal Policy Approaches to Address Medicaid Prescription Drug Spending, Rachel Garfield, Rachel Dolan, and Elizabeth Williams, Kaiser Family Foundation, June 22, 2021, available at https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-federal-policy-approaches-to-address-medicaid-prescription-drug-spending.

[17] Ohio Cracks Down on PBM Contracts After Audit Shows Egregious Spread Pricing in Medicaid, Rose Meltzer, *Fierce Healthcare*, August 16, 2018, available at https://www.fiercehealthcare.com/regulatory/ohio-takes-action-after-finding-pbms-engaged-egregious-spread-pricing-medicaid.

[18] Arkansas, Delaware, Georgia, Kentucky, Louisiana, Maine, Michigan, Minnesota, New York, Oklahoma, and Virginia have all passed laws seeking to curb spread pricing.

[19] Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization., GAO, July 2019, available at https://www.gao.gov/assets/gao-19-498.pdf.

Care Act (ACA) marketplaces. In September 2021, the Finance Committee requested information from public- and private-sector health care stakeholders to help the Committee better understand how to address mental health challenges. The Committee received over 300 responses from organizations and more than 200 responses from individuals on issues related to the workforce, parity, telehealth, care integration and coordination, and youth mental health.

In addition, the Finance Committee held a series of mental health care hearings to analyze system inadequacies and identify potential policy solutions. From 2021 through 2023, the Finance Committee held five hearings on mental health, including "Mental Health Care in America: Addressing Root Causes and Identifying Policy Solutions," "Protecting Youth Mental Health: Part I—An Advisory and Call to Action," "Protecting Youth Mental Health: Part II—Identifying and Addressing Barriers to Care," "Behavioral Health Care When Americans Need It: Ensuring Parity and Care Integration," and "Barriers to Mental Health Care: Improving Provider Directory Accuracy to Reduce the Prevalence of Ghost Networks." At these hearings, the Committee heard testimony from experts and impacted individuals including the United States Surgeon General, physician leaders, mental health advocates, patients, and the Government Accountability Office (GAO).

After gathering input on how to address gaps in mental health care, the Committee released five bipartisan mental health discussion drafts on workforce, telehealth, youth mental health, primary care and behavioral health care integration, and mental and physical health parity. These drafts included 47 provisions.

On May 3, 2023, Chairman Wyden released findings of a secret shopper study conducted by the committee majority staff.[20] This report was part of the Finance Committee's efforts to understand the prevalence of ghost networks, which are inaccurate health provider directories that can prevent Americans from obtaining health care, including mental health care. In reviewing directories from 12 MA plans in a total of 6 states and calling 10 providers from each plan, 33% of provider directory information was inaccurate, non-working numbers, or unreturned calls. Staff could only make appointments for an initial mental health visit 18% of the time.

Congress enacted several provisions from the Finance Committee's bipartisan mental health care drafts in subsequent legislative packages. The Bipartisan Safer Communities Act, enacted in June 2022, included provisions from the Committee's drafts to improve the mental health of children and adolescents and bolster the workforce. Specifically, the bill expanded the certified community behavioral health clinic (CCBHC) demonstration model, authorized for up to eight states in the Protecting Access to Medicare Act of 2014 and subsequently expanded by Congress to include all interested states. It also required the Centers for Medicare and Medicaid Services (CMS) to issue guidance, provide technical assistance, and award planning grants to states to expand mental health through schools using Medicaid dollars; to conduct comprehensive and reg-

[20] Majority Study Findings: Medicare Advantage Plan Directories Haunted by Ghost Networks, U.S. Senate Committee on Finance, May 3, 2023, available at https://www.finance.senate.gov/imo/media/doc/050323%20Ghost%20Network%20Hearing%20-%20Secret%20Shopper%20Study%20Report.pdf.

ular oversight of states' implementation of Medicaid's EPSDT benefit to strengthen children's access to comprehensive mental health care services; and to provide guidance to states on how they can increase access to behavioral health services through telehealth under Medicaid and CHIP.

The Consolidated Appropriations Act, 2023, enacted in December 2022, also included a number of mental health provisions developed through the bipartisan Committee process, including: establishing Medicare coverage for marriage and family therapist (MFT) and mental health counselor services; adding 200 additional Medicare-funded graduate medical education (GME) residency positions and dedicating 100 of these residency slots to psychiatry specialties; increasing Medicare payments for crisis psychotherapy services when they are provided by a mobile unit; requiring states to provide justice-involved youth Medicaid coverage for 30 days prior to their release; increasing flexibility for states to allow youth to maintain Medicaid/CHIP coverage when they are detained in jail settings prior to adjudication; implementing stronger requirements on Medicaid health plans to publish searchable and updated directories of the health providers in their networks; and directing GAO to study whether mental health and substance use disorder benefits are covered at parity with physical health services in MA and mental health and substance use disorder services in traditional Medicare.

Over the past eight years, the Finance Committee has worked to bring more transparency to prescription drug pricing and predatory practices within a highly complex prescription drug supply chain. In 2015, then-Ranking Member Ron Wyden and senior Finance Committee member (and then-Chairman of the Judiciary Committee) Chuck Grassley conducted an 18-month investigation into the pricing of Sovaldi and Harvoni, Gilead's breakthrough hepatitis C drugs. In 2018, then-Ranking Member Wyden released "A Tangled Web: Examination of the Drug Supply and Payment Chains," a report which examined how financial arrangements between different entities in the pharmaceutical delivery system have continually pushed drug prices higher. In 2021, then-Chairman Grassley and then-Ranking Member Wyden released "Insulin: Examining the Factors Behind the Rising Cost of a Century Old Drug," a report based on an investigation into how contracts and financial transactions between insulin manufacturers and PBMs influence prescription drug prices and drug spending.

In addition, the Finance Committee held a series of hearings on prescription drug pricing and the supply chain. In 2019, the Committee held three hearings, including a hearing in which executives from the nation's five largest PBMs testified. On March 30, 2023, Chairman Wyden and Ranking Member Crapo convened a hearing entitled "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers," building on the Committee's years-long consideration of practices across the prescription drug supply chain. Witnesses at these hearings provided testimony that demonstrated PBMs have become highly concentrated and vertically integrated with pharmacy and health plan businesses, enabling certain PBM practices to raise drug prices, patient out-of-pocket costs, and total drug spending across federal health programs under the Committee's jurisdiction. In addition, testimony revealed PBM market concentration has allowed PBMs

to engage in predatory contracting with community pharmacies that can undermine the financial viability and competitiveness of community pharmacies.

On April 20, 2023, Chairman Wyden and Ranking Member Crapo released the "Bipartisan Framework for Reducing Prescription Drug Costs by Modernizing the Supply Chain and Ensuring Meaningful Relief at the Pharmacy Counter." The framework outlined four key challenges facing federal prescription drug programs, including: (1) misaligned incentives that drive up drug prices and costs; (2) insufficient transparency that distorts the market; (3) hurdles to pharmacy access; and (4) behind-the-scenes practices that impede market competition and increase costs throughout the pharmaceutical supply chain. The framework also identified potential legislative solutions to modernize and enhance federal prescription drug programs and to help address these concerns.

On July 26, 2023, the Finance Committee held a markup of the "Modernizing and Ensuring PBM Accountability Act" that contained bipartisan provisions addressing PBM practices that increased spending under the Medicare and Medicaid program. This Act was voted favorably out of the Committee on a 26–1 vote.

Background on Congressional Extensions of Provisions of the Medicare and Medicaid Programs That Expire

Congress has enacted multiple, separate health care provisions that modify the Medicare and Medicaid program yet that have not been made permanent. One reason for not making provisions permanent is that while these health care programs are essential for patients, health care providers, and other stakeholders, modifications can be expensive to enact on a permanent basis. As result, Congress has on numerous occasions acted to extend certain statutory provisions that would otherwise expire. According to the Congressional Research Service, the Senate Finance Committee has jurisdiction over at least 10 temporary health care provisions that fall under the Medicare and Medicaid programs that expire in 2023 or on January 19, 2024.[21]

On November 6, 2023, Finance Committee Chairman Wyden released a Chairman's Mark entitled the "Better Mental Health Care, Lower-Cost Drugs, and Extenders Act" that contained bipartisan provisions addressing mental health care, prescription drug costs that are higher as result of PBM practices, and health extenders. The provisions, in addition to further proposals and modifications contained in the November 8, 2023, Modification to the Chairman's Mark, comprise the reported bill described below.

II. EXPLANATION OF THE BILL

SECTION 1. SHORT TITLE; TABLE OF CONTENTS

This section sets out the name of the bill—the "Better Mental Health Care, Lower-Cost Drugs, and Extenders Act"—and lists the Table of Contents of the legislation.

[21] Health Care-Related Expiring Provisions of the 118th Congress, First Session, Katherine Kehres and Phoenix Voorhies, Congressional Research Service, June 2023, available at https://www.crs.gov/reports/pdf/R47604/R47604.pdf.

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 Social Security Act (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 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, Pub. 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 (Pub. 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 SSA.

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 AND ACCURATE LISTS OF (REAL) HEALTH PROVIDERS ACT

Current Law

Section 1852(c)(1)(C) requires 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

These provisions would require that beginning in plan year (PY) 2026, each network-based MA plan would be responsible for maintaining an accurate provider directory on a public website and would meet the requirements described below.

These provisions would require MA plans to pay for covered items or services when delivered by a provider listed in the directory as in-network, but who was actually out-of-network when the appointment was made. MA plans would be required to submit annual reports of their provider directory accuracy. The accuracy of the plan directory would be reported on the plan's directory and to the HHS Secretary. The Comptroller General of the United States would be required to submit a study of this information submitted under this provision and related issues.

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.

I. Accurate Plan Provider Directory Requirements

This provision would amend Section 1852(c), requiring network-based MA plans to maintain an accurate provider directory on a publicly available website. Network-based plan has the meaning given in Section 1852(d)(5)(C) except that it includes private fee-for-service plans as determined by the Secretary. Each network-based MA plan would be required to verify provider directory information for each provider listed in such directory, at least every 90 days or in the case of a hospital or other facility the HHS Secretary can specify a lesser frequency that is in no case less than once every 12 months. MA plans would be required to note in the directory providers whose information could not be verified, to remove providers listed in a directory within five business days if the organization determines the provider is no longer participating in the network, and meet other requirements as specified by the HHS Secretary. Provider directories would be required to include information that the enrollee may need to access covered benefits from a contracted provider. The section provides examples of what directory information could include (such as provider name, specialty, contact information, primary office or facility address, whether the provider is accepting new patients, accommodations for people with disabilities, cultural and linguistic capabilities, and telehealth capabilities) but leaves the determination to the HHS Secretary.

This provision would amend Section 1852(d) requiring MA plans beginning in plan year 2026 to ensure that if an enrollee received care from an out-of-network provider that was listed on the date the appointment was made as an in-network provider in the plan's directory, the MA organization would be 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. This provision amends Section 1852(d)(1)(C) to require MA plans to cover services furnished upon reliance on incorrect provider directory information on an out of network basis. For plan year 2026, MA plans would notify enrollees of their cost-sharing protections on an explanation of benefits, annual notifications provided prior to the annual, coordinated election period under 1851(e)(3), and on the plan's provider directory.

II. Accountability and Transparency for Accurate Plan Provider Directories

This provision would amend Section 1857(e) to require MA contracts beginning plan year 2026 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 specifying methodologies that MA plans can use to estimate the accuracy of the provider directory information and their accuracy scores, would consider availability of various data sources, administrative burden on plans and providers, and the relative importance of certain directory information on access to care. Beginning in plan year 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 low enrollment MA plans, as defined by the Secretary. To implement these requirements, $1,000,000 to remain available until expended would be appropriated to CMS Program Management Account, out of the General Fund of the U.S. Treasury.

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).

III. Stakeholder Engagement and CMS Guidance to Improve Plan Provider Directories

Not later than 3 months after enactment, the HHS Secretary would be required to hold a public stakeholder meeting on maintaining accurate provider directories for MA plans, including approaches for reducing administrative burden such as data standardization and best practices to maintain provider directory information. Participants of the meeting shall include representatives from the Medicare program, Office of the National Coordinator for Health Information Technology, health care providers, companies that specialize in relevant technologies, health insurers, and patient advocates.

Not later than 12 months after enactment, the HHS Secretary would be required to issue guidance to MA Organizations on mainlining accurate provider directories for such plans taking into consideration comments submitted during the public stakeholder meeting. The guidance may include the following topics as determined appropriate by the Secretary: best practices for MA organizations on how to work with providers to maintain the accuracy of provider directories and reduce provider and MA organization burden with respect to maintaining the accuracy of provider directories; information on data sets and data sources with information that could be used by MA organizations to maintain accurate provider directories; approaches for utilizing data sources maintained by MA organizations and publicly available data sets to maintain accurate provider directories; and information to be included in the provider directory that may be useful for Medicare beneficiaries to assess plan networks when selecting a plan and accessing providers participating in plan networks during the plan year.

Not later than 12 months after enactment, the HHS Secretary would be required to issue guidance to Part B participating 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-covered 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; Pub. 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 mental health (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

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 CHIP Medicaid expansion programs.[22] 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.

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 SSA requires states to cover a wide-array of MH/SUD serv-

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

ices 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 Act requires the HHS Secretary to publish a report on the prevalence of 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 1st 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 MH conditions and MH treatment services provided to Medicaid enrollees, based on federally required state submissions of 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

CMS has issued guidance to encourage states to adopt strategies that promote the integration of physical and MH or 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.[23]

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

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; Pub. 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.

SECTION 115. DEFINING CERTIFIED COMMUNITY BEHAVIORAL HEALTH CLINICS (CCBHCS) WITHIN THE MEDICAID PROGRAM

Current Law

Section 223 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) authorized a Medicaid demonstration program which established CCBHCs.[24] CCBHCs are facilities operated by nonprofit, governmental, or tribal entities that offer a comprehensive range of behavioral health services. The HHS Secretary was required to publish criteria relating to staffing, care coordination,

[24] The Consolidated Appropriations Act of 2018 (Pub. L. 115–141) authorized a CCBHC expansion grant program which was further funded by additional laws passed in 2021 and 2022. Expansion grants provide supplemental funds directly to clinics in order to increase access and improve the quality of their behavioral health services.

and other clinic requirements for States to use to certify clinics.[25] States participating in the CCBHC demonstration program receive the enhanced federal medical assistance percentage (E–FMAP; i.e., the federal reimbursement rate used for the State CHIP for CCBHC services provided to Medicaid enrollees during the applicable demonstration period. In addition, the CCBHCs in these states receive greater Medicaid payment rates for the services provided to Medicaid enrollees through a prospective payment system (PPS) methodology. There are currently eight states participating in the demonstration with varying expirations. The Bipartisan Safer Communities Act of 2022 (Pub. L. 117–159) authorized the HHS Secretary to select up to 10 additional states for the Medicaid demonstration program beginning July 1, 2024, and every two years after that.

CCBHCs can be supported by a Medicaid demonstration program for states and/or discretionary grant funding for clinics from the Substance Abuse and Mental Health Services Administration (SAMHSA). States that are not part of the CCBHC Medicaid demonstration program are able to make Medicaid payments to CCBHCs, but these states are not required to pay CCBHCs through a PPS. In addition, only states participating in the Medicaid demonstration program are eligible for the E–FMAP for CCBHC services.

Provision

Section 115 would amend Section 1905 of the SSA (42 U.S.C. § 1396d) to add CCBHC services to the list of Medicaid optional service categories under traditional Medicaid. The provision would add a definition of CCBHC services which would include the same services that CCBHCs are required to provide in the demonstration program (e.g., crisis mental health services, targeted case management, psychiatric rehabilitation). A CCBHC would be defined as an organization that furnishes CCBHC services, is legally authorized to furnish such services under State law, agrees to furnish data as required as a condition of certification, and has been certified by a State to meet the criteria issued by the HHS Secretary as of January 1, 2024, and any subsequent updates to those criteria, regardless of whether the state is participating in the Medicaid demonstration program.[26] The effective date for this provision would be January 1, 2024.

TITLE II—REDUCING PRESCRIPTION DRUG COSTS UNDER MEDICARE AND MEDICAID

SECTION 201. ASSURING PHARMACY ACCESS AND CHOICE FOR MEDICARE BENEFICIARIES

Current Law

Under SSA Section 1860D–4(b) ((42 U.S.C. § 1395w–104(b)), Part D plans must contract with an adequate network of brick-and-mor-

[25] HHS issued the original CCBHC certification criteria in 2015, which outlined standards for staffing, provider credentialing, training requirements, linguistic competence, timely access, among others. In March 2023, HHS issued updated criteria which was informed by public input and includes updates to the standards related to developments in the field.

[26] There is bracketed text providing the following examples of the data states would need to furnish: "encounter data, clinical outcomes data, quality data, and such other data as the State or Secretary may require."

tar pharmacies each year in order to provide easy access for plan enrollees. Plan sponsors often contract with 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.[27] 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.[28] [29] 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.[30] 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.[31] 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.[32]

After a plan has developed an adequate network, Part D plan sponsors (except those offering the Part D defined standard benefit)

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[27] 42 C.F.R. § 423.505; Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.

[28] *Ibid.*

[29] Compliance with Any Willing Pharmacy (AWP) Requirements, Amy K. Larrick, CMS, August 13, 2015, available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/anywillingpharmacyguidance_166.pdf.

[30] Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Federal Register p. 1413, CMS, May 2022, available at https://www.federalregister.gov/d/2022-09375/p-1413.

[31] *Id.*

[32] A New World Order of Drastically Lower Pharmacy Reimbursement Series—Part 1: Lower Net Pharmacy Reimbursement Following CMS Final Rule on DIR Fees, Jonathan Levitt, Frier Levitt, June 2022, available at 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.

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 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.[33] A number of large Part D plans include no independent pharmacies in their preferred networks.[34]

Provisions

I. Reasonable and Relevant Codification

These provisions would amend SSA Section 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, including with respect to information on reimbursement and dispensing fees. 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 Section 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. Franchises and pharmacies associated with pharmacy services administrative organizations that meet the relevant requirements can qualify as independent community pharmacies under this provision.

An essential retail pharmacy would be defined as a pharmacy that: (1) is not an affiliate of a PBM or plan sponsor;[35] (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

[33] 42 C.F.R. § 423.505; Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.
[34] Small Pharmacies Walk Away from Medicare Part D's 2023 Preferred Networks, Adam Fein, Drug Channels, December 2022, available at https://www.drugchannels.net/2022/12/small-pharmacies-walk-away-from.html.
[35] 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).

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 Acquisition Cost[36] (NADAC) for such drug for retail community pharmacies. If there were no NADAC data for retail community pharmacies available, the NADAC 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 Section 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, with the ability to submit an additional allegation within a single plan year in the event of a substantive change in the terms or conditions offered under such contract. 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 Section 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.

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[36] 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.

IV. Oversight of Pharmacy Access Requirements

This provision would direct the Secretary to brief Congress and to compile and publish periodic reports, beginning no later than 90 days after the date of enactment of this legislation, through plan year 2027, on the following topics related to implementation of the Pharmacy DIR rule that takes effect in 2024, as well as related to statutory, regulatory, and sub-regulatory requirements and standards:

- Monitoring of changes to contract terms and conditions offered to pharmacies for network or preferred network participation;
- HHS enforcement or oversight activities related to regulatory and sub-regulatory requirements regarding Part D's any willing pharmacy provisions; and
- HHS plans, strategies, or initiatives to address or mitigate concerns related to convenient pharmacy access.

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, Pub. 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 NADAC survey. NADAC is a monthly survey of RCP acquisition costs paid for most covered outpatient drugs. CMS, through a 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.[37] 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.

[37] States Could Do More to Oversee Spending and Contain Medicaid Costs for Specialty Drugs, Suzanne Murrin, HHS OIG, December 2020, available at https://oig.hhs.gov/oei/reports/OEI-03-17-00430.pdf.

As of last year, the three largest specialty pharmacies were all PBM affiliates and accounted for a combined 65% of prescription revenue for pharmacy-dispensed specialty drugs.[38] 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.[39] 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 HHS 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 HHS 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 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 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 prohib-

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[38] DCI's Top 15 Specialty Pharmacies of 2022: Five Key Trends About Today's Marketplace, Adam Fein, Drug Channels, April 2023, available at https://www.drugchannels.net/2023/04/dcis-top-15-specialty-pharmacies-of.html.

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

ited 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 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 FY 2024 that would be available until expended to carry out oversight of the NADAC survey. The HHS Secretary would receive a $9-million appropriation for Fiscal Year (FY) 2024 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.[40]

[40] Key Facts About Medicare Part D Enrollment and Costs in 2023, Juliette Cubanski and Anthony Damico, Kaiser Family Foundation, July 2023, available at https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-and-costs-in-2023.

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.[41] As summarized by the 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."[42] 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 drug makers 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.[43] [44] 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 drug manufacturers to provide on branded drugs and biosimilars.[45] 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."[46] GAO found that for 79 of the 100 most highly rebated Part D drugs, beneficiaries paid more, on net, than their plan sponsors.[47] A *Journal of the American Medical Association* (JAMA) analysis concluded that rebate growth was associated with a $13 average increase in Medicare beneficiary cost sharing per prescription between 2014 and 2018.[48]

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

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[41] 42 U.S.C. § 1395w–102(d)(1).

[42] Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending, GAO, September 2023, available at https://www.gao.gov/assets/gao-23-105270.pdf.

[43] *Ibid*.

[44] Drug Pricing's $268 billion non-event, 46 brooklyn, January 2020, available at https://www.46brooklyn.com/research/2020/1/21/2018-medicare-part-d-data-review-sxfn7.

[45] Analysis of Part D data on drug rebates and discounts, Tara Hayes, Shinobu Suzuki, and Rachel Schmidt, MedPAC, September 2022, available at https://www.medpac.gov/wp-content/uploads/2021/10/DIR-Slides-MedPAC-29-Sept-2022.pdf.

[46] June 2023 Report to Congress, MedPAC, June 2023, available at https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch2_MedPAC_Report_To_Congress_SEC.pdf.

[47] *Id.*

[48] Association of Branded Prescription Drug Rebate Size and Patient Out-of-Pocket Costs in a Nationally Representative Sample, 2007–2018, Kai Yeung, Stacie Dusetzina, and Anirban Basu, JAMA Open Network, June 2021, available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780950.

"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 Section 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; and 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.

This provision would also direct the GAO to conduct a study and publish a report (along with subsequent reports, as determined appropriate), once relevant data becomes available, on certain effects and behavioral responses related to the implementation of the cost-sharing provisions specified in this section, including:

- Effects on enrollee cost sharing, utilization and adherence, formulary coverage and placement, and utilization management with respect to affected covered Part D drugs (discount-eligible drugs and covered Part D drugs for which, prior to implementation of these provisions, cost sharing exceeded net price for some beneficiaries), along with any effects on beneficiary premiums.
- Changes to pharmacy reimbursement methodologies and levels, if any, with respect to discount-eligible drugs.
- Changes in manufacturer rebating levels (relative to gross costs) for discount-eligible drugs.
- Other behavioral responses by PDP sponsors, enrollees, manufacturers, pharmacies, or other entities related to the implementation of these provisions.
- Other issues determined appropriate by the Comptroller General.

TITLE III—MEDICAID EXPIRING PROVISIONS

SECTION 301. DELAYING CERTAIN DISPROPORTIONATE SHARE HOSPITAL PAYMENT REDUCTIONS UNDER THE MEDICAID PROGRAM

Current Law

SSA Section 1923 requires states to make Medicaid disproportionate share hospital (DSH) payments to hospitals treating large numbers of low-income patients. 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. In FY 2028, DSH allotments are to rebound to the pre-reduced levels, with annual inflation adjustments for FY 2024 to FY 2027.[49]

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. 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 SUPPORT Act added a new Section 1915(l) of the 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.[50] 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.

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[49] The Continuing Appropriations Act, 2024, and Other Extensions Act (Pub. L. 118–15) amended the Medicaid DSH reductions by eliminating the reductions from September 30, 2023 through November 17, 2023. The Further Continuing Appropriations and Other Extensions Act (Pub. L. 118–22) amended the Medicaid DSH reductions by eliminating the reductions from November 17, 2023 until January 20, 2024.

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

TITLE IV—MEDICARE EXPIRING PROVISIONS AND PROVIDER PAYMENT CHANGES

SECTION 401. EXTENSION OF FUNDING FOR QUALITY MEASURE ENDORSEMENT, INPUT, AND SELECTION

Current Law

Under 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 prerulemaking process to select quality measures for use in the Medicare program. As part of this process, the HHS 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 HHS 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 (Pub. 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 FY 2021, $20 million for FY 2022, and $20 million for FY 2023.

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 FY 2009, Section 119 of the Medicare Improvements for Patients and Providers Act (MIPPA; Pub. L. 110–275) provided mandatory funding for outreach and assistance to low-income Medicare beneficiaries through State Health Insurance As-

sistance 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 (Pub. L. 116–260) through FY 2023. The HHS Secretary is required to transfer specified amounts for MIPPA program activities from the Medicare HI and SMI Trust Funds to the 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.[51]

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; Pub. 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, for performance year 2023, an eligible professional must either receive at least 50% of Medicare Part B payments through an AAPM entity or see at least 35% 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).

[51] The Further Continuing Appropriations and Other Extensions Act (Pub. L. 118–22) extended 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 January 19, 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 CARES Act 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 (Pub. 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 (ACA; Pub. 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 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, Pub. L. 115–123, Section 50301, and the Consolidated Appropriations Act of 2021, Pub. 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 HI and the SMI Trust Funds, in proportions determined appropriate by the HHS Secretary. The funding was made available for 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 FY 2024, 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 (Pub. 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 (Pub. L. 117–71) extended the increase through 2022 at the reduced level of 3.0%. The Consolidated Appropriations Act, 2023 (Pub. 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, Pub. L. 113–93) mandated a different method for determining clinical laboratory payments based on reported private insurance payment amounts and required the 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% for each Medicare clinical laboratory payment in 2024 through 2026.[52]

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 hos-

[52] The Further Continuing Appropriations and Other Extensions Act (Pub. L. 118–22) extended the moratorium on the reporting and collecting of private insurance payments for clinical laboratory services through December 31, 2024 and extended the zero-percent cap on payment reductions through December 31, 2024.

pice 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 (SSA § 1814(i)(2)(B)), limits a hospice agency's average annual payment per beneficiary. The latter cap is currently, for 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.

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. This policy allows the hospice payment rate and the aggregate hospice cap to grow using a common inflationary index.

TITLE V—OFFSETS

SECTION 501. MEDICAID IMPROVEMENT FUND

Current Law

Section 7002(b) of the Supplemental Appropriations Act of 2008 (Pub. L. 110–252) added 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 and Medicaid Services, including oversight of contracts and contractors and evaluation of demonstration projects." Pub. 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.[53]

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.

[53] The Continuing Appropriations Act, 2024, and Other Extensions Act (Pub. L. 118–15) amended SSA Section 1941 to reduce availability to the MIF for FY 2028 and thereafter from $7,000,000,000 to $6,357,117,810. The Further Continuing Appropriations and Other Extensions Act (Pub. L. 118–22) amended SSA Section 1941 to reduce funding availability to the MIF for FY 2028 and thereafter from $6,357,117,810 to $5,796,117,810.

SECTION 502. MEDICARE IMPROVEMENT FUND

Current Law

MIPPA added 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 HI Trust Fund and the SMI 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 FY 2022.[54]

Provision

This provision would change the amount available in the Medicare Improvement Fund for services furnished during and after FY 2022 to $936,000,000.

III. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATES

In compliance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate and section 308(a)(1) of the Congressional Budget and Impoundment Control Act of 1974, as amended (the "Budget Act"), the following statement is made concerning the estimated budget effects of the revenue provisions of the Better Mental Health Care, Lower-Cost Drugs, and Extenders Act, as reported. The spending effects of the bill will be included in the statement from the Congressional Budget Office that will be provided separately, as described in Part C below.

B. BUDGET AUTHORITY AND TAX EXPENDITURES

In compliance with section 308(a)(1) of the Budget Act, the Committee states that the extent to which the provisions of the bill as reported involve new or increased budget authority or affect levels of tax expenditures will be included in the statement from the Congressional Budget Office that will be provided separately, as described in Part C below.

C. CONSULTATION WITH CONGRESSIONAL BUDGET OFFICE

In accordance with section 403 of the Budget Act, the Committee advises that the Congressional Budget Office has not submitted a statement on the bill. The statement from the Congressional Budget Office will be provided separately.

[54] The Further Continuing Appropriations and Other Extensions Act (Pub. L. 118–22) changed the amount available in the Medicare Improvement Fund for services furnished during and after FY 2022 to $466,795,056.

IV. VOTES OF THE COMMITTEE

In compliance with paragraph 7(b) of rule XXVI of the Standing Rules of the Senate, the Committee states that, with a majority present, the Better Mental Health Care, Lower-Cost Drugs, and Extenders Act, was ordered favorably reported on November 8, 2023, by a roll call vote of 26 ayes and 0 nays. The vote was as follows:

Ayes: Wyden, Stabenow, Cantwell, Menendez, Carper, Cardin (proxy), Brown (proxy), Bennet (proxy), Casey, Warner, Whitehouse, Hassan, Cortez Masto, Warren, Crapo, Grassley (proxy), Cornyn (proxy), Thune (proxy), Scott (proxy), Cassidy (proxy), Lankford, Daines, Young (proxy), Barrasso (proxy), Tillis, and Blackburn.

Nays: None.

Not Voting: Johnson.

V. REGULATORY IMPACT AND OTHER MATTERS

A. REGULATORY IMPACT

Pursuant to paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee makes the following statement concerning the regulatory impact that might be incurred in carrying out the provisions of the bill.

Impact on individuals and businesses, personal privacy and paperwork

The bill includes various provisions relating to coverage and payment of services provided under the Medicare and Medicaid programs that are not expected to impose additional administrative requirements or regulatory burdens on individuals, providers, or businesses beyond those normally necessary under the Medicare and Medicaid programs. In carrying out other provisions of the bill, MA plans and individuals and businesses across the drug supply chain will be subject to new administrative requirements.

MA plans will be required to conduct annual reports on accuracy of their provider directories and submit those reports to the HHS Secretary, and to notify consumers of the cost-sharing protections for services based on reliance on incorrect provider directory information. Across the drug supply chain, Part D plans and the PBMs they contract with will be required to report information about rebates they receive from manufacturers and pharmacies will be required to report acquisition cost information. Pharmacies, on a voluntary basis, will be enabled to file complaints with the HHS Secretary with respect to PBM adherence to the codification of regulatory requirements that PBMs are required to follow. Part D plans and PBMs may have to report information related to such complaints to the HHS Secretary.

The provisions of the bill do not impact personal privacy.

B. UNFUNDED MANDATES STATEMENT

The Committee adopts as its own the estimate of federal mandates prepared by the Director of the Congressional Budget Office pursuant of section 423 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), which will be provided separately.

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In the opinion of the Committee, it is necessary in order to expedite the business of the Senate, to dispense with the requirements of paragraph 12 of rule XXVI of the Standing Rules of the Senate (relating to the showing of changes in existing law made by the bill as reported by the Committee).

○