

115TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session 115–726

MEDICAID PHARMACEUTICAL HOME ACT OF 2018

JUNE 12, 2018.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WALDEN, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany H.R. 5808]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5808) to amend title XIX of the Social Security Act to require States to operate drug management programs for at-risk beneficiaries, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

H.R. 5808 was introduced on May 15, 2018, by Rep. Gus Bilirakis (R-FL). The bill requires states to operate qualified drug management programs for at-risk beneficiaries beginning January 1, 2020, describes the elements of a qualified drug management program including enrollment, notification, and re-enrollment, and allows states that operate a drug management program under a fee-for-service financial arrangement upon enactment to be considered a qualified program.

BACKGROUND AND NEED FOR LEGISLATION

Deaths due to overdoses of opioids and other drugs have ravaged American communities. According to the Centers for Disease Control and Prevention (CDC), on average, 1,000 people are treated for opioid misuse in emergency departments per day, an average of 115 Americans die per day, and opioid-related overdoses have increased steadily since 1999.¹

While the impacts to Americans' health outcomes are staggering, the opioid crisis has negatively impacted society in numerous ways. The Centers for Disease Control and Prevention note that life expectancy dropped in 2015 and 2016 and that one of the reasons was an increase in unintentional injuries, a category that includes drug overdoses.² The opioid crisis has also resulted in a contraction in the labor force by almost 1 million workers in the years between 1999 and 2015, which resulted in a loss of \$702 billion in real output.³ In 2015, the total economic burden of the opioid epidemic was estimated to be \$504 billion.⁴ While all states were negatively impacted, there is geographic variation in the burden. West Virginia had the greatest loss per person (\$4,378) and Nebraska had the lowest loss per person (\$394).⁴ One recent analysis found that the annual cost for private sector employers for treating opioid addiction and overdoses has increased more than eight-fold since 2004, and more than one in five persons aged 55 to 64 had at least one opioid prescription in 2016.⁵

Medicaid is the largest source of federal funding for behavioral health services—mental health and substance use disorder services—with nearly \$71 billion in projected 2017 spending.⁶ As the Medicaid and CHIP Payment and Access Commission (MACPAC) stated in 2017, “the opioid epidemic, which has reached most communities across the U.S., disproportionately affects Medicaid bene-

¹ Centers for Disease Control and Prevention. “Drug Overdose Death Data.” December 19, 2017. Available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html>.

² Dowell, D., Arias E., Kochanek K. et al. “Contribution of Opioid-Involved Poisoning to the Change in Life Expectancy in the United States, 2000–2015.” JAMA, September 2017. Available at <https://jamanetwork.com/journals/jama/fullarticle/2654372>

³ American Action Forum. “The Labor Force and Output Consequences of the Opioid Crisis.” March 27, 2018. Available at <https://www.americanactionforum.org/research/labor-force-output-consequences-opioid-crisis/>

⁴ American Enterprise Institute. “The Geographic Variation in the Cost of the Opioid Crisis”. Available at https://www.aei.org/wp-content/uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf

⁵ Kaiser Family Foundation, “A Look at How the Opioid Crisis Has Affected People with Employer Coverage,” April 2018. Available online at: <https://www.kff.org/health-costs/press-release/analysis-cost-of-treating-opioid-addiction-rose-rapidly-for-large-employers-as-the-number-of-prescriptions-has-declined/>

⁶ Government Accountability Office, “Medicaid: States Fund Services for Adults in Institutions for Mental Disease Using a Variety of Strategies,” GAO-17-652, August 2017. Available at <https://www.gao.gov/assets/690/686456.pdf>

ficiaries.”⁷ Of the two million non-elderly Americans with opioid addiction, Medicaid provides health coverage for an estimated 38 percent of this population, which is the largest percentage of any insurer type.⁸ Medicaid provides care to 4 in 10 adults with opioid use disorder and compared to other insurance types, provides a significantly higher percentage of inpatient and outpatient substance use disorder treatment.⁹

MACPAC found that “Medicaid beneficiaries are prescribed pain relievers at higher rates than those with other sources of insurance. They also have a higher risk of overdose and other negative outcomes, from both prescription opioids and illegal opioids such as heroin and illicitly manufactured fentanyl.”¹⁰ Not only are the number of Medicaid beneficiaries with opioid misuse disproportionately high, so too are the number of overdoses. Studies from North Carolina and Washington indicate high rates of opioid-related deaths for the Medicaid population (33 percent and 45 percent, respectively).

For treatment, Medicaid has several pharmacy and medical benefits for treating opioid use disorder that vary by state. A primary pharmaceutical treatment offered to patients with opioid abuse and/or substance use disorder is medication-assisted treatment (MAT). The Substance Abuse and Mental Health Services Administration (SAMHSA) describes MAT as “the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a “whole-patient” approach to the treatment of substance use disorders.”¹¹

Non-pharmaceutical treatment of opioid use disorder in Medicaid occurs in inpatient, outpatient, residential, and community-based settings. MACPAC’s 2017 analysis found that “Medicaid is responding to the opioid crisis by covering treatment, innovating in the delivery of care, and working with other state agencies to reduce misuse of prescription opioids.”¹² State Medicaid programs adopt strategies and design their programs to meet the needs of their Medicaid beneficiaries resulting in variations in covered treatment services and settings. It is important state Medicaid programs provide a continuum of care to serve the needs of Medicaid beneficiaries.

However, as MACPAC noted, “there are gaps in the continuum of care, and states vary in the extent to which they cover needed treatment.”¹³ One of the barriers to appropriate treatment consistently identified by Medicaid directors and health policy experts is a statutory prohibition on federal Medicaid matching funds for pay-

⁷ Medicaid and CHIP Payment and Access Commission, “Medicaid and the Opioid Epidemic,” Chapter 2 in June 2017 Report to Congress on Medicaid and CHIP. Available at: <https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf>

⁸ Kaiser Family Foundation, “Medicaid’s Role in Addressing the Opioid Epidemic.” Available at <https://www.kff.org/infographic/medicaiads-role-in-addressing-opioid-epidemic/>

⁹ Kaiser Family Foundation, “Medicaid’s Role in Addressing the Opioid Epidemic.” Available at <https://www.kff.org/infographic/medicaiads-role-in-addressing-opioid-epidemic/>

¹⁰ Medicaid and CHIP Payment and Access Commission, “Medicaid and the Opioid Epidemic,” Chapter 2 in June 2017 Report to Congress on Medicaid and CHIP. Available at: <https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf>

¹¹ See SAMHSA website. Available at: <https://www.samhsa.gov/medication-assisted-treatment>

¹² Medicaid and CHIP Payment and Access Commission, “Medicaid and the Opioid Epidemic,” Chapter 2 in June 2017 Report to Congress on Medicaid and CHIP. Available at: <https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf>

¹³ Medicaid and CHIP Payment and Access Commission, “Medicaid and the Opioid Epidemic,” Chapter 2 in June 2017 Report to Congress on Medicaid and CHIP. Available at: <https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf>

ing for care for certain Medicaid beneficiaries in Institutions for Mental Diseases (IMD). As MACPAC has explained, “the Medicaid IMD exclusion acts a barrier for individuals with an opioid use disorder to receive residential treatment, which, depending on an individual’s treatment plan, may be the most appropriate setting for care.”¹⁴ Given these and other findings, there continues to be an opportunity for Congress and state Medicaid programs to work to improve access to timely, high-quality treatment across the continuum of care.

Federal law requires state Medicaid programs to permit beneficiaries to receive care from any institution, agency, community pharmacy, or person, qualified to perform the required services. States are permitted to waive the freedom-of-choice of provider requirements under certain conditions, such as to require beneficiaries to enroll in a managed care plan.

In addition to waivers of freedom-of-choice of provider for managed care, if a state Medicaid program determines that beneficiaries have over-utilized services, as determined by the state, the Medicaid program has the option to restrict beneficiaries, for a reasonable period of time, to receiving Medicaid services only from designated providers as long as the following conditions are met:

- The state gives beneficiaries notice and opportunity for a hearing (in accordance with procedures established by the state) before restricting provider access.
- The state ensures that beneficiaries have reasonable access (taking into account geographic location and reasonable travel time) to Medicaid services of adequate quality.
- The freedom-of-choice of provider restrictions do not apply to emergency services.

Programs to restrict patient access to certain providers are known as lock-in programs or Patient Review and Restrictive (PRR) programs. PRR programs often are used to prevent excessive or fraudulent drug utilization. In 2016, most state Medicaid programs reported that they had some form of controlled substance PRR. States have different PPR/lock-in policies, such as for over utilization of more than one controlled substance, seeking drugs from more than one provider or more than one pharmacy, or for multiple emergency room visits. In addition, some states lock-in beneficiaries to only one prescriber or only one pharmacy or both and have differing lock-in time periods.

PRR programs have resulted in cost savings and decreased drug utilization. For example, North Carolina’s lock-in decreased the mean number of per member per month opioid and benzodiazepine prescription fills by 17 percent.¹⁵ Washington found the average number of controlled substance prescriptions went from 3.07 to 1.63.¹⁶ Finally, the 2016 CMS Drug Utilization Report showed that on average states saved about \$1.5 million on drug avoidance/savings.¹⁷

¹⁴ Medicaid and CHIP Payment and Access Commission, “Medicaid and the Opioid Epidemic,” Chapter 2 in June 2017 Report to Congress on Medicaid and CHIP. Available at: <https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf>

¹⁵ Roberts AW, Farley JF, Holmes GM, et al. Controlled Substance Lock-In Programs: Examining an Unintended Consequence of a Prescription Drug Abuse Policy. Health Affairs. Oct 2016, Vol 35(10).

¹⁶ http://www.wsha.org/wp-content/uploads/ercareplans_PRC-webcast-May-1-2012-Final.pptx

¹⁷ Centers for Medicare and Medicaid Services, Center for Medicaid & CHIP Services. “Medicaid Drug Utilization Review State Comparison/ Summary Report FFY 2016 Annual Report.”

COMMITTEE ACTION

On April 11, 2018, the Subcommittee on Health held a hearing on the discussion draft entitled “Medicaid Pharmaceutical Home Act.” The Subcommittee received testimony from:

- Kimberly Brandt, Principal Deputy Administrator for Operations, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services;
- Michael Botticelli, Executive Director, Grayken Center for Addiction, Boston Medical Center;
- Toby Douglas, Senior Vice President, Medicaid Solutions, Centene Corporation;
- David Guth, Chief Executive Officer, Centerstone;
- John Kravitz, Chief Information Officer, Geisinger Health System; and,
- Sam Srivastava, Chief Executive Officer, Magellan Health.

On April 25, 2018, the Subcommittee on Health met in open markup session and forwarded the discussion draft, without amendment, to the full Committee by a record vote of 18 yeas and 14 nays. On May 17, 2018, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 5808, without amendment, favorably reported to the House by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 5808 reported.

OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 5808 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

October 2017. Available at: <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/2016-dur-summary-report.pdf>

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 6, 2018.

Hon. GREG WALDEN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed document with cost estimates for the opioid-related legislation ordered to be reported on May 9 and May 17, 2018.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Tom Bradley and Chad Chirico.

Sincerely,

MARK P. HADLEY
(For Keith Hall, Director).

Enclosure.

Opioid Legislation

Summary: On May 9 and May 17, 2018, the House Committee on Energy and Commerce ordered 59 bills to be reported related to the nation's response to the opioid epidemic. Generally, the bills would:

- Provide grants to facilities and providers that treat people with substance use disorders,
- Direct various agencies within the Department of Health and Human Services (HHS) to explore nonopioid approaches to treating pain and to educate providers about those alternatives,
- Modify requirements under Medicaid and Medicare for prescribing controlled substances,
- Expand Medicaid coverage for substance abuse treatment, and
- Direct the Food and Drug Administration (FDA) to modify its oversight of opioid drugs and other medications that are used to manage pain.

Because of the large number of related bills ordered reported by the Committee, CBO is publishing a single comprehensive document that includes estimates for each piece of legislation.

CBO estimates that enacting 20 of the bills would affect direct spending, and 2 of the bills would affect revenues; therefore, pay-as-you-go procedures apply for those bills.

CBO estimates that enacting H.R. 4998, the Health Insurance for Former Foster Youth Act, would increase net direct spending by more than \$2.5 billion and on-budget deficits by more than \$5 billion in at least one of the four consecutive 10-year periods beginning in 2029. None of the remaining 58 bills included in this estimate would increase net direct spending by more than \$2.5 billion or on-budget deficits by more than \$5 billion in any of the four consecutive 10-year periods beginning in 2029.

One of the bills reviewed for this document, H.R. 5795, would impose both intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the costs of those mandates on public and private enti-

ties would fall below the thresholds in UMRA (\$80 million and \$160 million, respectively, in 2018, adjusted annually for inflation). Five bills, H.R. 5228, H.R. 5333, H.R. 5554, H.R. 5687, and H.R. 5811, would impose private-sector mandates as defined in UMRA. CBO estimates that the costs of the mandates in three of the bills (H.R. 5333, H.R. 5554, and H.R. 5811) would not exceed the UMRA threshold for private entities. Because CBO is uncertain how federal agencies would implement new authority granted in the other two bills, H.R. 5228 and H.R. 5687, CBO cannot determine whether the costs of those mandates would exceed the UMRA threshold.

Estimated cost to the Federal Government: The estimates in this document do not include the effects of interactions among the bills. If all 59 bills were combined and enacted as one piece of legislation, the budgetary effects would be different from the sum of the estimates in this document, although CBO expects that any such differences would be small. The costs of this legislation fall within budget functions 550 (health), 570 (Medicare), 750 (administration of justice), and 800 (general government).

Basis of estimate: For this estimate, CBO assumes that all of the legislation will be enacted late in 2018 and that authorized and estimated amounts will be appropriated each year. Outlays for discretionary programs are estimated based on historical spending patterns for similar programs.

Uncertainty

CBO aims to produce estimates that generally reflect the middle of a range of the most likely budgetary outcomes that would result if the legislation was enacted. Because data on the utilization of mental health and substance abuse treatment under Medicaid and Medicare is scarce, CBO cannot precisely predict how patients or providers would respond to some policy changes or what budgetary effects would result. In addition, several of the bills would give the Department of Health and Human Services (HHS) considerable latitude in designing and implementing policies. Budgetary effects could differ from those provided in CBO's analyses depending on those decisions.

Direct Spending and Revenues

Table 1 lists the 22 bills of the 59 ordered to be reported that would affect direct spending or revenues.

TABLE 1.—ESTIMATED CHANGES IN MANDATORY SPENDING AND REVENUES

	By fiscal year, in millions of dollars—										2019–2023
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	
INCREASES OR DECREASES (—) IN DIRECT SPENDING											
Legislation Primarily Affecting Medicaid:											
H.R. 1925, At-Risk Youth Medicaid Protection Act of 2017	0	*	5	5	5	10	10	10	10	10	25
H.R. 4998, Health Insurance for Former Foster Youth Act	0	0	0	0	*	10	21	33	46	61	*
H.R. 5477, Rural Development of Opioid Capacity Services Act	0	13	35	58	68	83	27	9	3	3	301
H.R. 5583, a bill to amend title XI of the Social Security Act to require States to annually report on certain adult health quality measures, and for other purposes	0	*	*	*	*	*	*	*	*	*	*
H.R. 5797, IMD CARE Act	0	38	158	251	265	279	0	0	0	0	991
H.R. 5799, Medicaid DRUG Improvement Act. ^a	0	*	*	1	1	1	1	1	1	1	5
H.R. 5801, Medicaid Providers Are Required To Note Experiences in Record Systems to Help In-Need Patients (PARTNERSHIP) Act. ^a	0	*	*	*	*	*	*	*	*	*	*
H.R. 5808, Medicaid Pharmaceutical Home Act of 2018. ^a	0	*	-1	-1	-1	-1	-2	-2	-2	-2	-13
H.R. 5810, Medicaid Health HOME Act	0	94	58	62	56	52	48	43	38	32	323
Legislation Primarily Affecting Medicare:											
H.R. 3528, Every Prescription Conveyed Securely Act	0	0	0	-24	-35	-33	-30	-33	-32	-31	-92
H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018	0	0	*	*	*	*	*	*	*	*	*
H.R. 5603, Access to Telehealth Services for Opioid Use Disorders Act	0	2	*	*	*	1	1	1	2	2	3
H.R. 5605, Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act	0	0	0	15	26	24	23	23	10	1	*
H.R. 5675, a bill to amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries	0	0	0	-6	-7	-7	-7	-8	-9	-9	-11
H.R. 5684, Protecting Seniors From Opioid Abuse Act	0	0	*	*	*	*	*	*	*	*	*
H.R. 5796, Responsible Education Achieves Care and Healthy Outcomes for Users Treatment Act of 2018	0	10	25	50	10	5	0	0	0	0	100
H.R. 5798, Opioid Screening and Chronic Pain Management Alternatives for Seniors Act	0	0	*	1	1	1	1	1	1	1	2
H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act. ^a	0	0	25	30	25	20	10	5	0	0	115
H.R. 5809, Postoperative Opioid Prevention Act of 2018	0	0	0	10	15	25	30	35	45	25	180
Legislation Primarily Affecting the Food and Drug Administration:											

∞

		INCREASES OR DECREASES (-) IN REVENUES ^b			
H.R. 5333, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018 ^a	0	0	*	*	*
H.R. 5752, Stop Illicit Drug Importation Act of 2018	0	*	*	*	*

Legislation Primarily Affecting Medicaid. The following nine bills would affect direct spending for the Medicaid program.

H.R. 1925, the At-Risk Youth Medicaid Protection Act of 2017, would require states to suspend, rather than terminate, Medicaid eligibility for juvenile enrollees (generally under 21 years of age) who become inmates of public correctional institutions. States also would have to redetermine those enrollees' Medicaid eligibility before their release and restore their coverage upon release if they qualify for the program. States would be required to process Medicaid applications submitted by or on behalf of juveniles in public correctional institutions who were not enrolled in Medicaid before becoming inmates and ensure that Medicaid coverage is provided when they are released if they are found to be eligible. On the basis of an analysis of juvenile incarceration trends and of the per enrollee spending for Medicaid foster care children, who have a similar health profile to incarcerated juveniles, CBO estimates that implementing the bill would cost \$75 million over the 2019–2028 period.

H.R. 4998, the Health Insurance for Former Foster Youth Act, would require states to provide Medicaid coverage to adults up to age 25 who had aged out of foster care in any state. Under current law, such coverage is mandatory only if the former foster care youth has aged out in the state in which the individual applies for coverage. The policy also would apply to former foster children who had been in foster care upon turning 14 years of age but subsequently left foster care to enter into a legal guardianship with a kinship caregiver. The provisions would take effect respect for foster youth who turn 18 on or after January 1, 2023. On the basis of spending for Medicaid foster care children and data from the Census Bureau regarding annual migration rates between states, CBO estimates that implementing the bill would cost \$171 million over the 2019–2028 period.

H.R. 5477, the Rural Development of Opioid Capacity Services Act, would direct the Secretary of HHS to conduct a five-year demonstration to increase the number and ability of providers participating in Medicaid to provide treatment for substance use disorders. On the basis of an analysis of federal and state spending for treatment of substance use disorders and the prevalence of such disorders, CBO estimates that enacting the bill would increase direct spending by \$301 million over the 2019–2028 period.

H.R. 5583, a bill to amend title XI of the Social Security Act to require States to annually report on certain adult health quality measures, and for other purposes, would require states to include behavioral health indicators in their annual reports on the quality of care under Medicaid. Although the bill would add a requirement for states, CBO estimates that its enactment would not have a significant budgetary effect because most states have systems in place for reporting such measures to the federal government.

H.R. 5797, the IMD CARE Act, would expand Medicaid coverage for people with opioid use disorder who are in institutions for mental disease (IMDs) for up to 30 days per year. Under a current-law policy known as the IMD exclusion, the federal government generally does not make matching payments to state Medicaid programs for most services provided by IMDs to adults between the ages of 21 and 64. Recent administrative changes have made fed-

eral financing for IMDs available in limited circumstances, but the statutory prohibition remains in place. CBO analyzed several data sets, primarily those collected by the Substance Abuse and Mental Health Services Administration (SAMHSA), to estimate current federal spending under Medicaid for IMD services and to estimate spending under H.R. 5797. Using that analysis, CBO estimates that enacting H.R. 5797 would increase direct spending by \$991 million over the 2019–2028 period.

H.R. 5799, the Medicaid DRUG Improvement Act, would require state Medicaid programs to implement additional reviews of opioid prescriptions, monitor concurrent prescribing of opioids and certain other drugs, and monitor use of antipsychotic drugs by children. CBO estimates that the bill would increase direct spending by \$5 million over the 2019–2028 period to cover the administrative costs of complying with those requirements. On the basis of stakeholder feedback, CBO expects that the bill would not have a significant effect on Medicaid spending for prescription drugs because many of the bill's requirements would duplicate current efforts to curb opioid and antipsychotic drug use. (If enacted, H.R. 5799 also would affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5801, the Medicaid Providers Are Required To Note Experiences in Record Systems to Help In-Need Patients (PARTNERSHIP) Act, would require providers who are permitted to prescribe controlled substances and who participate in Medicaid to query prescription drug monitoring programs (PDMPs) before prescribing controlled substances to Medicaid patients. PDMPs are statewide electronic databases that collect data on controlled substances dispensed in the state. The bill also would require PDMPs to comply with certain data and system criteria, and it would provide additional federal matching funds to certain states to help cover administrative costs. On the basis of a literature review and stakeholder feedback, CBO estimates that the net budgetary effect of enacting H.R. 5801 would be insignificant. Costs for states to come into compliance with the systems and administrative requirements would be roughly offset by savings from small reductions in the number of controlled substances paid for by Medicaid under the proposal. (If enacted, H.R. 5801 also would affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5808, the Medicaid Pharmaceutical Home Act of 2018, would require state Medicaid programs to operate pharmacy programs that would identify people at high risk of abusing controlled substances and require those patients to use a limited number of providers and pharmacies. Although nearly all state Medicaid programs currently meet such a requirement, a small number of high-risk Medicaid beneficiaries are not now monitored. Based on an analysis of information about similar state and federal programs, CBO estimates that net Medicaid spending under the bill would decrease by \$13 million over the 2019–2028 period. That amount represents a small increase in administrative costs and a small reduction in the number of controlled substances paid for by Medicaid under the proposal. (If enacted, H.R. 5808 also would affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5810, the Medicaid Health HOME Act, would allow states to receive six months of enhanced federal Medicaid funding for programs that coordinate care for people with substance use disorders. Based on enrollment and spending data from states that currently participate in Medicaid's Health Homes program, CBO estimates that the expansion would cost approximately \$469 million over the 2019–2028 period. The bill also would require states to cover all FDA-approved drugs used in medication-assisted treatment for five years, although states could seek a waiver from that requirement. (Medication-assisted treatment combines behavioral therapy and pharmaceutical treatment for substance use disorders.) Under current law, states already cover most FDA-approved drugs used in such programs in some capacity, although a few exclude methadone dispensed by opioid treatment programs. CBO estimates that a small share of those states would begin to cover methadone if this bill was enacted at a federal cost of about \$39 million over the 2019–2028 period. In sum, CBO estimates that the enacting H.R. 5810 would increase direct spending by \$509 million over the 2019–2028 period.

Legislation Primarily Affecting Medicare. The following ten bills would affect direct spending for the Medicare program.

H.R. 3528, the Every Prescription Conveyed Securely Act, would require prescriptions for controlled substances covered under Medicare Part D to be transmitted electronically, starting on January 1, 2021. Based on CBO's analysis of prescription drug spending, spending for controlled substances is a small share of total drug spending. CBO also assumes a small share of those prescriptions would not be filled because they are not converted to an electronic format. Therefore, CBO expects that enacting H.R. 3528 would reduce the number of prescriptions filled and estimates that Medicare spending would be reduced by \$250 million over the 2019–2028 period.

H.R. 4841, the Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018, would require health care professionals to submit prior authorization requests electronically, starting on January 1, 2021, for drugs covered under Medicare Part D. Taking into account that many prescribers already use electronic methods to submit such requests, CBO estimates that enacting H.R. 4841 would not significantly affect direct spending for Part D.

H.R. 5603, the Access to Telehealth Services for Opioid Use Disorders Act, would permit the Secretary of HHS to lift current geographic and other restrictions on coverage of telehealth services under Medicare for treatment of substance use disorders or co-occurring mental health disorders. Under the bill, the Secretary of HHS would be directed to encourage other payers to coordinate payments for opioid use disorder treatments and to evaluate the extent to which the demonstration reduces hospitalizations, increases the use of medication-assisted treatments, and improves the health outcomes of individuals with opioid use disorders during and after the demonstration. Based on current use of Medicare telehealth services for treatment of substance use disorders, CBO estimates that expanding that coverage would increase direct spending by \$11 million over the 2019–2028 period.

H.R. 5605, the Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act, would establish a five-year demonstra-

tion program to increase access to treatment for opioid use disorder. The demonstration would provide incentive payments and funding for care management services based on criteria such as patient engagement, use of evidence-based treatments, and treatment length and intensity. Under the bill, the Secretary of HHS would be directed to encourage other payers to coordinate payments for opioid use disorder treatments and to evaluate the extent to which the demonstration reduces hospitalizations, increases the use of medication-assisted treatments, and improves the health outcomes of individuals with opioid use disorders during and after the demonstration. Based on historical utilization of opioid use disorder treatments and projected spending on incentive payments and care management fees, CBO estimates that increased use of treatment services and the demonstration's incentive payments would increase direct spending by \$122 million over the 2019–2028 period.

H.R. 5675, a bill to amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries, would require Part D prescription drug plans to provide drug management programs for Medicare beneficiaries who are at risk for prescription drug abuse. (Under current law, Part D plans are permitted but not required to establish such programs as of 2019.) Based on an analysis of the number of plans currently providing those programs, CBO estimates that enacting H.R. 5675 would lower federal spending by \$64 million over the 2019–2028 period by reducing the number of prescriptions filled and Medicare's payments for controlled substances.

H.R. 5684, the Protecting Seniors From Opioid Abuse Act, would expand medication therapy management programs under Medicare Part D to include beneficiaries who are at risk for prescription drug abuse. Because relatively few beneficiaries would be affected by this bill, CBO estimates that its enactment would not significantly affect direct spending for Part D.

H.R. 5796, the Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment Act of 2018, would allow the Secretary of HHS to award grants to certain organizations that provide technical assistance and education to high-volume prescribers of opioids. The bill would appropriate \$100 million for fiscal year 2019. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5796 would cost \$100 million over the 2019–2028 period.

H.R. 5798, the Opioid Screening and Chronic Pain Management Alternatives for Seniors Act, would add an assessment of current opioid prescriptions and screening for opioid use disorder to the Welcome to Medicare Initial Preventive Physical Examination. Based on historical use of the examinations and pain management alternatives, CBO expects that enacting the bill would increase use of pain management services and estimates that direct spending would increase by \$5 million over the 2019–2028 period.

H.R. 5804, the Post-Surgical Injections as an Opioid Alternative Act, would freeze the Medicare payment rate for certain analgesic injections provided in ambulatory surgical centers (ASCs). (For injections identified by specific billing codes, Medicare would pay the 2016 rate, which is higher than the current rate, during the 2020–2024 period.) Based on current utilization in the ASC setting, CBO

estimates that enacting the legislation would increase direct spending by about \$115 million over the 2019–2028 period. (If enacted, H.R. 5804 also would affect spending subject to appropriation; see Table 3.)

H.R. 5809, the Postoperative Opioid Prevention Act of 2018, would create an additional payment under Medicare for nonopioid analgesics. Under current law, certain new drugs and devices may receive an additional payment—separate from the bundled payment for a surgical procedure—in outpatient hospital departments and ambulatory surgical centers. The bill would allow nonopioid analgesics to qualify for a five-year period of additional payments. Based on its assessment of current spending for analgesics and on the probability of new nonopioid analgesics coming to market, CBO estimates that H.R. 5809 would increase direct spending by about \$180 million over the 2019–2028 period.

Legislation Primarily Affecting the Food and Drug Administration. One bill related to the FDA would affect direct spending.

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, would change the way that the FDA regulates the marketing of over-the-counter (OTC) medicines, and it would authorize that agency to grant 18 months of exclusive market protection for certain qualifying OTC drugs, thus delaying the entry of other versions of the same qualifying OTC product. Medicaid currently provides some coverage for OTC medicines, but only if a medicine is the least costly alternative in its drug class. On the basis of stakeholder feedback, CBO expects that delaying the availability of additional OTC versions of a drug would not significantly affect the average net price paid by Medicaid. As a result, CBO estimates that enacting H.R. 5333 would have a negligible effect on the federal budget. (If enacted, H.R. 5333 also would affect spending subject to appropriation; see Table 3.)

Legislation with Revenue Effects. Two bills would affect revenues. However, CBO estimates that one bill, H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, would have only a negligible effect.

H.R. 5752, the Stop Illicit Drug Importation Act of 2018, would amend the Federal, Food, Drug, and Cosmetic Act (FDCA) to strengthen the FDA's seizure powers and enhance its authority to detain, refuse, seize, or destroy illegal products offered for import. The legislation would subject more people to debarment under the FDCA and thus increase the potential for violations, and subsequently, the assessment of civil penalties, which are recorded in the budget as revenues. CBO estimates that those collections would result in an insignificant increase in revenues. Because H.R. 5752 would prohibit the importation of drugs that are in the process of being scheduled, it also could reduce amounts collected in customs duties. CBO anticipates that the result would be a negligible decrease in revenues. With those results taken together, CBO estimates, enacting H.R. 5752 would generate an insignificant net increase in revenues over the 2019–2028 period.

Spending subject to appropriation

For this document, CBO has grouped bills with spending that would be subject to appropriation into four general categories:

- Bills that would have no budgetary effect,

- Bills with provisions that would authorize specified amounts to be appropriated (see Table 2),
- Bills with provisions for which CBO has estimated an authorization of appropriations (see Table 3), and
- Bills with provisions that would affect spending subject to appropriation for which CBO has not yet completed an estimate.

No Budgetary Effect. CBO estimates that 6 of the 59 bills would have no effect on direct spending, revenues, or spending subject to appropriation.

H.R. 3192, the CHIP Mental Health Parity Act, would require all Children's Health Insurance Program (CHIP) plans to cover mental health and substance abuse treatment. In addition, states would not be allowed to impose financial or utilization limits on mental health treatment that are lower than limits placed on physical health treatment. Based on information from the Centers for Medicare and Medicaid Services, CBO estimates that enacting the bill would have no budgetary effect because all CHIP enrollees are already in plans that meet those requirements.

H.R. 3331, a bill to amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology, would give the Center for Medicare and Medicaid Innovation (CMMI) explicit authorization to test a program offering incentive payments to behavioral health providers that adopt and use certified electronic health record technology. Because it is already clear to CMMI that it has that authority, CBO estimates that enacting the legislation would not affect federal spending.

H.R. 5202, the Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018, would clarify permission for pharmacists to deliver controlled substances to providers under certain circumstances. Because this provision would codify current practice, CBO estimates that H.R. 5202 would not affect direct spending or revenues during the 2019–2028 period.

H.R. 5685, the Medicare Opioid Safety Education Act of 2018, would require the Secretary of HHS to include information on opioid use, pain management, and nonopioid pain management treatments in future editions of Medicare & You, the program's handbook for beneficiaries, starting on January 1, 2019. Because H.R. 5685 would add information to an existing administrative document, CBO estimates that enacting the bill would have no budgetary effect.

H.R. 5686, the Medicare Clear Health Options in Care for Enrollees Act of 2018, would require prescription drug plans that provide coverage under Medicare Part D to furnish information to beneficiaries about the risks of opioid use and the availability of alternative treatments for pain. CBO estimates that enacting the bill would not affect direct spending because the required activities would not impose significant administrative costs.

H.R. 5716, the Commit to Opioid Medical Prescriber Accountability and Safety for Seniors Act, would require the Secretary of HHS on an annual basis to identify high prescribers of opioids and furnish them with information about proper prescribing methods. Because HHS already has the capacity to meet those requirements,

CBO estimates that enacting that provision would not impose additional administrative costs on the agency.

Specified Authorizations. Table 2 lists the ten bills that would authorize specified amounts to be appropriated over the 2019–2023 period. Spending from those authorized amounts would be subject to appropriation.

TABLE 2.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH SPECIFIED AUTHORIZATIONS

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
H.R. 4684, Ensuring Access to Quality Sober Living Act:							
Authorization Level	0	3	0	0	0	0	3
Estimated Outlays	0	1	2	*	*	*	3
H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act of 2018:							
Authorization Level	0	25	25	25	25	25	125
Estimated Outlays	0	9	19	23	25	25	100
H.R. 5176, Preventing Overdoses While in Emergency Rooms Act of 2018:							
Authorization Level	0	50	0	0	0	0	50
Estimated Outlays	0	16	26	6	2	1	50
H.R. 5197, Alternatives to Opioids (ALTO) in the Emergency Department Act:							
Authorization Level	0	10	10	10	0	0	30
Estimated Outlays	0	3	8	10	7	2	30
H.R. 5261, Treatment, Education, and Community Help to Combat Addiction Act of 2018:							
Authorization Level	0	4	4	4	4	4	20
Estimated Outlays	0	1	3	4	4	4	16
H.R. 5327, Comprehensive Opioid Recovery Centers Act of 2018:							
Authorization Level	0	10	10	10	10	10	50
Estimated Outlays	0	3	8	10	10	10	41
H.R. 5329, Poison Center Network Enhancement Act of 2018:							
Authorization Level	0	30	30	30	30	30	151
Estimated Outlays	0	12	25	29	29	29	125
H.R. 5353, Eliminating Opioid-Related Infectious Diseases Act of 2018:							
Authorization Level	0	40	40	40	40	40	200
Estimated Outlays	0	15	34	38	39	40	166
H.R. 5580, Surveillance and Testing of Opioids to Prevent Fentanyl Deaths Act of 2018:							
Authorization Level	30	30	30	30	30	0	120
Estimated Outlays	0	11	25	29	29	19	113
H.R. 5587, Peer Support Communities of Recovery Act:							
Authorization Level	0	15	15	15	15	15	75
Estimated Outlays	0	5	13	14	15	15	62

Annual amounts may not sum to totals because of rounding. * = between zero and \$500,000.

H.R. 4684, the Ensuring Access to Quality Sober Living Act, would direct the Secretary of HHS to develop and disseminate best practices for organizations that operate housing designed for people recovering from substance use disorders. The bill would authorize a total of \$3 million over the 2019–2021 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 4684 would cost \$3 million over the 2019–2023 period.

H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act of 2018, would establish a loan repayment program for mental health professionals who practice in areas with few mental health providers or with high rates of death from overdose and would authorize \$25 million per year over the 2019–2028 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5102 would cost \$100 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5176, the Preventing Overdoses While in Emergency Rooms Act of 2018, would require the Secretary of HHS to develop protocols and a grant program for health care providers to address the needs of people who survive a drug overdose, and it would authorize \$50 million in 2019 for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5176 would cost \$50 million over the 2019–2023 period.

H.R. 5197, the Alternatives to Opioids (ALTO) in the Emergency Department Act, would direct the Secretary of HHS to carry out a demonstration program for hospitals and emergency departments to develop alternative protocols for pain management that limit the use of opioids and would authorize \$10 million annually in grants for fiscal years 2019 through 2021. Based on historical spending patterns for similar programs, CBO estimates that implementing H.R. 5197 would cost \$30 million over the 2019–2023 period.

H.R. 5261, the Treatment, Education, and Community Help to Combat Addiction Act of 2018, would direct the Secretary of HHS to designate regional centers of excellence to improve the training of health professionals who treat substance use disorders. The bill would authorize \$4 million annually for grants to those programs over the 2019–2023 period. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5261 would cost \$16 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5327, the Comprehensive Opioid Recovery Centers Act of 2018, would direct the Secretary of HHS to award grants to at least 10 providers that offer treatment services for people with opioid use disorder, and it would authorize \$10 million per year over the 2019–2023 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5327 would cost \$41 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5329, the Poison Center Network Enhancement Act of 2018, would reauthorize the poison control center toll-free number, national media campaign, and grant program under the Public Health Service Act. Among other actions, H.R. 5329 would increase the share of poison control center funding that could be provided by federal grants. The bill would authorize a total of about \$30 million per year over the 2019–2023 period. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5329 would cost \$125 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5353, the Eliminating Opioid Related Infectious Diseases Act of 2018, would amend the Public Health Service Act by broadening the focus of surveillance and education programs from pre-

venting and treating hepatitis C virus to preventing and treating infections associated with injection drug use. It would authorize \$40 million per year over the 2019–2023 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5353 would cost \$166 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5580, the Surveillance and Testing of Opioids to Prevent Fentanyl Deaths Act of 2018, would establish a grant program for public health laboratories that conduct testing for fentanyl and other synthetic opioids. It also would direct the Centers for Disease Control and Prevention to expand its drug surveillance program, with a particular focus on collecting data on fentanyl. The bill would authorize a total of \$30 million per year over the 2018–2022 period for those activities. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5580 would cost \$113 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5587, Peer Support Communities of Recovery Act, would direct the Secretary of HHS to award grants to nonprofit organizations that support community-based, peer-delivered support, including technical support for the establishment of recovery community organizations, independent, nonprofit groups led by people in recovery and their families. The bill would authorize \$15 million per year for the 2019–2023 period. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5587 would cost \$62 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

Estimated Authorizations. Table 3 shows CBO’s estimates of the appropriations that would be necessary to implement 19 of the bills. Spending would be subject to appropriation of those amounts.

H.R. 449, the Synthetic Drug Awareness Act of 2018, would require the Surgeon General to report to the Congress on the health effects of synthetic psychoactive drugs on children between the ages of 12 and 18. Based on spending patterns for similar activities, CBO estimates that implementing H.R. 449 would cost approximately \$1 million over the 2019–2023 period.

H.R. 4005, the Medicaid Reentry Act, would direct the Secretary of HHS to convene a group of stakeholders to develop and report to the Congress on best practices for addressing issues related to health care faced by those returning from incarceration to their communities. The bill also would require the Secretary to issue a letter to state Medicaid directors about relevant demonstration projects. Based on an analysis of anticipated workload, CBO estimates that implementing H.R. 4005 would cost less than \$500,000 over the 2018–2023 period.

H.R. 4275, the Empowering Pharmacists in the Fight Against Opioid Abuse Act, would require the Secretary of HHS to develop and disseminate materials for training pharmacists, health care practitioners, and the public about the circumstances under which a pharmacist may decline to fill a prescription. Based on historical spending patterns for similar activities, CBO estimates that costs to the federal government for the development and distribution of those materials would not be significant.

TABLE 3.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH ESTIMATED AUTHORIZATIONS

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
H.R. 449, Synthetic Drug Awareness Act of 2018:							
Estimated Authorization Level	0	*	*	*	0	0	1
Estimated Outlays	0	*	*	*	0	0	1
H.R. 4005, Medicaid Reentry Act:							
Estimated Authorization Level	*	*	0	0	0	0	*
Estimated Outlays	*	*	0	0	0	0	*
H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5009, Jessie's Law:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5041, Safe Disposal of Unused Medication Act:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018:							
Estimated Authorization Level	0	1	1	1	1	1	4
Estimated Outlays	0	1	1	1	1	1	4
H.R. 5333, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018: ^a							
Food and Drug Administration:							
Collections from fees:							
Estimated Authorization Level	0	-22	-22	-26	-35	-42	-147
Estimated Outlays	0	-22	-22	-26	-35	-42	-147
Spending of fees:							
Estimated Authorization Level	0	22	22	26	35	42	147
Estimated Outlays	0	6	17	30	44	41	137
Net effect on FDA:							
Estimated Authorization Level	0	0	0	0	0	0	0
Estimated Outlays	0	-17	-6	4	9	*	-10
Government Accountability Office:							
Estimated Authorization Level	0	0	0	0	0	*	*
Estimated Outlays	0	0	0	0	0	*	*
Total, H.R. 5333:							
Estimated Authorization Level	0	0	0	0	0	*	*
Estimated Outlays	0	-17	-6	4	9	*	-10
H.R. 5473, Better Pain Management Through Better Data Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	0	1
Estimated Outlays	0	*	*	*	*	*	1
H.R. 5483, Special Registration for Telemedicine Clarification Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5554, Animal Drug and Animal Generic Drug User Fee Amendments of 2018:							
Collections from fees:							
Animal drug fees	0	-30	-31	-32	-33	-34	-159
Generic animal drug fees	0	-18	-19	-19	-20	-21	-97
Total, Estimated Authorization Level	0	-49	-50	-51	-53	-55	-257
Total, Estimated Outlays	0	-49	-50	-51	-53	-55	-257
Spending of fees:							
Animal drug fees	0	30	31	32	33	34	159
Generic animal drug fees	0	18	19	19	20	21	97
Total, Estimated Authorization Level	0	49	50	51	53	55	257
Total, Estimated Outlays	0	39	47	51	52	54	243

TABLE 3.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH ESTIMATED AUTHORIZATIONS—Continued

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
Net changes in fees:							
Estimated Authorization Level	0	0	0	0	0	0	0
Estimated Outlays	0	-10	-3	*	*	*	-14
Other effects:							
Estimated Authorization Level	0	3	1	1	1	1	6
Estimated Outlays	0	2	1	1	1	1	6
Total, H.R. 5554:							
Estimated Authorization Level	0	3	1	1	1	1	6
Estimated Outlays	0	-8	-2	1	*	*	-8
H.R. 5582, Abuse Deterrent Access Act of 2018:							
Estimated Authorization Level	0	0	*	0	0	0	*
Estimated Outlays	0	0	*	0	0	0	*
H.R. 5590, Opioid Addiction Action Plan Act:							
Estimated Authorization Level	*	*	*	*	*	*	2
Estimated Outlays	*	*	*	*	*	*	2
H.R. 5687, Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5715, Strengthening Partnerships to Prevent Opioid Abuse Act:							
Estimated Authorization Level	0	2	2	2	2	2	9
Estimated Outlays	0	2	2	2	2	2	9
H.R. 5789, a bill to require the Secretary of Health and Human Services to issue guidance to improve care for infants with neonatal abstinence syndrome and their mothers, and to require the Comptroller General of the United States to conduct a study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder:							
Estimated Authorization Level	0	2	0	0	0	0	2
Estimated Outlays	0	2	0	0	0	0	2
H.R. 5795, Overdose Prevention and Patient Safety Act:							
Estimated Authorization Level	0	1	0	0	0	0	1
Estimated Outlays	0	1	0	0	0	0	1
H.R. 5800, Medicaid IMD ADDITIONAL INFO Act:							
Estimated Authorization Level	0	1	0	0	0	0	1
Estimated Outlays	0	*	*	0	0	0	1
H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act: ^a							
Estimated Authorization Level	0	0	0	0	1	1	1
Estimated Outlays	0	0	0	0	1	1	1
H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*

Annual amounts may not sum to totals because of rounding. * = between -\$500,000 and \$500,000.

^aThis bill also would affect mandatory spending (see Table 1).

H.R. 5009, Jessie's Law, would require HHS, in collaboration with outside experts, to develop best practices for displaying information about opioid use disorder in a patient's medical record. HHS also would be required to develop and disseminate written materials annually to health care providers about what disclosures could be made while still complying with federal laws that govern health care privacy. Based on spending patterns for similar activities, CBO estimates that implementing H.R. 5009 would have an insignificant effect on spending over the 2019–2023 period.

H.R. 5041, the Safe Disposal of Unused Medication Act, would require hospice programs to have written policies and procedures for the disposal of controlled substances after a patient's death. Certain licensed employees of hospice programs would be permitted to assist in the disposal of controlled substances that were lawfully dispensed. Using information from the Department of Justice (DOJ), CBO estimates that implementing the bill would cost less than \$500,000 over the 2019–2023 period.

H.R. 5272, the Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018, would require the newly established National Mental Health and Substance Use Policy Laboratory to issue guidance to applicants for SAMHSA grants that support evidence-based practices. Using information from HHS about the historical cost of similar activities, CBO estimates that enacting this bill would cost approximately \$4 million over the 2019–2023 period.

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, would change the FDA's oversight of the commercial marketing of OTC medicines and authorize the collection and spending of fees through 2023 to cover the costs of expediting the FDA's administrative procedures for certain regulatory activities relating to OTC products. Under H.R. 5333, CBO estimates, the FDA would assess about \$147 million in fees over the 2019–2023 period that could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. Because the FDA could spend those fees, CBO estimates that the estimated budget authority for collections and spending would offset each other exactly in each year, although CBO expects that spending initially would lag behind collections. Assuming appropriation action consistent with the bill, CBO estimates that implementing H.R. 5333 would reduce net discretionary outlays by \$10 million over the 2019–2023 period, primarily because of that lag. The bill also would require the Government Accountability Office to study exclusive market protections for certain qualifying OTC drugs authorized by the bill—a provision that CBO estimates would cost less than \$500,000. (If enacted, H.R. 5333 also would affect mandatory spending; see Table 1.)

H.R. 5473, the Better Pain Management Through Better Data Act of 2018, would require that the FDA conduct a public meeting and issue guidance to industry addressing data collection and labeling for medical products that reduce pain while enabling the reduction, replacement, or avoidance of oral opioids. Using information from the agency, CBO estimates that implementing H.R. 5473 would cost about \$1 million over the 2019–2023 period.

H.R. 5483, the Special Registration for Telemedicine Clarification Act of 2018, would direct DOJ, within one year of the bill's enactment, to issue regulations concerning the practice of telemedicine (for remote diagnosis and treatment of patients). Using information from DOJ, CBO estimates that implementing the bill would cost less than \$500,000 over the 2019–2023 period.

H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, would authorize the FDA to collect and spend fees to cover the cost of expedited approval for the development and marketing of certain drugs for use in animals. The legislation would extend through fiscal year 2023, and make several changes

to, the FDA's existing approval processes and fee programs for brand-name and generic veterinary drugs, which expire at the end of fiscal year 2018. CBO estimates that implementing H.R. 5554 would reduce net discretionary outlays by \$8 million over the 2019–2023 period, primarily because the spending of fees lags somewhat behind their collection.

Fees authorized under the bill would supplement funds appropriated to cover the FDA's cost of reviewing certain applications and investigational submissions for brand-name and generic drugs for use in animals. Those fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. Under H.R. 5554, CBO estimates, the FDA would assess about \$257 million in fees over the 2019–2023 period. Because the FDA could spend those funds, CBO estimates that budget authority for collections and spending would offset each other exactly in each year. CBO estimates that the delay between collecting and spending fees under the reauthorized programs would reduce net discretionary outlays by \$14 million over the 2019–2023 period, assuming appropriation actions consistent with the bill.

Enacting H.R. 5554 would increase the FDA's workload because the legislation would expand eligibility for conditional approval for certain drugs. The agency's administrative costs also would increase because of regulatory activities required by a provision concerning petitions for additives intended for use in animal food. H.R. 5554 also would require the FDA to publish guidance or produce regulations on a range of topics, transmit a report to the Congress, and hold public meetings. CBO expects that the costs associated with those activities would not be covered by fees, and it estimates that implementing such provisions would cost \$6 million over the 2019–2023 period.

H.R. 5582, the Abuse Deterrent Access Act of 2018, would require the Secretary of HHS to report to the Congress on existing barriers to access to “abuse-deterrent opioid formulations” by Medicare Part C and D beneficiaries. Such formulations make the drugs more difficult to dissolve for injection, for example, and thus can impede their abuse. Assuming the availability of appropriated funds and based on historical spending patterns for similar activities, CBO estimates that implementing the legislation would cost less than \$500,000 over the 2019–2023 period.

H.R. 5590, the Opioid Addiction Action Plan Act, would require the Secretary of HHS to develop an action plan by January 1, 2019, for increasing access to medication-assisted treatment among Medicare and Medicaid enrollees. The bill also would require HHS to convene a stakeholder meeting and issue a request for information within three months of enactment, and to submit a report to the Congress by June 1, 2019. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5590 would cost approximately \$2 million over the 2019–2023 period.

H.R. 5687, the Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018, would permit the FDA to require certain packaging and disposal technologies, controls, or measures to mitigate the risk of abuse and misuse of drugs. Based on information from the FDA, CBO estimates that implementing H.R. 5687 would not significantly affect spending over the 2019–

2023 period. This bill would also require that the GAO study the effectiveness and use of packaging technologies for controlled substances—a provision that CBO estimates would cost less than \$500,000.

H.R. 5715, the Strengthening Partnerships to Prevent Opioid Abuse Act, would require the Secretary of HHS to establish a secure Internet portal to allow HHS, Medicare Advantage plans, and Medicare Part D plans to exchange information about fraud, waste, and abuse among providers and suppliers no later than two years after enactment. H.R. 5715 also would require organizations with Medicare Advantage contracts to submit information on investigations related to providers suspected of prescribing large volumes of opioids through a process established by the Secretary no later than January 2021. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5715 would cost approximately \$9 million over the 2019–2023 period.

H.R. 5789, a bill to require the Secretary of Health and Human Services to issue guidance to improve care for infants with neonatal abstinence syndrome and their mothers, and to require the Comptroller General of the United States to conduct a study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder, would direct the Secretary of HHS to issue guidance to states on best practices under Medicaid and CHIP for treating infants with neonatal abstinence syndrome. H.R. 5789 also would direct the Government Accountability Office to study Medicaid coverage for pregnant and postpartum women with substance use disorders. Based on information from HHS and historical spending patterns for similar activities, CBO estimates that enacting H.R. 5789 would cost approximately \$2 million over the 2019–2023 period.

H.R. 5795, the Overdose Prevention and Patient Safety Act, would amend the Public Health Service Act so that requirements pertaining to the confidentiality and disclosure of medical records relating to substance use disorders align with the provisions of the Health Insurance Portability and Accountability Act of 1996. The bill would require the Office of the Secretary of HHS to issue regulations prohibiting discrimination based on data disclosed from such medical records, to issue regulations requiring covered entities to provide written notice of privacy practices, and to develop model training programs and materials for health care providers and patients and their families. Based on spending patterns for similar activities, CBO estimates that implementing H.R. 5795 would cost approximately \$1 million over the 2019–2023 period.

H.R. 5800, Medicaid IMD ADDITIONAL INFO Act, would direct the Medicaid and CHIP Payment and Access Commission to study institutions for mental diseases in a representative sample of states. Based on information from the commission about the cost of similar work, CBO estimates that implementing H.R. 5800 would cost about \$1 million over the 2019–2023 period.

H.R. 5804, the Post-Surgical Injections as an Opioid Alternative Act, would freeze the Medicare payment rate for certain analgesic injections provided in ambulatory surgical centers. The bill also would mandate two studies of Medicare coding and payments arising from enactment of this legislation. Based on the cost of similar activities, CBO estimates that those reports would cost \$1 million

over the 2019–2023 period. (If enacted, H.R. 5804 also would affect mandatory spending; see Table 1.)

H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes, would allow the FDA to require that pharmaceutical manufacturers study certain drugs after they are approved to assess any potential reduction in those drugs' effectiveness for the conditions of use prescribed, recommended, or suggested in labeling. CBO anticipates that implementing H.R. 5811 would not significantly affect the FDA's costs over the 2019–2023 period.

Other Authorizations. The following nine bills would increase authorization levels, but CBO has not completed estimates of amounts. All authorizations would be subject to future appropriation action.

- H.R. 4284, Indexing Narcotics, Fentanyl, and Opioids Act of 2017
- H.R. 5002, Advancing Cutting Edge Research Act
- H.R. 5228, Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act (see Table 1 for an estimate of the revenue effects of H.R. 5228)
- H.R. 5752, Stop Illicit Drug Importation Act of 2018 (see Table 1 for an estimate of the revenue effects of H.R. 5752)
- H.R. 5799, Medicaid DRUG Improvement Act (see Table 1 for an estimate of the direct spending effects of H.R. 5799)
- H.R. 5801, Medicaid Providers and Pharmacists Are Required to Note Experiences in Record Systems to Help In-Need Patients (PARTNERSHIP) Act (see Table 1 for an estimate of the direct spending effects of H.R. 5801)
- H.R. 5806, 21st Century Tools for Pain and Addiction Treatments Act
- H.R. 5808, Medicaid Pharmaceutical Home Act of 2018 (see Table 1 for an estimate of the direct spending effects of H.R. 5808)
- H.R. 5812, Creating Opportunities that Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies Act (CONNECTIONS) Act

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. Twenty-two of the bills discussed in this document contain direct spending or revenues and are subject to pay-as-you-go procedures. Details about the amount of direct spending and revenues in those bills can be found in Table 1.

Increase in long-term direct spending and deficits: CBO estimates that enacting H.R. 4998, the Health Insurance for Former Foster Youth Act, would increase net direct spending by more than \$2.5 billion and on-budget deficits by more than \$5 billion in at least one of the four consecutive 10-year periods beginning in 2029.

CBO estimates that none of the remaining 58 bills included in this estimate would increase net direct spending by more than \$2.5 billion or on-budget deficits by more than \$5 billion in any of the four consecutive 10-year periods beginning in 2029.

Mandates: One of the 59 bills included in this document, H.R. 5795, would impose both intergovernmental and private-sector

mandates as defined in UMRA. CBO estimates that the costs of that bill's mandates on public and private entities would fall below UMRA's thresholds (\$80 million and \$160 million, respectively, for public- and private-sector entities in 2018, adjusted annually for inflation).

In addition, five bills would impose private-sector mandates as defined in UMRA. CBO estimates that the costs of the mandates in three of those bills (H.R. 5333, H.R. 5554, and H.R. 5811) would fall below the UMRA threshold. Because CBO does not know how federal agencies would implement new authority granted in the other two of those five bills, H.R. 5228 and 5687, CBO cannot determine whether the costs of their mandates would exceed the threshold.

For large entitlement grant programs, including Medicaid and CHIP, UMRA defines an increase in the stringency of conditions on states or localities as an intergovernmental mandate if the affected governments lack authority to offset those costs while continuing to provide required services. Because states possess significant flexibility to alter their responsibilities within Medicaid and CHIP, the requirements imposed by various bills in the markup on state administration of those programs would not constitute mandates as defined in UMRA.

Mandates Affecting Public and Private Entities

H.R. 5795, the Overdose Prevention and Patient Safety Act, would impose intergovernmental and private-sector mandates by requiring entities that provide treatment for substance use disorders to notify patients of their privacy rights and also to notify patients in the event that the confidentiality of their records is breached. In certain circumstances, H.R. 5795 also would prohibit public and private entities from denying entry to treatment on the basis of information in patient health records. Those requirements would either supplant or narrowly expand responsibilities under existing law, and compliance with them would not impose significant additional costs. CBO estimates that the costs of the mandates would fall below the annual thresholds established in UMRA.

Mandates Affecting Private Entities

Five bills included in this document would impose private-sector mandates:

H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, would require drug distributors to cease distributing any drug that the Secretary of HHS determines might present an imminent or substantial hazard to public health. CBO cannot determine what drugs could be subject to such an order nor can it determine how private entities would respond. Consequently, CBO cannot determine whether the aggregate cost of the mandate would exceed the annual threshold for private-sector mandates.

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, would require developers and manufacturers of OTC drugs to pay certain fees to the FDA. CBO estimates that about \$30 million would be collected each year, on average, for a total of \$147 million over the 2019–2023 period. Those amounts

would not exceed the annual threshold for private-sector mandates in any year during that period.

H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 would require developers and manufacturers of brand-name and generic veterinary drugs to pay application, product, establishment, and sponsor fees to the FDA. CBO estimates that about \$51 million would be collected annually, on average, for a total of \$257 million over the 2019–2023 period. Those amounts would not exceed the annual threshold for private-sector mandates in any year during that period.

H.R. 5687, the Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018, would permit the Secretary of HHS to require drug developers and manufacturers to implement new packaging and disposal technology for certain drugs. Based on information from the agency, CBO expects that the Secretary would use the new regulatory authority provided in the bill; however, it is uncertain how or when those requirements would be implemented. Consequently, CBO cannot determine whether the aggregate cost of the mandate would exceed the annual threshold for private entities.

H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes, would expand an existing mandate that requires drug developers to conduct postapproval studies or clinical trials for certain drugs. Under current law, in certain instances, the FDA can require studies or clinical trials after a drug has been approved. H.R. 5811 would permit the FDA to use that authority if the reduction in a drug's effectiveness meant that its benefits no longer outweighed its costs. CBO estimates that the incremental cost of the mandate would fall below the annual threshold established in UMRA because of the small number of drugs affected and the narrow expansion of the authority that exists under current law.

None of the remaining 53 bills included in this document would impose an intergovernmental or private-sector mandate.

Previous CBO estimate: On June 6, 2018, CBO issued an estimate for seven opioid-related bills ordered reported by the House Committee on Ways and Means on May 16, 2018. Two of those bills contain provisions that are identical or similar to the legislation ordered reported by the Committee on Energy and Commerce, and for those provisions, CBO's estimates are the same.

In particular, five bills listed in this estimate contain provisions that are identical or similar to those in several sections of H.R. 5773, the Preventing Addiction for Susceptible Seniors Act of 2018:

- H.R. 5675, which would require prescription drug plans to implement drug management programs, is identical to section 2 of H.R. 5773.
- H.R. 4841, regarding electronic prior authorization for prescriptions under Medicare's Part D, is similar to section 3 of H.R. 5773.
- H.R. 5715, which would mandate the creation of a new Internet portal to allow various stakeholders to exchange information, is identical to section 4 of H.R. 5773.
- H.R. 5684, which would expand medication therapy management, is the same as section 5 of H.R. 5773.

- H.R. 5716, regarding prescriber notification, is identical to section 6 of H.R. 5773.

In addition, in this estimate, a provision related to Medicare beneficiary education in H.R. 5686, the Medicare Clear Health Options in Care for Enrollees Act of 2018, is the same as a provision in section 2 of H.R. 5775, the Providing Reliable Options for Patients and Educational Resources Act of 2018, in CBO's estimate for the Committee on Ways and Means.

Estimate prepared by: Federal Costs: Rebecca Yip (Centers for Disease Control and Prevention), Mark Grabowicz (Drug Enforcement Agency), Julia Christensen, Ellen Werble (Food and Drug Administration), Emily King, Andrea Noda, Lisa Ramirez-Branum, Robert Stewart (Medicaid and Children's Health Insurance Program), Philippa Haven, Lara Robillard, Colin Yee, Rebecca Yip (Medicare), Philippa Haven (National Institutes of Health), Alice Burns, Andrea Noda (Office of the Secretary of the Department of Health and Human Services), Philippa Haven, Lori Housman, Emily King (Substance Abuse and Mental Health Services Administration, Health Resources and Services Administration); Federal Revenues: Jacob Fabian, Peter Huether, and Cecilia Pastrone; Fact Checking: Zachary Byrum and Kate Kelly; Mandates: Andrew Laughlin.

Estimate reviewed by: Tom Bradley, Chief, Health Systems and Medicare Cost Estimates Unit; Chad M. Chirico, Chief, Low-Income Health Programs and Prescription Drugs Cost Estimates Unit; Sarah Masi, Special Assistant for Health; Susan Willie, Chief, Mandates Unit; Leo Lex, Deputy Assistant Director for Budget Analysis; Theresa A. Gullo, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to require states to operate a drug management program for at-risk beneficiaries that identifies Medicaid beneficiaries at-risk for substance use disorder and assigns them to a pharmaceutical home program. The pharmaceutical home program must set reasonable limits on the number of prescribers and dispensers that beneficiaries may utilize.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 5808 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111-139 or the most recent Catalog of Federal Domestic Assistance.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congres-

sional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 5808 contains no earmarks, limited tax benefits, or limited tariff benefits.

DISCLOSURE OF DIRECTED RULE MAKINGS

Pursuant to section 3(i) of H. Res. 5, the Committee finds that H.R. 5808 contains no directed rule makings.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides that the Act may be cited as the “Medicaid Pharmaceutical Home Act of 2018.”

Section 2. Drug management program for at-risk beneficiaries

Section 2 would amend section 1927A of the Social Security Act to require states to operate a qualified drug management program under which a State may enroll certain at-risk beneficiaries identified by the State by January 1, 2020.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * *

TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

* * * * *

SEC. 1927A. DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.

(a) *IN GENERAL.*—Beginning January 1, 2020, a State shall operate a qualified drug management program under which a State

may enroll certain at-risk beneficiaries identified by the State under the program.

(b) *QUALIFIED DRUG MANAGEMENT PROGRAM.*—*For purposes of this section, the term “qualified drug management program” means, with respect to a State, a program carried out by the State (including through a contract with a pharmacy benefit manager) that provides at least for the following:*

(1) *IDENTIFICATION OF AT-RISK INDIVIDUALS.*—*Under the program, the State identifies, in accordance with subsection (c), individuals enrolled under the State plan (or waiver of the State plan) who are at-risk beneficiaries.*

(2) *ELEMENTS OF PROGRAM.*—

(A) *IN GENERAL.*—*Under the program, the State, with respect to each individual identified under paragraph (1) and enrolled under the program under paragraph (5)—*

(i) *subject to subparagraphs (B) and (C), selects at least one, but not more than three, health care providers and at least one, but not more than three, pharmacies for each such individual for purposes of clause (ii), in accordance with a selection process that takes into account reasonable factors such as the individual’s previous utilization of items and services from health care providers and pharmacies, geographic proximity of the individual to such health care providers and pharmacies, access of the individual to health care, reasonable travel time, information regarding housing status, and any known preference of the individual for a certain health care provider or pharmacy; and*

(ii) *requires that any controlled substance furnished to such individual during the period for which such individual is enrolled under the program be prescribed by a health care provider selected under clause (i) for such individual and dispensed by a pharmacy selected under clause (i) for such individual in order for such controlled substance to be covered under the State plan (or waiver).*

(B) *BENEFICIARY PREFERENCE.*—*In the case of an individual receiving a notice under paragraph (3)(A) of being identified as potentially being an at-risk beneficiary described in such paragraph, such individual may submit, during the 30-day period following receipt of such notice, preferences for which health care providers and pharmacies the individual would prefer the State to select under subparagraph (A). The State shall select or change the selection of health care providers and pharmacies under subparagraph (A) for the individuals based on such preferences, except that in the case that State determines that such selection (or change of selection) of a health care provider or pharmacy under subparagraph (A) is contributing or would contribute to prescription drug abuse or drug diversion by the individual, the State may select or change the selection of health care provider or pharmacy for the individual without regard to the preferences of the individual described in this subparagraph. If the State selects or changes the selection pursuant to the preceding sentence*

without regard to the preferences of the individual, the State shall provide the individual with at least 30 days written notice of the selection or change of selection and a rationale for the selection or change.

(C) *TREATMENT OF PHARMACY WITH MULTIPLE LOCATIONS.*—*For purposes of subparagraph (A)(i), in the case of a pharmacy that has multiple locations that share real-time electronic prescription data and the same chain identification number, all such locations of the pharmacy shall collectively be treated as one pharmacy.*

(D) *TREATMENT OF EXISTING FFS DRUG MANAGEMENT PROGRAMS.*—*In the case of a patient review and restriction program (as identified in the annual report submitted to the Secretary under section 1927(g)(3)(D)) operated by a State pursuant to section 1915(a)(2) before the date of the enactment of this section, such program shall be treated as a qualified drug management program.*

(E) *REASONABLE ACCESS.*—*The program shall ensure, including through waiver of elements of the program (including under subparagraph (A)(ii)), reasonable access to health care (including access to health care providers and pharmacies with respect to prescription drugs described in subparagraph (A)) in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services (as defined for purposes of section 1860D-4(c)(5)(D)(ii)(II)).*

(3) *NOTIFICATION TO IDENTIFIED INDIVIDUALS.*—*Under the program, the State provides each individual who is identified under paragraph (1), prior to enrolling such individual under the program, at least one notification of each of the following:*

(A) *Notice that the State has identified the individual as potentially being an at-risk beneficiary for abuse or misuse of a controlled substance.*

(B) *The name, address, and contact information of each health care provider and pharmacy that may be selected for the individual under paragraph (2)(A).*

(C) *Information describing all State and Federal public health resources that are designed to address such abuse or misuse to which the individual has access, including mental health services and other counseling services.*

(D) *Notice of, and information about, the right of the individual to—*

(i) *submit preferences of the individual for health care providers and pharmacies to be selected under paragraph (2)(A), including as described in paragraph (2)(B);*

(ii) *appeal under paragraph (4)—*

(I) *such identification described in subparagraph (A); and*

(II) *the selection of health care providers and pharmacies under paragraph (2)(A).*

(E) *An explanation of the meaning and consequences of the identification of the individual as potentially being an*

at-risk beneficiary for abuse or misuse of a controlled substance, including an explanation of the program.

(F) Information, including a contact list and clear instructions, that explain how the individual can contact the appropriate entities administering the program in order to submit preferences described in paragraph (2)(B) and any other communications relating to the program.

(4) APPEALS PROCESS.—*Under the program, the State provides for an appeals process under which, with respect to an individual identified under paragraph (1)—*

(A) such individual may appeal—

(i) such identification; and

(ii) the selection of a health care provider or pharmacy under paragraph (2)(A);

(B) in the case of an appeal described in subparagraph (A)(ii), the State shall accommodate the health care provider or pharmacy preferred by the individual for selection for purposes of paragraph (2)(A), unless the State determines that a change to the selection of health care provider or pharmacy under such paragraph is contributing or would contribute to prescription drug abuse or drug diversion by the individual;

(C) such individual is provided a period of not less than 30 days following the date of receipt of the notice described in paragraph (3) to submit such appeal; and

(D) the State must make a determination with respect to an appeal described in subparagraph (A), and notify the individual of such determination, prior to enrollment of such individual in the program.

(5) ENROLLMENT.—*Under the program, the State initially enrolls individuals who are identified under paragraph (1) in the program for a 12-month period—*

(A) in the case of such an individual who does not submit an appeal under paragraph (4) within the period applied by the State pursuant to subparagraph (C) of such paragraph, beginning on the day after the last day of such period; and

(B) in the case of such an individual who does submit an appeal under paragraph (4) within the period applied by the State pursuant to subparagraph (C) of such paragraph but such appeal is denied, beginning not later than 30 days after the date of such denial.

(6) NOTIFICATION OF HEALTH CARE PROVIDERS AND PHARMACIES.—*Under the program, the State provides to each health care provider and pharmacy selected for an individual under paragraph (2)—*

(A) notification that the individual is an at-risk beneficiary enrolled under the program and that the provider or pharmacy has been selected for the individual under paragraph (2);

(B) information on such program and the role of being so selected; and

(C) a process through which the provider or pharmacy can submit a concern or complaint with respect to being so

selected and refuse to be a provider or pharmacy so selected.

(7) *CONTINUATION OF ENROLLMENT.*—Under the program, the State, with respect to an individual enrolled under the program, provides for a process to—

(A) not later than 30 days before the end of the 12-month period for which the individual is so enrolled pursuant to paragraph (5)—

(i) assess, in accordance with publicly available evidence-based guidelines, whether or not such individual should continue to be enrolled under the program; and
(ii) notify such individual of the results of the assessment under clause (i);

(B) continue, subject to subparagraph (C), enrollment of such individual if such assessment recommends such continuation; and

(C) appeal the continuation of enrollment in accordance with the appeals process described in paragraph (4).

(c) *AT-RISK BENEFICIARY.*—

(1) *IDENTIFICATION.*—For purposes of this section, a State shall identify an individual enrolled under the State plan (or waiver of the State plan) as an at-risk beneficiary if the individual is not an exempted individual described in paragraph (2) and—

(A) is identified as such an at-risk beneficiary through the use of publicly available evidence-based guidelines that indicate misuse or abuse of a controlled substance; or

(B) the State received notification from a PDP sponsor or Medicare Advantage organization that such individual was identified as being an at-risk beneficiary for prescription drug abuse for enrollment in a drug management program established by the sponsor or organization pursuant to section 1860D-4(c)(5) and such identification has not been terminated under subparagraph (F) of such section.

(2) *EXEMPTED INDIVIDUAL DESCRIBED.*—For purposes of paragraph (1), an exempted individual described in this paragraph is an individual who—

(A) is receiving—

(i) hospice or palliative care; or
(ii) treatment for cancer;

(B) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

(C) the State elects to treat as an exempted individual for purposes of paragraph (1).

(d) *APPLICATION OF PRIVACY RULES CLARIFICATION.*—The Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note), related to the sharing of data under subsection (b)(6) in the same manner as the Secretary is required under subparagraph (J) of section 1860D-4(c)(5) to clarify privacy requirements related to the sharing of data described in such subparagraph.

(e) REPORTS.—

(1) ANNUAL REPORTS.—A State operating a qualified drug management program shall include in the annual report submitted to the Secretary under section 1927(g)(3)(D), beginning with such reports submitted for 2021, the following information:

(A) The number of individuals enrolled under the State plan (or waiver of the State plan) who are enrolled under the program and the percentage of individuals enrolled under the State plan (or waiver) who are enrolled under such program.

(B) The number of prescriptions for controlled substances that were dispensed per month during each such year per individual enrolled under the program, including the dosage and pill count for each such prescription.

(C) The number of pharmacies filling prescriptions for controlled substances for individuals enrolled under such program.

(D) The number of health care providers writing prescriptions for controlled substances (other than prescriptions for a refill) for individuals enrolled under such program.

(E) Any other data that the Secretary may require.

(F) Any report submitted by a managed care entity under subsection (e)(2) with respect to years.

For each such report for a year after 2021, the information described in this paragraph shall be provided in a manner that compares such information with respect to the prior calendar year to such information with respect to the second prior calendar year.

(2) MACPAC REPORTS AND REVIEW.—Not later than two years after the date of the enactment of this section, the Medicaid and CHIP Payment and Access Commission (in this section referred to as “MACPAC”), in consultation with the National Association of Medicaid Directors, pharmacy benefit managers, managed care organizations, health care providers (including pharmacists), beneficiary advocates, and other stakeholders, shall publish a report that includes—

(A) best practices for operating drug management programs, based on a review of a representative sample of States administering such a program;

(B) a summary of the experience of the appeals process under drug management programs operated by several States, such as the frequency at which individuals appealed the identification of being an at-risk individual, the frequency at which individuals appealed the selection of a health care provider or pharmacy under such a program, the timeframes for such appeals, a summary of the reasons for such appeals, and the design of such appeals processes;

(C) a summary of trends and the effectiveness of qualified drug management programs operated under this section; and

(D) recommendations to States on how improvements can be made with respect to the operation of such programs.

In reporting on State practices, the MACPAC shall consider how such programs have been implemented in rural areas,

under fee-for-service as well as managed care arrangements, and the extent to which such programs have resulted in increased efficiencies to such States or to the Federal Government under this title.

(3) *REPORT ON PLAN FOR COORDINATED CARE.*—Not later than January 1, 2021, each State operating a qualified drug management program shall submit to the Administrator of the Centers for Medicare & Medicaid Services a report on how such State plans to provide coordinated care for individuals enrolled under the State plan (or waiver of the State plan) and—

- (A) who are enrolled under the program; or
- (B) who are enrolled with a managed care entity and enrolled under such a qualified drug management program operated by such entity.

(f) *APPLICABILITY TO MANAGED CARE ENTITIES.*—

(1) *IN GENERAL.*—With respect to any contract that a State enters into on or after January 1, 2020, with a managed care entity (as defined in section 1932(a)(1)(B)) pursuant to section 1903(m), the State shall, as a condition of the contract, require the managed care entity—

(A) to operate a qualified drug management program (as defined in subsection (b)) for at-risk beneficiaries who are enrolled with such entity and identified by the managed care entity by means of application of paragraph (2);

(B) to submit to the State an annual report on the matters described in subparagraphs (A) through (E) of subsection (e)(1); and

(C) to submit to the State a list (and as necessary update such list) of individuals enrolled with such entity under the qualified drug management program operated by such entity under subparagraph (A) for purposes of allowing State plans for which medical assistance is paid on a fee-for-service basis to have access to such information.

(2) *APPLICATION.*—For purposes of applying, with respect to a managed care entity—

- (A) under paragraph (1)(A)—

(i) the definition of the term “qualified drug management program” under subsection (b), other than paragraph (2)(D) of such subsection; and

(ii) the provisions of paragraphs (1) and (2) of subsection (c); and

(B) under paragraph (1)(B), the report requirements described in subparagraphs (A) through (E) of subsection (e)(1);

each reference in such subsection (b) and paragraphs of subsection (c) to “a State” or “the State” (other than to “a State plan” or “the State plan”) shall be deemed a reference to the managed care entity, each reference under such subsection, paragraphs, or subparagraphs to individuals enrolled under the State plan (or waiver of the State plan) shall be deemed a reference to individuals enrolled with such entity, and each reference under such subsection, paragraphs, or subparagraphs to individuals enrolled under the qualified drug management program operated by the State shall be deemed a reference to indi-

viduals enrolled under the qualified drug management program operated by the managed care entity.

(g) **CONTROLLED SUBSTANCE DEFINED.**—*For purposes of this section, the term “controlled substance” means a drug that is included in schedule II, III, or IV of section 202(c) of the Controlled Substances Act, or any combination thereof, as specified by the State.*

* * * * *

ADDITIONAL VIEWS

Currently, many states operate one, or more, patient review and restriction program. As such, it is of critical importance, as outlined by the National Association of Counties¹ and other stakeholders, that these programs are properly financed and that there is oversight and monitoring to ensure no adverse beneficiary impact. In the event of enactment, the Minority notes the importance of careful implementation that prioritizes the needs of Medicaid beneficiaries and stringently enforces notifications and appeals requirements on states.

FRANK PALLONE, Jr.,
Ranking Member.



¹ NNACo Legislative Analysis, “Opioid Legislation in the 115th Congress,” May 2018. Available at: <http://www.naco.org/sites/default/files/documents/Final%20-%20Opioid%20Legislative%20Analysis%20-%2005.31.2018.pdf>