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Part 1

BLOCK, REPORT, AND SUSPEND SUSPICIOUS SHIPMENTS ACT OF 2020

NOVEMBER 16, 2020.—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. 3878]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3878) to amend the Controlled Substances Act to clarify the process for registrants to exercise due diligence upon discovering a suspicious order, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Block, Report, And Suspend Suspicious Shipments Act of 2020".

SEC. 2. CLARIFICATION OF PROCESS FOR REGISTRANTS TO EXERCISE DUE DILIGENCE UPON DISCOVERING A SUSPICIOUS ORDER.

(a) IN GENERAL.—Paragraph (3) of section 312(a) of the Controlled Substances Act (21 U.S.C. 832(a)) is amended to read as follows:

"(3) upon discovering a suspicious order or series of orders—

"(A) exercise due diligence;

"(B) establish and maintain (for not less than a period to be determined by the Administrator of the Drug Enforcement Administration) a record of the due diligence that was performed;

"(C) decline to fill the order or series of orders if the due diligence fails to resolve all of the indicators that gave rise to the suspicion that filling the order or series of orders would cause a violation of this title by the registrant or the prospective purchaser; and

"(D) notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business of—

"(i) each suspicious order or series of orders discovered by the registrant; and

"(ii) the indicators giving rise to the suspicion that filling the order or series of orders would cause a violation of this title by the registrant or the prospective purchaser.".

(b) APPLICABILITY.—Section 312(a)(3) of the Controlled Substances Act, as amended by subsection (a), shall apply beginning on the day that is 6 months after the date of enactment of this Act. Until such day, section 312(a)(3) of the Controlled Substances Act shall apply as such section 312(a)(3) was in effect on the day before the date of enactment of this Act.

I. PURPOSE AND SUMMARY

H.R. 3878, the "Block, Report, And Suspend Suspicious Shipments Act of 2020", was introduced by Representatives David B. McKinley (R–WV) and Debbie Dingell (D–MI). This bill would create additional requirements for drug manufacturers and distributors who discover a suspicious order for controlled substances. In addition to reporting the suspicious order to the Drug Enforcement Administration (DEA), a manufacturer or distributor must also exercise due diligence, decline to fill the order or series of orders, notify the DEA of each suspicious order or series of orders, and provide information on the indicators that led to the belief that filling such orders would be a violation. These requirements would become effective six months following enactment of the bill.

II. BACKGROUND AND NEED FOR LEGISLATION

In 2018, 67,367 Americans died of a drug overdose, and of those deaths, nearly 70 percent involved an opioid.[1] Those opioids include prescription pain relievers, heroin, and other synthetic opioids such as fentanyl.[2] The DEA requires entities that manufacture or distribute controlled substances to register with a system that tracks the manufacture, distribution, and dispensing of such substances in order to prevent diversion. The DEA also has established the Suspicious Orders Reporting System (SORS) to identify and receive reports of suspicious orders, which are orders of a controlled substance of unusual size, orders of controlled substances deviating

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

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

substantially from normal patterns, and orders of controlled substances of unusual frequency.[3]

Recent reviews of the DEA's suspicious orders work, however, found flaws and inefficiencies. A Department of Justice Inspector General report found that the SORS did not include all suspicious reports provided to the DEA, "thereby significantly impacting its usefulness."[4] This bill would clarify existing efforts put forward by the DEA and ensure that registrants and the agency would comply with the suspicious order requirements established by regulations and the Controlled Substances Act.

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. 3878:

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:

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

Representatives McKinley and Dingell introduced H.R. 3878 on July 23, 2019, and the bill was referred to the Committee on Energy and Commerce. H.R. 3878 was then referred to the Sub-

[3] 21 U.S.C. 802.

[4] U.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).

committee on Health on July 24, 2019. A legislative hearing was held on the bill on March 3, 2020.

On September 9, 2020, H.R. 3878 was discharged from further consideration by the Subcommittee on Health 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, pursuant to notice, to consider H.R. 3878. During consideration of the bill, an amendment offered by Mr. McKinley was agreed to by a voice vote. Upon conclusion of consideration of the bill, the full Committee agreed to a motion on final passage offered by Mr. Pallone, Chairman of the committee, to order H.R. 3878 reported favorably to the House, amended, 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. 3878, including the motion for final passage of the bill.

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 findings 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 clarify the process for registrants who discover a suspicious order for controlled substances, including requiring such registrants to exercise due diligence upon discovering a suspicious order or decline to fill the order, and for other purposes.

XI. Duplication of Federal Programs

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 3878 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. 3878 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 "Block, Report, And Suspend Suspicious Shipments Act of 2020".

Sec. 2. Clarification of process for registrants to exercise due diligence upon discovering a suspicious order

Section 2 amends the Controlled Substances Act to add registrant reporting requirements regarding suspicious orders. Upon discovering a suspicious order or series of orders, the registrant must exercise due diligence, keep record of the due diligence that was performed, decline to fill the order or orders, and notify the DEA Administrator and Special Agent in Charge of the Divisions Office of the DEA where the registrant is located of each suspicious order or series of orders and the indicators that gave rise to the suspicion that filing the order or orders would be in violation of the Act. This change goes into effect six months after enactment of this Act.

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 (existing law proposed to be omitted is enclosed in black brackets, 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

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

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SEC. 312. SUSPICIOUS ORDERS.

(a) REPORTING.—Each registrant shall—

(1) design and operate a system to identify suspicious orders for the registrant;

(2) ensure that the system designed and operated under paragraph (1) by the registrant complies with applicable Federal and State privacy laws; and

[(3) upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.]

(3) upon discovering a suspicious order or series of orders—

(A) exercise due diligence;

(B) establish and maintain (for not less than a period to be determined by the Administrator of the Drug Enforcement Administration) a record of the due diligence that was performed;

(C) decline to fill the order or series of orders if the due diligence fails to resolve all of the indicators that gave rise to the suspicion that filling the order or series of orders would cause a violation of this title by the registrant or the prospective purchaser; and

(D) notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business of—

(i) each suspicious order or series of orders discovered by the registrant; and

(ii) the indicators giving rise to the suspicion that filling the order or series of orders would cause a violation of this title by the registrant or the prospective purchaser.

(b) SUSPICIOUS ORDER DATABASE.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Attorney General shall establish a centralized database for collecting reports of suspicious orders.

(2) SATISFACTION OF REPORTING REQUIREMENTS.—If a registrant reports a suspicious order to the centralized database established under paragraph (1), the registrant shall be considered to have complied with the requirement under subsection (a)(3) to notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.

(c) SHARING INFORMATION WITH THE STATES.—

(1) IN GENERAL.—The Attorney General shall prepare and make available information regarding suspicious orders in a State, including information in the database established under subsection (b)(1), to the point of contact for purposes of administrative, civil, and criminal oversight relating to the diversion of controlled substances for the State, as designated by the Governor or chief executive officer of the State.

(2) TIMING.—The Attorney General shall provide information in accordance with paragraph (1) within a reasonable period of time after obtaining the information.

(3) COORDINATION.—In establishing the process for the provision of information under this subsection, the Attorney General shall coordinate with States to ensure that the Attorney General has access to information, as permitted under State law, possessed by the States relating to prescriptions for controlled substances that will assist in enforcing Federal law.

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