

ENSURING COMPLIANCE AGAINST DRUG DIVERSION ACT
OF 2019

NOVEMBER 16, 2020.—Committed to the Committee of the Whole House on the
State of the Union and ordered to be printed

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

R E P O R T

[To accompany H.R. 4812]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4812) to amend the Controlled Substances Act to provide for the modification, transfer, and termination of a registration to manufacture, distribute, or dispense controlled substances or list I chemicals, and for other purposes, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

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I. PURPOSE AND SUMMARY

H.R. 4812, the “Ensuring Compliance Against Drug Diversion Act of 2019”, was introduced by Representative H. Morgan Griffith (R-VA). This bill terminates the controlled substance registration of any registrant if the registrant dies, ceases legal existence, discontinues business or professional practice, or surrenders registration. A registrant who ceases legal existence or discontinues business is required to notify the Attorney General. Registrants must receive written consent from the Attorney General in order to assign or transfer a registration. Registrants are also required to return certain documentation if a registrant’s work is discontinued.

II. BACKGROUND AND NEED FOR LEGISLATION

In 2018, 67,367 Americans died of a drug overdose and nearly 70 percent involved an opioid.¹ Those opioids include prescription pain relievers, heroin, and other synthetic opioids such as fentanyl.² The Drug Enforcement Administration (DEA) has established a registration system for controlled substances, including opioids, meant to track the manufacture, distribution, and dispensing of such substances and prevent diversion of substances.

Multiple oversight agencies have found, however, that DEA has not been fully effective in detecting and combating the diversion of opioids and other controlled substances. A 2016 Government Accountability Office report found that 705 registrants in DEA’s system may have been ineligible to have controlled substance registrations because the registrants were reportedly deceased.³ Additionally, a Department of Justice Inspector General report found that DEA policy allowed registrants who surrendered their registration to reapply for registration the day after a surrender occurred.⁴

This bill would codify existing efforts put forward by DEA to ensure accuracy of registrations and limit inappropriate transfers of such registrations.

III. COMMITTEE HEARINGS

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress, the following hearing was used to develop or consider H.R. 4812:

The Subcommittee on Health held a legislative hearing on Tuesday, March 3, 2020, entitled, “Combatting an Epidemic: Legislation to Help Patients with Substance Use Disorders.” The Subcommittee received testimony from the following witnesses:

¹Centers for Disease Control and Prevention, *Opioid Overdose, Understanding the Epidemic* (<https://www.cdc.gov/drugoverdose/epidemic/index.html>) (accessed September 19, 2020).

²Centers for Disease Control and Prevention, *Opioid Overdose, Data Analysis and Resources* (<https://www.cdc.gov/drugoverdose/data/analysis.html>) (accessed September 19, 2020).

³Government Accountability Office, *CONTROLLED SUBSTANCES DEA Should Take Additional Actions to Reduce Risks in Monitoring the Continued Eligibility of its Registrants*. GAO-16-310. (May 2016).

⁴U.S. Department of Justice Office of the Inspector General, *Review of the Drug Enforcement Administration’s Regulatory and Enforcement Efforts to Control the Diversion of Opioids*. (September 2019).

Panel I:

- ADM Brett P. Giroir, M.D., Assistant Secretary for Health and Senior Adviser to the Secretary on Opioid Policy, Department of Health and Human Services
- Kimberly Brandt, Principal Deputy Administrator for Policy & Operations, Centers for Medicare & Medicaid Services
- Thomas W. Prevoznik, Deputy Assistant Administrator, Diversion Control Division, Drug Enforcement Administration

Panel II:

- Michael P. Botticelli, Executive Director, Grayken Center for Addiction, Boston Medical Center
- Smita Das, M.D., Ph.D., M.P.H., Addiction Psychiatrist, Dual Diagnosis Clinic, Clinical Assistant Professor, Psychiatry and Behavioral Sciences, Stanford University School of Medicine
- Patty McCarthy, Chief Executive Officer, Faces & Voices of Recovery
- Robert I.L. Morrison, Executive Director/Director of Legislative Affairs, National Association of State Alcohol and Drug Abuse Directors
- Margaret B. Rizzo, Executive Director, JSAS HealthCare, Inc.
- Shawn A. Ryan, M.D., M.B.A, Chair, Legislative Advocacy Committee, American Society of Addiction Medicine

IV. COMMITTEE CONSIDERATION

H.R. 4812 was introduced by Rep. Griffith on October 23, 2019, and referred to the Committee on Energy and Commerce. The bill was then referred to the Subcommittee on Health on October 26, 2019. The bill was included in a legislative hearing held by the Subcommittee on March 3, 2020.

H.R. 4812 was discharged from the Subcommittee on Health on September 9, 2020, as the bill was called up for consideration by the full Committee on Energy and Commerce. The full Committee met in virtual open markup session on September 9, 2020, on the bill. No amendments were offered to H.R. 4812, and subsequently the full Committee agreed to a motion offered by Mr. Pallone, Chairman of the committee, to order H.R. 4812 reported favorably to the House, without amendment, by a voice vote, a quorum being present.

V. COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there were no record votes taken on H.R. 4812, including on the motion on final passage offered by Mr. Pallone.

VI. OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight find-

ings and recommendations of the Committee are reflected in the descriptive portion of the report.

VII. NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

VIII. CONGRESSIONAL BUDGET OFFICE ESTIMATE

Controlled Substances Act Legislation			
As ordered reported by the House Committee on the Judiciary on September 9, 2020			
By Fiscal Year, Millions of Dollars	2021	2021-2025	2021-2030
Direct Spending (Outlays)	*	*	*
Revenues	0	0	0
Increase or Decrease (-) in the Deficit	*	*	*
Spending Subject to Appropriation (Outlays)	0	0	not estimated
Statutory pay-as-you-go procedures apply?	Yes	Mandate Effects	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2031?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	Yes, Cannot Determine Costs
* = between zero and \$500,000.			

On September 9, 2020, the House Committee on the Judiciary ordered reported the following pieces of legislation that would make changes to the Drug Enforcement Administration's (DEA) Diversion Control Program:

- H.R. 3878, the Block, Report, and Suspend Suspicious Shipments Act of 2019, would require registrants who manufacture, distribute, or dispense controlled substances to take additional steps in reporting suspicious orders, including maintaining a record of due diligence, declining to fill the order, and notifying DEA.
- H.R. 4806, the DEBAR Act of 2019, would allow the Attorney General to issue an order prohibiting applicants from registering as a manufacturer, distributor, or dispenser of controlled substances if they meet certain criteria.
- H.R. 4812, the Ensuring Compliance Against Drug Diversion Act of 2019, would terminate authority to manufacture, distribute, or dispense controlled substances when a registrant dies, ceases legal existence, or discontinues business.

The Diversion Control Program is funded by registration fees, which are treated in the budget as reductions in direct spending; DEA is authorized to spend those fees without further appropriation. Each bill would either codify existing regulations or clarify

procedures already in place. On that basis, and using information from the agency, CBO estimates that under the bill the increase in spending of those fees above current levels would not be significant.

H.R. 3878 would impose a private-sector mandate on manufacturers, distributors, and dispensers of controlled substances by expanding reporting requirements and prohibiting them from fulfilling unresolved suspicious orders. CBO is uncertain how DEA would implement the new requirements and cannot evaluate the potential costs for the mandated entities to comply. In 2019, DEA received reports of 370,000 suspicious orders; however, CBO cannot predict the number of orders that would be precluded by the bill or the value of such orders. CBO cannot estimate the potential foregone revenue and therefore cannot determine whether the aggregate cost of the mandates would exceed the annual threshold established in UMRA for private-sector mandates (\$168 million in 2020, adjusted annually for inflation).

H.R. 4806 and H.R. 4812 do not contain private-sector mandates as defined in UMRA.

None of the bills contain intergovernmental mandates as defined in UMRA.

The CBO staff contacts for this estimate are Lindsay Wylie (for federal costs) and Lilia Ledezma (for mandates). The estimate was reviewed by H. Samuel Papenfuss, Deputy Director of Budget Analysis.

IX. 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.

X. 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 amend the Controlled Substances Act to provide for the modification, transfer, and termination of a registration to manufacture, distribute, or dispense controlled substances or list I chemicals.

XI. DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 4812 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.

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

XIII. EARMARKS, 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. 4812 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIV. ADVISORY COMMITTEE STATEMENT

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

XV. 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.

XVI. SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the short title may be cited as the “Ensuring Compliance Against Drug Diversion Act of 2019”.

Sec. 2. Modification, transfer, and termination of registration to manufacture, distribute, or dispense controlled substances

Section 2 amends section (a) of section 302 of the Controlled Substances Act to add a new paragraph (3)(A). This new paragraph terminates the controlled substance registration of a registrant to manufacture, distribute, or dispense controlled substances of list I chemicals if the registrant: (i) dies; (ii) ceases legal existence; (iii) discontinues business or professional practice; or (iv) surrenders registration. The new paragraph adds that a registrant who ceases legal existence or discontinues business must notify the Attorney General. Finally, registrants must receive written consent from the Attorney General in order to assign or transfer a registration and must return certain documentation, such as the registrant’s certificate of registration or unexecuted order forms, if a registrant’s work is discontinued.

XVII. 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 italics and existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

TITLE II—CONTROL AND ENFORCEMENT

* * * * *

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

* * * * *

PERSONS REQUIRED TO REGISTER

SEC. 302. (a)(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event; however, shall such registrations be issued for less than one year nor for more than three years.

(3)(A) *Except as provided in subparagraph (C), the registration of any registrant under this title to manufacture, distribute, or dispense controlled substances or list I chemicals terminates if and when such registrant—*

- (i) dies;*
- (ii) ceases legal existence;*
- (iii) discontinues business or professional practice; or*
- (iv) surrenders such registration.*

(B) In the case of such a registrant who ceases legal existence or discontinues business or professional practice, such registrant shall promptly notify the Attorney General in writing of such fact.

(C) No registration under this title to manufacture, distribute, or dispense controlled substances or list I chemicals, and no authority conferred thereby, may be assigned or otherwise transferred except upon such conditions as the Attorney General may specify and then only pursuant to written consent. A registrant to whom a registration is assigned or transferred pursuant to the preceding sentence may not manufacture, distribute, or dispense controlled substances or list I chemicals pursuant to such registration until the Attorney General receives such written consent.

(D) In the case of a registrant under this title to manufacture, distribute, or dispense controlled substances or list I chemicals desiring to discontinue business or professional practice altogether or with respect to controlled substances and list I chemicals (without assigning or transferring such business or professional practice to another entity), such registrant shall return to the Attorney General for cancellation—

- (i) the registrant's certificate of registration;*
 - (ii) any unexecuted order forms in the registrant's possession;*
- and*
- (iii) any other documentation that the Attorney General may require.*

(b) Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity

in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this title.

(c) The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this title:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 102(25).

(d) The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e)(1) A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(2) Notwithstanding paragraph (1), a registrant who is a veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice.

(f) The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

(g)(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

(A) the person receiving the controlled substance is authorized under this title to engage in such activity; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

(3) The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(4) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

(5)(A) In the case of a person receiving hospice care, an employee of a qualified hospice program, acting within the scope of employment, may handle, without being registered under this section, any controlled substance that was lawfully dispensed to the person receiving hospice care, for the purpose of disposal of the controlled substance so long as such disposal occurs onsite in accordance with all applicable Federal, State, Tribal, and local law and—

(i) the disposal occurs after the death of a person receiving hospice care;

(ii) the controlled substance is expired; or

(iii)(I) the employee is—

(aa) the physician of the person receiving hospice care; and

(bb) registered under section 303(f); and

(II) the hospice patient no longer requires the controlled substance because the plan of care of the hospice patient has been modified.

(B) For the purposes of this paragraph:

(i) The terms “hospice care” and “hospice program” have the meanings given to those terms in section 1861(dd) of the Social Security Act.

(ii) The term “employee of a qualified hospice program” means a physician, physician assistant, nurse, or other person who—

(I) is employed by, or pursuant to arrangements made by, a qualified hospice program;

(II)(aa) is licensed to perform medical or nursing services by the jurisdiction in which the person receiving hospice care was located; and

(bb) is acting within the scope of such employment in accordance with applicable State law; and

(III) has completed training through the qualified hospice program regarding the disposal of controlled substances in a secure and responsible manner so as to discourage abuse, misuse, or diversion.

(iii) The term “qualified hospice program” means a hospice program that—

(I) has written policies and procedures for assisting in the disposal of the controlled substances of a person receiving hospice care after the person's death;

(II) at the time when the controlled substances are first ordered—

(aa) provides a copy of the written policies and procedures to the patient or patient representative and family;

(bb) discusses the policies and procedures with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe disposal of controlled substances; and

(cc) documents in the patient's clinical record that the written policies and procedures were provided and discussed; and

(III) at the time following the disposal of the controlled substances—

(aa) documents in the patient's clinical record the type of controlled substance, dosage, route of administration, and quantity so disposed; and

(bb) the time, date, and manner in which that disposal occurred.

* * * * *

