CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

May 31, 2016

H.R. 4981
Opioid Use Disorder Treatment Expansion and Modernization Act

As passed by the House of Representatives on May 11, 2016

SUMMARY

H.R. 4981 would permit nurse practitioners and physician assistants who meet certain criteria to apply for waivers administered by the Substance Abuse and Mental Health Services Administration (SAMHSA). Those waivers would allow them to prescribe buprenorphine products to patients with opioid dependency. Additionally, the bill would permit pharmacists to fill only part of a prescription for certain drugs upon the request of the prescribing physician or the patient.

CBO estimates that enacting H.R. 4981 would reduce net direct spending by $37 million over the 2017-2026 period. Section 3 of the bill would increase direct spending by $85 million, while section 5 would decrease direct spending by $122 million. H.R. 4981 also would have a discretionary cost of about $2 million; any such spending would be subject to the availability of appropriated funds. Pay-as-you-go procedures apply because enacting the legislation would affect direct spending. H.R. 4981 would not affect revenues.

CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2027.

H.R. 4981 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments. CBO estimates that some provisions of the bill would result in additional spending and other provisions would yield savings for states. CBO estimates that the net change in overall spending for states would be minimal over the 2017-2026 period.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary effect of H.R. 4981 is shown in the following table. The costs of this legislation fall within budget functions 550 (health), 570 (Medicare), and 750 (administration of justice).

	By Fiscal Year, in Millions of Dollars											
	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2017-2021	2017-2026
INCREASES OR DECREASES (-) IN DIRECT SPENDING												
Section 3. Opioid Use Treatment Modernization												
Estimated Budget Authority	0	15	31	21	3	3	3	3	3	3	70	85
Estimated Outlays	0	15	31	21	3	3	3	3	3	3	70	85
Section 5. Partial Fills of Schedule II Controlled Substances												
Estimated Budget Authority	-2	-8	-11	-12	-13	-14	-15	-15	-16	-16	-46	-122
Estimated Outlays	-2	-8	-11	-12	-13	-14	-15	-15	-16	-16	-46	-122
Total Changes												
Estimated Budget Authority	-2	7	20	9	-10	-11	-12	-12	-13	-13	24	-37
Estimated Outlays	-2	7	20	9	-10	-11	-12	-12	-13	-13	24	-37

Note: CBO estimates that implementing Section 3 of H.R. 4981 would result in administrative costs for the Department of Health and Human Services and the Drug Enforcement Agency totaling about $2 million over the 2017-2021 period, subject to the availability of appropriated funds.

BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 4981 will be enacted near the end of fiscal year 2016.

Background

An opioid is a type of drug that has a high potential for addiction and abuse. Opioids include heroin and certain prescription drugs that treat pain, such as oxycodone or morphine. Buprenorphine is a type of opioid used in medication-assisted treatment (MAT) to help people who are addicted to opioids reduce or stop using those drugs. Buprenorphine is one component of MAT, which typically also includes intensive medical and social services.

Current law places substantial limits on the ability of medical professionals to prescribe buprenorphine products for the treatment of opioid addiction. Physicians who meet certain

training requirements must apply to SAMHSA for a waiver to prescribe buprenorphine. A physician who receives a waiver is permitted to prescribe the drug to a maximum of 30 patients at a time during the first year after receiving a waiver. After one year, the physician may apply for an increase to 100 patients. (SAMHSA has published a proposed rule that, if made final, would increase that limit to 200 patients.) As of May 2016, about 33,000 physicians were approved to prescribe buprenorphine. Nurse practitioners (NPs) and physician assistants (PAs) are not currently permitted to apply for waivers to prescribe buprenorphine.

Based on a review of available information, CBO estimates that about 850,000 people are being treated for opioid addiction with buprenorphine in 2016 and that an additional 1.5 million people could benefit from such treatment. Survey data from SAMHSA published in 2014 highlight several significant barriers to receiving treatment for substance abuse that are not directly related to the number of providers available to provide such treatment. Those barriers include:

- Inability to pay for treatment if uninsured or if health insurers impose coverage limitations;

- Not feeling ready to seek treatment; and

- Not knowing where to look to find the necessary treatment.

Given these barriers to accessing treatment, CBO expects that even if there were no constraints on the supply of MAT providers, most of the 1.5 million people who currently do not receive treatment for opioid addiction would remain untreated. In CBO's judgment, the greatest number of people who would take advantage of MAT if it were available is about 1.3 million people, about 50 percent more than the estimated number currently receiving treatment.

Direct Spending

Opioid Use Disorder Treatment Modernization. Section 3 of H.R. 4981 would permit NPs and PAs who meet certain criteria to apply for waivers to prescribe buprenorphine products to patients dependent on opioid drugs. Those practitioners would be required to receive 24 hours of specialized training or meet other training requirements set forth by the Secretary of Health and Human Services. In addition, in states where NPs or PAs are required to practice in collaboration with, or under the supervision of, a physician, the bill would require that the collaborating or supervising physician also have a waiver. The authority for NPs and PAs to provide MAT services under a waiver would expire three years after the date of enactment.

CBO estimates that enacting section 3 would increase the number of people who receive MAT services. By 2019, the last year in which the new waivers would be available, CBO expects that number would reach about 40,000. Direct spending for Medicaid, Medicare, and other federal health care programs would increase by $70 million over the 2017-2021 period and by $85 million over the 2017-2026 period, CBO estimates.

To develop that estimate, CBO consulted with experts and analyzed administrative data to assess the effects of expanding SAMSHA's authority to provide waivers to NPs and PAs on the number of people who would newly receive treatment under the legislation. After adjusting that estimate to reflect a proposed regulation that would increase the number of patients a physician could treat under a waiver, CBO estimated the share that would have federally funded health care coverage and the per-person spending for MAT treatment in each program. Finally, CBO adjusted the estimates to take account of the time it would take for the legislation to be fully implemented and the expiration of the authority after three years.

CBO first analyzed administrative data to determine the rate at which physicians currently apply for waivers and the average number of opioid-dependent patients each physician treats. If NPs and PAs applied for waivers at the same rate as physicians and treated the same number of patients on average, CBO estimates that the number of additional people who would use MAT services for opioid use disorders would gradually increase to about 300,000 over several years. In CBO's judgment, about two-thirds of that increase would result from an expansion in availability of MAT services in communities and medical practices where it is not currently available and one-third would result from greater availability of MAT in medical practices that already provide such treatment.

Under H.R. 4891, NPs and PAs in most states would be required to work in collaboration with or under the supervision of a waivered physician. That requirement would probably limit the potential increase in the availability of MAT services to medical practices that already provide such treatment and that would limit the increase in the number of people who could be treated with buprenorphine to about 100,000 people over several years.

The analysis described above is based on estimates of the number of people being treated with buprenorphine under current limits and on the number of patients a physician with a waiver may treat. On March 30, 2016, SAMHSA published a proposed rule that would increase the patient limit from 100 patients to 200 patients. Like H.R. 4981, that proposed change would also have the effect of increasing the number of people treated with buprenorphine. CBO expects that there is substantial overlap between the people who would gain access to MAT under that rule, if it were made final, and under H.R. 4981. In accordance with CBO's standard practice for incorporating the effects of proposed rules, this estimate reflects an assumption that there is a 50 percent chance that the rule will

become final.[1] To incorporate that effect in this estimate, CBO reduced the estimated number of people who ultimately could be treated with MAT as a result of enacting H.R. 4981 by 40,000.

CBO estimates that about one-quarter of people treated for opioid addiction with buprenorphine have health care coverage through a federal health program, with about 75 percent of those people enrolled in Medicaid. CBO further assumed the same proportions would apply to the increase in the total number of people who would receive such treatment as a result of enacting H.R. 4981.

Based on data published in the proposed rule and on administrative data for the Medicaid and Medicare programs, CBO estimates that the cost to the federal government of MAT will average about $2,000 for people covered by Medicaid and about $4,300 for people covered by Medicare and other federal programs in 2017.

For this estimate, CBO assumes that H.R. 4981 will be enacted near the end of fiscal year 2016 and that SAMHSA will issue a final rule implementing the bill in fiscal year 2017. We expect SAMHSA would begin issuing waivers to NPs and PAs in fiscal year 2018. The bill specifies that the authority to issue those waivers would expire three years after the date of enactment, making them available only for 2018 and 2019. Taking into account the effect of the proposed rule and the gradual increase in the number of MAT users under the proposal, CBO estimates that the number of newly treated people would peak in 2019, at about 40,000. After the waiver authority expires, CBO expects that the number of people treated would decrease substantially, returning to levels just slightly above the number expected to receive treatment under current law.

Permit partial fills of Schedule II controlled substances. Section 5 of H.R. 4981 would permit pharmacists to dispense "partial fills" of prescription drugs that are listed in Schedule II of the Controlled Substances Act (CSA) upon the request of the prescribing physician or of the patient to whom the drug was prescribed. Schedule II drugs are prescription drugs that have a high potential for addiction and abuse. A partial fill occurs when a pharmacist does not dispense the full amount of a prescription. For example, a physician could prescribe a 30-day supply of a drug and direct the pharmacist to fill only enough for the first week to ensure that the patient can tolerate taking the medication before receiving the entire 30-day supply.

Under current law, partial fills of Schedule II drugs are permitted only when a pharmacy does not have enough pills to fill the entire prescription, a patient resides in a long term care

1. See Congressional Budget Office letter to the Honorable John M. Spratt about how CBO reflects anticipated administrative actions in its baseline projections and how it estimates the budgetary impact of legislation directing or prohibiting such actions (May 2, 2007): https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/05-02-letteronregs.pdf

facility, or a patient has a terminal illness. H.R. 4981 would permit partial fills any time a prescribing physician or a patient requests one.

Based on information from stakeholders, CBO expects that permitting partial fills would lead to a small reduction (less than 1 percent) in the number of Schedule II drugs dispensed. As a result, CBO estimates that federal spending for those drugs would be reduced by about two-tenths of a percent; that is, federal spending for Medicare, Medicaid, and other healthcare programs would decline by about $122 million over the 2017-2026 period. Savings to the Medicare Part D prescription drug program account for $95 million of that total.

Spending Subject to Appropriation

CBO estimates that implementing section 3 of H.R. 4981 would cost about $2 million over the 2017-2021 period. About $1 million would be used to pay for administrative expenses associated with approving new provider waivers to prescribe buprenorphine and, subsequently, issuing Drug Enforcement Agency numbers. The remaining amount would be used by HHS to update treatment protocols for opioid-dependent patients in office-based settings and to submit a report to the Congress two years after enactment and every five years thereafter, that provides information about the utilization of treatment for opioid use disorder. Any such spending would be subject to the availability of appropriated funds.

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. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in the following table. The legislation would not affect revenues.

CBO Estimate of Pay-As-You-Go Effects for H.R. 4981, as passed by the House of Representatives on May 11, 2016.

	By Fiscal Year, in Millions of Dollars												
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2016-2021	2016-2026
NET INCREASE OR DECREASE (-) IN THE BUDGET DEFICIT													
Statutory Pay-As-You-Go Impact	0	-2	7	20	9	-10	-11	-12	-12	-13	-13	24	-37

INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS

CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2027.

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

H.R. 4981 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments. CBO estimates that some provisions of the bill would result in additional spending and other provisions would yield savings for states. CBO estimates that the net change in overall spending would be minimal over the 2017-2026 period.

PREVIOUS ESTIMATE

On May 27, 2016, CBO transmitted a cost estimate for H.R. 4599, the Reducing Unused Medications Act of 2016, as passed by the House of Representatives on May 11, 2016. H.R. 4599 is similar to Section 5 of this bill and the estimated budgetary effects are the same.

ESTIMATE PREPARED BY:

Federal Costs: Tom Bradley, Andrea Noda, Matt Schmit, and Rebecca Yip
Impact on State, Local, and Tribal Governments: Leo Lex
Impact on the Private Sector: Amy Petz

ESTIMATE APPROVED BY:

Holly Harvey
Deputy Assistant Director for Budget Analysis