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The SUPPORT for Patients and Communities Act (P.L. 115-271): Food and Drug Administration and Controlled Substance Provisions

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SUMMARY

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The SUPPORT for Patients and Communities Act (P.L. 115-271): Food and Drug Administration and Controlled Substance Provisions

On October 24, 2018, President Trump signed into law H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271; the SUPPORT for Patients and Communities Act, or the SUPPORT Act).

The SUPPORT Act is a sweeping measure designed to address widespread overprescribing and abuse of opioids in the United States. The act includes provisions involving law enforcement, public health, and health care financing and coverage. Broadly, the legislation imposes tighter oversight of opioid production and distribution; imposes additional reporting and safeguards to address fraud; and limits coverage of prescription opioids, while expanding coverage of and access to opioid addiction treatment services. The bill also authorizes a number of programs that seek to expand consumer education on opioid use and train additional providers to treat individuals with opioid use disorders.

The SUPPORT Act builds on recent efforts by the federal government to address the opioid epidemic, including the Comprehensive Addiction and Recovery Act of 2016 (CARA; P.L. 114-198) and the 21st Century Cures Act (Cures Act; P.L. 114-255). CARA addressed substance use issues broadly, targeting the opioid crisis predominantly through public health and law enforcement strategies.[1] The Cures Act, enacted that same year, largely focused on medical innovation but also authorized additional funding to combat opioid addiction and included provisions addressing various mental health and substance use activities.

CRS is publishing a series of reports on the SUPPORT Act, which consists of eight titles. This report summarizes the provisions in Title III—the FDA (Food and Drug Administration) and Controlled Substance Provisions, as well as Section 4004 "Modernizing the Reporting Requirements of Biological and Biosimilar Products" in Title IV—Offsets.

Subtitle A of Title III addresses FDA medical product regulation and includes provisions that, among other things,

- facilitate the development of new medical products for treatment of pain,
- provide for special packaging and disposal mechanisms for opioids, and
- amend postmarket study and labeling requirements.

Subtitle B of Title III addresses Drug Enforcement Administration (DEA) regulation of controlled substances and includes provisions that, among other things,

- provide additional flexibility with respect to medication-assisted treatment (MAT) for opioid use disorders,
- modify controlled substances disposal requirements at qualified hospice programs, and
- authorize grants to states to increase participation of eligible collectors in drug-disposal programs.

Section 4004 of Title IV amends reporting requirements for certain agreements between brand drug, generic drug, and biosimilar product manufacturers.

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Introduction

On October 24, 2018, President Trump signed into law H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271; the SUPPORT for Patients and Communities Act, or the SUPPORT Act). The final agreement on the bill was approved by the House 393-8 on September 28, 2018, and cleared the Senate by 98-1 on October 3, 2018.[1]

Over the past several years, there has been growing concern among the public and lawmakers in the United States about rising drug overdose deaths. Opioid overdose deaths, in particular, have increased significantly in the past 15 years. In 2015, an estimated 33,091 Americans died of opioid-related overdoses, almost three times as many as in 2002 around the beginning of the epidemic.[2] In 2016, that number increased to 42,249.[3] In October 2017, President Trump declared the opioid epidemic a national public health emergency.[4]

The SUPPORT Act is a sweeping measure designed to address widespread overprescribing and abuse of opioids in the United States. The act includes provisions involving law enforcement, public health, and health care financing and coverage. Broadly, the legislation imposes tighter oversight of opioid production and distribution; imposes additional reporting and safeguards to address fraud; and limits coverage of prescription opioids, while expanding coverage of and access to opioid addiction treatment services. The bill also authorizes a number of programs that seek to expand consumer education on opioid use and train additional providers to treat individuals with opioid use disorders.

Budgetary Impact

The SUPPORT Act includes a number of legislative changes that affect direct spending and revenues. The purpose of this report is not to summarize the budgetary effect of every provision in Title III of the SUPPORT Act. As such, this report does not discuss the budgetary impact of individual provisions, with the exception of Section 4004 (see "Title IV—Offsets"). Overall, the Congressional Budget Office (CBO) estimated that the SUPPORT Act would increase the on-budget deficit by $1,001 million over 5 years (FY2019-2023), but reduce the on-budget deficit by $52 million over 10 years (FY2019-FY2028).[5] Generally, pay-as-you-go (PAYGO) scorecards record the effects resulting from legislative changes affecting direct spending and revenues;

[1] A different version of H.R. 6 passed the House on June 22, 2018, by a vote of 396-14, and an amended version of the bill was passed by the Senate on September 17, 2018, by a vote of 99-1. On September 28, 2018, the House passed a final agreement on H.R. 6 by a vote of 393-8 and on October 3, the Senate passed the final version of H.R. 6 by a vote of 98-1. See Energy and Commerce Committee, "Opioid Legislation," October 24, 2018, https://energycommerce.house.gov/opioids-legislation/.

[2] U.S. Department of Health and Human Services, National Institutes of Health, National Institute on Drug Abuse, *Overdose Death Rates*, Updated September 2017, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates.

[3] Centers for Disease Control and Prevention, "Data Brief 294. Drug Overdose Deaths in the United States, 1999–2016," Data table for Figure 4, December 2017, https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#1.

[4] White House, "President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis," October 26, 2017, https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis/.

[5] CBO, Estimated Direct Spending and Revenue Effects of H.R. 6, Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, September 27, 2018, https://www.cbo.gov/system/files?file=2018-09/hr6ConferenceSept27.pdf.

however, Section 8231 of the SUPPORT ACT excludes such budgetary effects from PAYGO scorecards, thus precluding any possible sequestration as a result of the enactment of the legislation.[6]

Related Prior Laws

The SUPPORT Act builds on recent efforts by the federal government to address the opioid epidemic, including the Comprehensive Addiction and Recovery Act of 2016 (CARA; P.L. 114-198) and the 21st Century Cures Act (Cures Act; P.L. 114-255). CARA addressed substance use issues broadly, targeting the opioid crisis predominantly through public health and law enforcement strategies.[7] The Cures Act, enacted that same year, largely focused on medical innovation, amending Food and Drug Administration (FDA) pathways for medical product development and review and authorizing new funding for biomedical research. The Cures Act also authorized additional funding to combat opioid addiction and included provisions addressing various mental health and substance use activities.[8]

SUPPORT Act Organization

The SUPPORT Act consists of eight titles:

- Title I—Medicaid Provisions to Address the Opioid Crisis
- Title II—Medicare Provisions to Address the Opioid Crisis
- Title III—FDA and Controlled Substance Provisions
- Title IV—Offsets
- Title V—Other Medicaid Provisions
- Title VI—Other Medicare Provisions
- Title VII—Public Health Provisions
- Title VIII—Miscellaneous

CRS is publishing a series of reports on the SUPPORT Act. This report summarizes the provisions in Title III—the FDA and Controlled Substance Provisions, as well as Section 4004 "Modernizing the Reporting Requirements of Biological and Biosimilar Products" in Title IV—Offsets. Subtitle A of Title III addresses FDA medical product regulation and includes provisions that facilitate the development of new medical products for treatment of pain; provide for special packaging and disposal mechanisms for opioids; and amend postmarket study and labeling requirements. Subtitle B of Title III addresses Drug Enforcement Administration (DEA) regulation of controlled substances and includes provisions that, among other things, provide additional flexibility with respect to medication-assisted treatment (MAT) for opioid use disorders; modify controlled substances disposal requirements at qualified hospice programs; and authorize grants to states to increase participation of eligible collectors in drug-disposal programs.

[6] For more information on the PAYGO scorecards, see CRS Report R41157, *The Statutory Pay-As-You-Go Act of 2010: Summary and Legislative History*, and CRS Report RL31943, *Budget Enforcement Procedures: The Senate Pay-As-You-Go (PAYGO) Rule*.

[7] CRS Report R44493, *The Comprehensive Addiction and Recovery Act of 2016 (S. 524): Comparison of Senate- and House-Passed Versions*.

[8] CRS Report R44720, *The 21st Century Cures Act (Division A of P.L. 114-255)*, and CRS Report R44718, *The Helping Families in Mental Health Crisis Reform Act of 2016 (Division B of P.L. 114-255)*.

Section 4004 of Title IV amends reporting requirements for certain agreements between brand drug, generic drug, and biosimilar product manufacturers.

The report describes each section in Title III and Title IV in order. Relevant background is provided for context. The report concludes with an **Appendix** that catalogues deadlines and reporting requirements included in Title III provisions. This report is intended to reflect the SUPPORT Act at enactment (i.e., October 24, 2018). It does not track the law's implementation or funding and will not be updated. This report uses a number of acronyms, which are listed below.

Table 1. Abbreviations Used in This Report

ANDA	Abbreviated New Drug Application
APQ	Aggregate Production Quota
ARCOS	Automated Reports and Consolidated Orders System
CARA	Comprehensive Addiction and Recovery Act
CBO	Congressional Budget Office
CBP	Customs and Border Patrol
CDC	Centers for Disease Control and Prevention
CSA	Controlled Substances Act
DATA	Drug Addiction Treatment Act of 2000
DEA	Drug Enforcement Administration
DHS	Department of Homeland Security
DOJ	Department of Justice
ETASU	Elements to Assure Safe Use
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FTC	Federal Trade Commission
GAO	Government Accountability Office
HHS	Health and Human Services
IMF	International Mail Facility
IND	Investigational New Drug Application
MAT	Medication-Assisted Treatment
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
NDA	New Drug Application
PAYGO	Pay-As-You-Go
REMS	Risk Evaluation and Mitigation Strategies
RLD	Reference Listed Drug
RWE	Real World Evidence
SAMHSA	Substance Abuse and Mental Health Services Administration
SUPPORT	Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment

U.S.C.	United States Code
USPS	United States Postal Service

Title III—FDA and Controlled Substance Provisions

Subtitle A—FDA Provisions

FDA, pursuant to its authority under the Federal Food, Drug, and Cosmetic Act (FFDCA), is responsible for ensuring the safety and effectiveness of prescription and nonprescription drugs sold in the United States, regardless of whether they are controlled substances. FDA regulates the full life-cycle of a drug product, starting with drug development, through the approval process, and then for as long as the product remains on the market. Subtitle A addresses FDA medical product regulation and includes provisions that, among other things, facilitate the development of new medical products for treatment of pain; provide for special packaging and disposal mechanisms for opioids; and amend postmarket study and labeling requirements.

Chapter 1—In General

Section 3001. Clarifying FDA Regulation of Non-addictive Pain Products

Background

Before a drug may be marketed in the United States, it must be approved by FDA. To obtain FDA approval, the sponsor (generally the manufacturer) must submit to the agency a new drug application (NDA).[9] In reviewing an NDA, FDA considers whether the drug is safe and effective for the proposed use and that its benefits outweigh the risks; whether the labeling is appropriate; and whether the manufacturing methods and quality controls are adequate to ensure the drug's identity, strength, quality, and purity.[10] While the FFDCA requires *substantial evidence* of effectiveness, FDA generally exercises flexibility in what it requires as evidence, and not all reviews and applications follow the standard procedures. Legislation has required FDA to establish programs to expedite the development and review of drugs that address unmet needs or serious conditions, have potential to offer better outcomes or fewer side effects, or meet other criteria associated with improved public health. For example, the FDA Safety and Innovation Act (P.L. 112-144) established the breakthrough therapy designation, which requires FDA to expedite the development and review of a drug to treat a serious or life-threatening disease or condition if preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies. The 21st Century Cures Act (P.L. 114-255) further modified FDA drug and device regulatory pathways, addressing use of patient experience data, novel clinical trial design, and real world evidence (RWE) to support drug development and application approval.[11]

[9] CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*.

[10] FDA, "New Drug Application (NDA): Introduction," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm.

[11] For additional information about the 21st Century Cures Act provisions, see CRS Report R44720, *The 21st Century Cures Act (Division A of P.L. 114-255)*.

Provision

Section 3001(a) requires the Health and Human Services (HHS) Secretary, acting through the FDA Commissioner, to hold at least one public meeting with stakeholders to "address the challenges and barriers of developing non-addictive medical products intended to treat acute or chronic pain or addiction." This may include how the HHS Secretary incorporates the risks of misuse and abuse of a controlled substance into the risk-benefit assessments when reviewing a new drug or device; application of novel clinical trial designs and use of RWE and patient experience data for development of nonaddictive medical products intended to treat pain or addiction; development of opioid-sparing data for inclusion in the labeling of medical products intended for treatment of pain; and the application of breakthrough therapy designation for nonaddictive medical products intended to treat pain. Section 3001(c) defines *opioid-sparing* to mean "reducing, replacing, or avoiding the use of opioids or other controlled substances intended to treat acute or chronic pain."

Section 3001(b) requires the HHS Secretary, within one year of such public meeting(s), to issue at least one final guidance addressing the challenges of developing nonaddictive medical products for treatment of pain or addiction. The guidance must address the aforementioned topics, as specified.

Section 3002. Evidence-Based Opioid Analgesic Prescribing Guidelines and Report

Background

In 2016, the Centers for Disease Control and Prevention (CDC) issued guidelines for prescribing opioids for chronic pain.[12] These guidelines are recommendations and are not binding for prescribers. Instead, they are intended to strengthen communication between health care providers and patients, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid use. The CDC has not issued similar recommendations for opioid prescribing for acute pain.

Provision

Section 3002 requires the FDA Commissioner to develop evidence-based opioid analgesic prescribing guidelines for the treatment of acute pain, but only for the relevant therapeutic areas where such guidelines do not exist. In developing the guidelines, the Commissioner must consult with stakeholders, collaborate with the CDC Director and other federal agencies as appropriate, and provide for public notice and comment. Not later than one year after enactment or, if earlier, at the time the guidelines are finalized, the Commissioner must submit to Congress and post on the FDA website a report on how FDA will use the guidelines to protect the public health. The Commissioner must periodically update the guidelines and submit to Congress and post on the agency's website an updated report. The guidelines must be accompanied by a statement clarifying that they are not intended to be used to restrict, limit, delay, or deny coverage for, or access to, opioids prescribed for legitimate medical purposes and are intended to help inform clinical decisionmaking by prescribers and patients.

[12] Deborah Dowell, Tamara M. Haegerich, and Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, Atlanta, GA, March 18, 2016, https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

Chapter 2—Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now

Section 3012 and Section 3013. Notification, Nondistribution, and Recall of Controlled Substances; Single Source Pattern of Imported Illegal Drugs

Background

FFDCA Section 301 lists prohibited acts, such as the marketing of products that are adulterated or misbranded, or failure to comply with specific requirements in law.[13] FDA has various administrative tools for enforcing the FFDCA, including warning and untitled letters, import alerts, recalls, debarments, and civil monetary penalties. Other enforcement actions, such as injunctions and seizures, require assistance from the Department of Justice (DOJ).[14]

While FDA has the authority to require a recall of certain FDA-regulated products (e.g., food, tobacco, and medical devices), the agency does not have such mandatory recall authority over drug products. Instead, FDA can ask a manufacturer to voluntarily recall a drug product. Although the procedures for mandatory recalls depend upon the product at issue, in general, FDA initiates a mandatory recall by issuing an administrative order, which provides the responsible person subject to the recall an opportunity for an informal hearing.[15]

FFDCA Section 801(a) specifies the conditions under which an article shall be refused admission in the United States; for example, if it appears from the examination of samples or otherwise that the article has been manufactured, processed, or packed under insanitary conditions.[16]

Provisions

Section 3012 creates a new FFDCA Section 569D, which allows the HHS Secretary, upon determining with reasonable probability that a controlled substance would cause serious adverse health consequences or death, to issue an order requiring manufacturers, importers, distributors, or pharmacists of the controlled substance to immediately cease distribution. The person subject to the order must be provided the opportunity for an informal hearing, as specified, on whether adequate evidence exists to justify amending the order. Following issuance of an order, the HHS Secretary must (1) vacate the order if inadequate grounds exist to support the actions required by the order, (2) continue the order ceasing distribution until a date specified in the order, or (3) amend the order to require a recall of the controlled substance. If the HHS Secretary determines that the risk of recalling a controlled substance presents a greater health risk than not recalling, then the order must not include a recall or an order to cease distribution, as applicable. A person subject to the order must immediately cease distribution of or recall the controlled substance, as applicable. The HHS Secretary is allowed to require the person subject to the order to provide notice to appropriate persons (e.g., the manufacturer, distributor, importer of the controlled substance). An order under this section may be issued only by the HHS Secretary or an official designated by the Secretary if that official is the Director of FDA's Center for Drug Evaluation and Research (CDER) or an official senior to the CDER Director.

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[13] 21 U.S.C. §331.

[14] CRS Report R43609, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues*.

[15] FDA, Regulatory Procedures Manual, Chapter 7—Recall Procedures, August 2018, https://www.fda.gov/downloads/iceci/compliancemanuals/regulatoryProceduresManual/UCM074312.pdf.

[16] 21 U.S.C. §381.

Section 3012 also amends (1) FFDCA Section 301 to include as a prohibited act the failure to comply with an order to cease distribution under FFDCA Section 569D, and (2) FFDCA Section 801(a) to require an article to be refused admission if it appears upon examination or otherwise that it is a controlled substance subject to an order to cease distribution of or recall the drug.

Section 3013 amends FFDCA Section 801 by adding a new subsection (t), which allows the HHS Secretary, upon determining that a person is subject to debarment as a result of engaging in a pattern of importing or offering for import controlled substances or drugs from the same manufacturer, distributor, or importer, to issue an order determining that all drugs being offered for import by that entity are adulterated or misbranded unless evidence shows otherwise.

Section 3014. Strengthening FDA and CBP Coordination and Capacity

Background

Most drugs subject to FDA's administrative destruction authority come through international mail.[17] To prevent entry of unapproved, counterfeit, and potentially dangerous drugs, FDA investigators at International Mail Facilities (IMFs), in coordination with Customs and Border Protection (CBP), are responsible for monitoring mail importations of FDA-regulated products. Mail entering from abroad first arrives at a United States Postal Service (USPS) sorting facility, where it is sent to CBP for examination. CBP refers FDA-regulated products to FDA for review. Due to the volume of mail and amount of time it takes to inspect one package, FDA reportedly has been able to inspect less than 0.06% of packages presumed to contain drug products shipped through IMFs.[18] In FY2017, of the packages that FDA reviewed, 86% "contained illegal, illicit, unapproved, counterfeit and potentially dangerous drugs."[19]

The FY2018 Consolidated Appropriations Act (P.L. 115-141) provided $94 million for FDA to expand efforts related to processing opioids and other articles imported through IMFs, to be used for enhancing inspection capacity (e.g., increasing staffing, obtaining necessary equipment and supplies, and expanding and upgrading infrastructure, laboratory facilities, and data libraries).

Provision

Section 3014(a) requires the HHS Secretary, acting through the FDA Commissioner, to coordinate with the Secretary of the Department of Homeland Security (DHS) to carry out activities related to customs and border protection and in response to illegal controlled substances and drug imports, including at IMFs, that will provide improvements to such facilities.

Section 3014(b) requires the HHS Secretary, in collaboration with the DHS Secretary and Postmaster General, to provide import facilities that FDA operates in with facility upgrades and improved capacity for inspection and detection capabilities (e.g., improvements in equipment), as well as innovative technology, which must be interoperable with technology used by other federal agencies, including CBP.

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[17] FDA, "FDA's Administrative Destruction Authority," https://www.fda.gov/Forindustry/importProgram/Resources/ucm494173.htm.

[18] FDA, "FDA is Using Innovative Methods to Prevent Illegal Products with Hidden Drug Ingredients from Entering the United States," March 21, 2018, https://blogs.fda.gov/fdavoice/index.php/tag/fda-international-mail-facilities/.

[19] FDA, "Statement from FDA Commissioner Scott Gottlieb, M.D., on how new regulatory authorities will assist the agency in more forcefully addressing opioid crisis; included as part of the newly enacted Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act," October 24, 2018, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624268.htm.

Section 3014(c) requires the HHS Secretary, in consultation with the DHS Secretary and Postmaster General, to report to Congress on implementation of this section.

Chapter 3—Stop Illicit Drug Importation

Section 3022. Restricting Entrance of Illicit Drugs

Background: Section 3022(a)

To prevent entry of unapproved, counterfeit, and potentially dangerous drugs, FDA works with CBP to monitor mail importations of FDA-regulated products. Mail entering from abroad first arrives at a USPS sorting facility, where it is sent to CBP for examination. CBP refers FDA-regulated products (e.g., dietary supplements, drugs, and medical devices) to FDA for review. If during FDA screening a package is found or suspected to contain a controlled substance, it is referred to CBP for an "admissibility determination."[20] If an illegal controlled substance is initially identified in the IMF, CBP will seize it and the product will not go to FDA investigators.[21]

Provision: Section 3022(a)

Section 3022(a) requires the HHS Secretary, acting through the FDA Commissioner and in consultation with CBP, to develop and periodically update a mutually agreed upon list of controlled substances that the HHS Secretary will refer to CBP when they are offered for import through international mail and appear to violate applicable laws. The HHS Secretary must transfer to CBP controlled substances on that list and may transfer to CBP additional packages that appear to be the same as the package containing a controlled substance. CBP must receive such packages consistent with requirements of the CSA. Within nine months of enactment, the HHS Secretary, acting through the FDA Commissioner and in consultation with the Department of Homeland Security (DHS) Secretary, must submit a report to Congress on the implementation of this agreement.

Background: Section 3022(b)

Under FFDCA Section 301(cc), importation into the United States of an article of food by, with the assistance of, or at the direction of a person debarred is a prohibited act.[22] FFDCA Section 306(b) allows the HHS Secretary to debar or "prohibit" a person from importing or offering for import an article of food if the person has been convicted of a felony for conduct relating to the importation of food, or if the person has engaged in a pattern of importing adulterated food that presents a threat of serious adverse health or death to humans or animals.[23]

[20] FDA, International Mail Facilities, https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/ucm607485.htm.

[21] Statement of Dr. Scott Gottlieb, FDA Commissioner, before the Committee on Energy and Commerce, Subcommittee on Health, U.S. House of Representatives, "Combatting the Opioid Crisis: Prevention and Public Health Solution," March 21, 2018, https://docs.house.gov/meetings/IF/IF14/20180321/108049/HHRG-115-IF14-Wstate-GottliebS-20180321.pdf.

[22] 21 U.S.C. §331(cc).

[23] 21 U.S.C. §335a(b).

Provision: Section 3022(b)

Section 3022(b)(1) amends FFDCA Section 301(cc) to prohibit the importation of a drug by, with the assistance of, or at the direction of a person debarred.[24] Section 3022(b)(2) amends FFDCA Section 306(b) to allow the HHS Secretary to debar a person from importing or offering for import a drug if that person (1) has been convicted of a felony for conduct relating to the importation of any drug or controlled substance or (2) has engaged in a pattern of importing controlled substances that are prohibited from importation, or adulterated or misbranded drugs, as specified.

Background: Sections 3022(c) and 3022(d)

The importation of unapproved new drugs into the United States is prohibited. FFDCA Section 801(a) requires the Treasury Secretary to deliver to the HHS Secretary, upon request, "samples of food, drugs, devices, tobacco products, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of [HHS] and have the right to introduce testimony."[25] The HHS Secretary must provide to the Treasury Secretary a list of registered foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of drugs, devices, or tobacco products for importation into the United States. If any such establishments are not so registered, the HHS Secretary must request samples of such products to be delivered by the Treasury Secretary. FFDCA Section 801(a) specifies the conditions under which an article shall be refused admission.

Provisions: Sections 3022(c) and 3022(d)

Section 3022(c) amends FFDCA Section 801(a) to expand the circumstances under which an article must be refused admission to include if such article is a drug that is being imported or offered for import in violation of Section 301(cc) (i.e., by, with the assistance of, or at the direction of, a person debarred, as amended by this act). If it appears from examination of samples or otherwise that the article is a counterfeit drug, then its admission must be refused.

Section 3022(d) amends FFDCA Section 801 to add a new subsection (u), which allows an article, solely for purposes of importation, to be treated as a drug if (1) the article is not accompanied by an electronic import entry submitted using an authorized electronic data interchange system and is not designated in such system as a drug, device, dietary supplement, or other FFDCA-regulated product, and (2) the article is an ingredient that presents significant public health concern and is, or contains, an active ingredient that is either found in an approved drug or biologic, has been investigated under an investigational new drug application (IND), or has a chemical structure that is "substantially similar" to the chemical structure of an active ingredient to a drug or biologic that is approved or being investigated under an IND.

[24] FFDCA Section 301(cc) continues to prohibit importation of an article of food by, with the assistance of, or at the direction of a person debarred.

[25] 21 U.S.C. §381(a).

Chapter 4—Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging

Section 3032. Safety-Enhancing Packaging and Disposal Features

Background

FFDCA Section 505-1 allows the HHS Secretary (FDA by delegation of authority) to require a risk evaluation and mitigation strategy (REMS) for certain drugs, under specified conditions, to ensure that the benefits of a drug outweigh the risks.[26] As part of a REMS, the drug manufacturer may be required to provide certain information to patients (e.g., a medication guide or patient package insert) or a communication plan to health care providers,[27] or to impose certain restrictions on a drug's sale and distribution via one or more "Elements to Assure Safe Use" (ETASU).[28] An ETASU may, for example, require health care providers who prescribe the drug to have particular training, or pharmacies that dispense the drug to be specially certified. ETASU must not be "unduly burdensome on patient access to the drug," taking into consideration patients with serious or life-threatening diseases or conditions, and patients who have difficulty accessing health care (e.g., patients in rural areas).[29] If the reference listed drug (RLD, generally the brand-name drug) is subject to REMS, the generic product referencing the RLD is subject to two of the REMS components: (1) the medication guide or package insert and (2) the ETASU, specifically that the generic and RLD must enter into a single, shared system of ETASU.[30]

In December 2017, FDA held a public workshop to obtain input from stakeholders regarding the role of packaging, storage, and disposal options to address abuse, misuse, or inappropriate access of prescription opioids.[31]

Provision

Section 3032(a) amends FFDCA Section 505-1(e) to allow the HHS Secretary to require, as part of a REMS for a drug that has a serious risk of an adverse event occurring from an overdose of the drug (accidental or intentional) or from abuse of the drug, (1) that the drug be made available for dispensing to certain patients in packaging that may mitigate such risk (e.g., unit dose packaging), or (2) that the drug be dispensed to certain patients with a safe disposal packaging or safe disposal system for purposes of rendering drugs nonretrievable, if doing so may mitigate such serious risk and is sufficiently available.

Section 3032(b) amends FFDCA Section 505-1(f)(2)(C) to require the HHS Secretary to include patients with functional limitations when considering whether an ETASU is unduly burdensome on patient access to the drug.

Section 3032(c) amends FFDCA Section 505-1(i)(1) to require that if the RLD is subject to REMS with a packaging or disposal requirement, then the generic drug referencing that product

[26] 21 U.S.C. §355-1.

[27] 21 U.S.C. §355-1(e).

[28] 21 U.S.C. §355-1(f).

[29] 21 U.S.C. §355-1(f)(2)(C).

[30] 21 U.S.C. §355-1(i)(1).

[31] See FDA, "Packaging, Storage, and Disposal Options To Enhance Opioid Safety-Exploring the Path Forward; Public Workshop; Request for Comments," 82 *Federal Register* 50429, October 31, 2017.

would also be subject to the packaging or disposal requirement. FDA must allow packaging systems and safe disposal systems that are different from those required for the RLD.

Section 3032(d) requires the Government Accountability Office (GAO), not later than one year after enactment, to report to Congress on packaging and disposal technologies, as specified.

Chapter 5—Postapproval Study Requirements

Section 3041. Clarifying FDA Postmarket Authorities

Background

FFDCA Section 505-1(b)(1) defines, for the purposes of the REMS authority, an *adverse drug experience* to mean

> any adverse event associated with the use of a drug in humans, whether or not considered drug related, including—(A) an adverse event occurring in the course of the use of the drug in professional practice; (B) an adverse event occurring from an overdose of the drug, whether accidental or intentional; (C) an adverse event occurring from abuse of the drug; (D) an adverse event occurring from withdrawal of the drug; and (E) any failure of expected pharmacological action of the drug.[32]

According to FDA, there are limited data on the long-term efficacy of opioid use, and whether long-term use increases the likelihood of addiction.[33] More research on the safety and efficacy profile of opioids already on the market is needed.[34]

FFDCA Section 505(o)(4) allows the HHS Secretary to require safety-related labeling changes based on new safety information that becomes available after approval of the drug or biological product.[35] The HHS Secretary is required to promptly notify the responsible person, who is then required, within 30 days, to submit proposed changes to the approved labeling that reflect the new safety information (e.g., changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions), or to notify the Secretary that the responsible person does not believe a labeling change is warranted. The law specifies the process by which the Secretary is to review the supplement and to address with the responsible person disagreement regarding the labeling.

Provision

Section 3041(a) amends the definition of *adverse drug experience* in FFDCA Section 505-1(b)(1) to clarify FDA's authority to require postmarket studies on certain drugs that may have reduced effectiveness over time (e.g., opioids).[36]

Section 3041(b) amends FFDCA Section 505(o)(4) to allow the HHS Secretary to require labeling changes based on new effectiveness information. It also modifies the process for

[32] 21 U.S.C. §355-1(b)(1).

[33] FDA, "Statement from FDA Commissioner Scott Gottlieb, M.D., on how new regulatory authorities will assist the agency in more forcefully addressing opioid crisis; included as part of the newly enacted Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act," October 24, 2018.

[34] Ibid.

[35] 21 U.S.C. §355(o)(4).

[36] More specifically, section 3041(a) amends the definition of *adverse drug experience* in FFDCA Section 505-1(b)(1)(E) to include "reduced effectiveness under the conditions of use prescribed in the labeling of such drug, but which may not include reduced effectiveness that is in accordance with such labeling."

notification by the Secretary and submission of new information by the responsible person to include the new effectiveness information.

Section 3041(c) requires the HHS Secretary, within one year of enactment, to issue guidance addressing the circumstances under which FDA may require postmarket studies or clinical trials to assess the potential reduction in effectiveness of a drug, as well as how FDA may require postmarket studies or clinical trials and safety labeling changes related to use of controlled substances for acute or chronic pain.

Subtitle B—Controlled Substance Provisions

The DEA, under the Controlled Substances Act (CSA), has primary responsibility for regulating the use of controlled substances for legitimate medical, scientific, research, and industrial purposes, and for preventing these substances from being diverted for illegal purposes. While the FFDCA requires that certain drugs be dispensed only pursuant to a prescription from a health care provider, the CSA sets forth requirements for dispensing controlled substances specifically. Subtitle B addresses DEA regulation of controlled substances and includes provisions that, among other things, provide additional flexibility with respect to medication-assisted treatment (MAT) for opioid use disorders; modify controlled substances disposal requirements at qualified hospice programs; and authorize grants to states to increase participation of eligible collectors in drug-disposal programs.

Chapter 1—More Flexibility with Respect to Medication-Assisted Treatment for Opioid Use Disorders

Section 3201-3203. Allowing for More Flexibility with Respect to Medication-Assisted Treatment for Opioid Use Disorders; Medication-Assisted Treatment for Recovery from Substance Use Disorder; and Grants to Enhance Access to Substance Use Disorder Treatment

Background

Under the CSA, substances are placed into one of five schedules based on their medical use, potential for abuse, and safety or dependence liability.[37] Schedule I substances have "a high potential for abuse" with "no currently accepted medical use in treatment in the United States" whereas substances in schedules II-V have recognized medical uses.[38] Every person who manufactures, distributes, or dispenses any controlled substance is required to register with the Attorney General,[39] unless they are exempt.[40] A qualifying practitioner who dispenses controlled substances for purposes of maintenance or detoxification treatment is required to obtain a

[37] 21 U.S.C. §812.

[38] For more information, see CRS Report R45164, *Legal Authorities Under the Controlled Substances Act to Combat the Opioid Crisis*.

[39] 21 U.S.C. §822.

[40] 21 U.S.C. §822(c). For more information, see CRS Report R45164, *Legal Authorities Under the Controlled Substances Act to Combat the Opioid Crisis*.

separate annual registration from DEA.[41] However, if the qualifying practitioner dispenses schedule III, IV, or V controlled substances approved for maintenance or detoxification treatment, he or she may apply for a waiver from the separate registration, provided certain requirements are met.[42] This waiver is referred to as a "DATA waiver," named after the law by which it was established—the Drug Addiction Treatment Act of 2000 (DATA 2000; P.L. 106-310). Buprenorphine is a schedule III controlled substance and currently the only medication that meets the conditions for the waiver.

Under current law, a DATA-waived qualified practitioner may treat 30 patients at one time the first year and may submit a second notification of intent after a year to increase the patient limit to 100. In 2016, the Secretary promulgated final regulations setting the patient limit at 275 after two years, subject to certain conditions.[43]

Pursuant to DATA 2000, the term "qualifying practitioner" included only physicians. However, CARA added a temporary authority allowing "qualifying other practitioners" (i.e., nurse practitioners and physician assistants) to obtain DATA waivers until October 1, 2021. The DEA issued a final rule in January 2018 that implemented these changes.[44]

To obtain a DATA waiver, the practitioner must meet certain requirements. For a practitioner who is a "qualifying physician," he or she must be licensed under state law and must meet at least one of the other specified conditions (e.g., board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties).[45] Current law does not specify whether a qualifying physician may be granted a waiver if some of these training requirements are met during medical school or residency.

Provisions

Section 3201(a) amends the CSA[46] by allowing a DATA-waived qualified practitioner to treat 100 patients at any one time, if the practitioner holds "additional credentialing"[47] or provides medication-assisted treatment (MAT)[48] with drugs that have been approved for such purpose in a qualified practice setting.[49] Section 3201(a) allows a qualified practitioner to treat 275 patients at any one time if additional requirements are met, as specified in regulations.[50]

Section 3201(b) amends the CSA by removing the time limit imposed by CARA during which nurse practitioners and physician assistants may provide controlled substances maintenance and

[41] 21 U.S.C. §823(g)(1).

[42] 21 U.S.C. §823(g)(2).

[43] HHS, SAMHSA, "Medication Assisted Treatment for Opioid Use Disorders," 81 *Federal Register* 44711-44739, July 8, 2016.

[44] DEA, "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder," 83 *Federal Register* 3,071, January 23, 2018.

[45] 21 U.S.C. §823(g)(2)(G)(ii).

[46] 21 U.S.C. §823(g)(2)(B)(iii).

[47] 42 C.F.R. §8.2 defines "additional credentialing" as board certification in addiction medicine or addiction psychiatry by the American Board of Addiction Medicine, the American Board of Medical Specialties, or the American Osteopathic Association or certification by the American Board of Addiction Medicine, or the American Society of Addiction Medicine.

[48] Medication-assisted treatment is defined as the combined use of medication and other services to treat addiction. For more information, see CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*.

[49] "Qualified practice setting" is defined in 42 C.F.R. §8.615.

[50] 42 C.F.R. §§8.610-8.655.

detoxification treatment, effectively making this authority permanent.[51] Section 3201(d) expands the definition of "qualifying other practitioner" to include clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives, while Section 3201(c) imposes a time limit on these new qualifying other practitioners, authorizing them to obtain DATA waivers until October 1, 2023.

Section 3201(e) requires the Secretary, in consultation with the DEA, to submit a report to Congress, not later than two years after enactment, assessing the care provided by qualifying physicians treating more than 100 patients and qualifying other practitioners treating more than 30 patients, with appropriate recommendations based on the findings. The report shall also study opioid use disorder treatment more generally, such as average frequency that qualifying practitioners see their patients and treatment retention rates for patients.

Section 3202(a) amends the CSA to expand the conditions under which a physician may be considered "qualified" in order to be granted a DATA waiver.[52] These new conditions include a physician that (1) graduated in good standing from an accredited U.S. school of allopathic or osteopathic medicine, and (2) received training on treating and managing opioid-dependent patients, as well as other training that the Secretary determines should be included in the allopathic or osteopathic medicine curriculum (e.g., pain management training). Section 3202(b) requires the Secretary to consider ways to ensure that an adequate number of qualifying practitioners with a specialty in pediatrics can be granted a DATA waiver to treat youth with substance use disorders.

Section 3203(a) requires the Secretary to establish a grant program for accredited allopathic or osteopathic schools and teaching hospitals to develop curricula that meet the requirements outlined in Section 3202. Section 3203(b) authorizes an appropriation of $4 million for each of FY2019 through FY2023.

Section 3204. Delivery of a Controlled Substance by a Pharmacy to be Administered by Injection or Implantation

Background

Under the CSA, a pharmacist may not dispense a controlled substance to anyone other than the ultimate user,[53] which has reportedly caused issues for patients and physicians in cases where controlled substances require in-office administration (e.g., those administered by injection or implantation).[54] Buprenorphine is a schedule III controlled substance prescribed for treatment of opioid use disorders that may require administration via injection or implantation.[55]

[51] 21 U.S.C. §823(g)(2)(G).

[52] 21 U.S.C. §823(g)(2)(G)(ii).

[53] The CSA (21 U.S.C. §802(27)) defines an *ultimate user* as a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household. The CSA (21 U.S.C. §802(10)) also defines *dispense* to mean "to deliver a controlled substance to an ultimate user ... by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance."

[54] See FDA Law Blog, "Legislation Would End "Constructive Transfer" and Change CSA Definition of "Dispense" to Permit Pharmacy Delivery of Controlled Substances to Physicians for In-Office Administration," September 26, 2014, http://www.fdalawblog.net/2014/09/legislation-would-end-constructive-transfer-and-change-csa-definition-of-dispense-to-permit-pharmacy/.

[55] For more information, see CRS Report R45279, *Buprenorphine and the Opioid Crisis: A Primer for Congress*.

Provision

Section 3204(a) amends the CSA by allowing a pharmacy, under specified conditions, to deliver a controlled substance to the practitioner, pursuant to a prescription, to be administered by the practitioner to the patient by injection or implantation for the purpose of maintenance or detoxification treatment.[56] It must be administered to the patient by the physician within 14 days after the physician has received the controlled substance. The Attorney General, in coordination with the Secretary, can reduce the number of days within which the physician must administer the controlled substance if such reduction will reduce risk of diversion or protect public health. However, the Attorney General cannot make a modification that is less than seven days. Section 3204(b) requires the GAO to study and submit a report to Congress on access to and potential diversion of controlled substances administered by injection or implantation not later than two years after enactment.

Chapter 2—Empowering Pharmacists in the Fight Against Opioid Abuse

Section 3212. Programs and Materials for Training on Certain Circumstances Under Which a Pharmacist May Decline to Fill a Prescription

Background

According to the DEA, pharmacists should remain vigilant about forged or altered prescriptions, as the pharmacist holds legal responsibility for knowingly dispensing a prescription that was not issued for professional treatment.[57] The circumstances under which a controlled substance can be prescribed and dispensed vary, depending on the schedule of the substance.[58] Per DEA regulations, a prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner, and the pharmacist has a corresponding responsibility with the prescribing practitioner for the controlled substances prescription.[59] However, pharmacists, health care providers, and patients may not always be aware of circumstances under which a pharmacist can decline to fill a prescription, specifically relating to forged or altered prescriptions.[60]

Provision

Section 3212 requires the Secretary, in consultation with the DEA Administrator, FDA Commissioner, CDC Director, and Assistant Secretary for Mental Health and Substance Use at SAMHSA, and with input from relevant stakeholders, to develop and disseminate materials for pharmacists, health care providers, and patients. The purpose of these materials is to describe (1) the circumstances under which a pharmacist may deny filling a prescription for a controlled substance because the pharmacist suspects the prescription is fraudulent, forged, or suspicious,

[56] Section 3204(a) adds a new CSA Section 309A.

[57] DEA, A Pharmacist's Guide to Prescription Fraud, https://www.deadiversion.usdoj.gov/pubs/brochures/pharmguide.htm.

[58] 21 U.S.C. §829.

[59] 21 C.F.R. §1306.04.

[60] DEA, A Pharmacist's Guide to Prescription Fraud, https://www.deadiversion.usdoj.gov/pubs/brochures/pharmguide.htm.

and (2) other federal requirements pertaining to declining a prescription for a controlled substance. The Secretary is required to include instructions for the pharmacist on how to decline to fill a prescription, as well as information for health care practitioners and the public on the pharmacist's ability to decline to fill a prescription.

Chapter 3—Safe Disposal of Unused Medication

Sections 3222-3223. Disposal of Controlled Substances of a Hospice Patient by Employees of a Qualified Hospice Program; GAO Study and Report on Hospice Safe Drug Management

Background

To make it easier for patients to dispose of unwanted controlled substances, in 2010, the Secure and Responsible Drug Disposal Act (the "Disposal Act"; P.L. 111-273) was signed into law. The Disposal Act amended the CSA to authorize ultimate users (i.e., patients) to deliver their pharmaceutical controlled substances to another entity for the purpose of disposal in accord with regulations promulgated by the Attorney General.[61] In 2014, the DEA issued a final rule on the disposal of controlled substances that expanded the entities to which ultimate users can transfer controlled substances, as well as the methods by which these controlled substances can be collected.[62] However, the final rule clarified that while a member of the hospice patient's household may dispose of an unused medication, a home hospice employee could not do so unless authorized by law (such as state law). Home hospice is often the last line of medical care provided to a patient; therefore, medications with high risk for diversion and misuse by those for whom the medication was not intended can often be left in the home once it is no longer needed.

Provision

Section 3222(a) amends the CSA to allow an employee of a qualified hospice program to dispose of a controlled substance after (1) the death of a person receiving hospice care, (2) the expiration of the controlled substance, or (3) a modification in the plan of care of the hospice patient if the employee is the physician of the person receiving hospice care and has a DEA registration.[63] Section 3222(a) defines a "qualified hospice program" as a hospice program that has written policies and procedures for disposal of the controlled substance after the patient's death that are in place when the controlled substance is first ordered and that documents the disposal in the patient's clinical record after disposal is completed.

Section 3222(b) allows the Attorney General to issue guidance to hospice programs to fulfill the requirements under Section 3222(a). Section 3222(c) is a rule of construction provision that clarifies that nothing in this section is to be construed as preventing a state or local government from imposing additional controls or restrictions relating to the regulation of disposal of controlled substances in hospice programs.

Section 3223 requires GAO to study and report to Congress, not later than 18 months after enactment, on the federal requirements applicable to the management and disposal of controlled

[61] 21 U.S.C. §822. For more information, see CRS Report R45164, *Legal Authorities Under the Controlled Substances Act to Combat the Opioid Crisis*.

[62] DEA, "Disposal of Controlled Substances," 79 *Federal Register* 53,520, September 9, 2014.

[63] 21 U.S.C. §822(g).

substances in the home, as well as the challenges encountered by select qualified hospice programs regarding the disposal of controlled substances.

Chapter 4—Special Registration for Telemedicine Clarification

Section 3232. Regulations Relating to a Special Registration for Telemedicine

Background

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("Ryan Haight Act"; P.L. 110-425) was enacted as a response to the increase in illegal online sales of controlled substances. Among other things, the Ryan Haight Act amended the CSA to prohibit the delivery, distribution, and dispensing of a controlled substance via the internet without a valid prescription issued pursuant to an in-person medical evaluation.[64] The law exempts from the in-person medical evaluation requirement "a practitioner engaged in the practice of telemedicine," as defined, and allows the Attorney General to issue a special registration to practice telemedicine.[65] The law requires the Attorney General to promulgate regulations specifying the limited circumstances in which a special registration for telemedicine may be issued and the procedures for obtaining such a special registration.[66] A final regulation specifying the limited circumstances and procedures for obtaining such registration has not yet been promulgated.[67]

Provision

Section 3232 would amend CSA Section 311(h)(2) to require that not later than one year after enactment, the Attorney General, in consultation with the HHS Secretary, promulgate final regulations specifying the limited circumstances in which a special registration for telemedicine may be issued and the procedure for obtaining the registration.

Chapter 5—Synthetic Abuse and Labeling of Toxic Substances

Section 3241. Controlled Substance Analogues

Background

The Controlled Substances Analogue Enforcement Act of 1986 (the Analogue Enforcement Act) was enacted as Subtitle E of the Anti-Drug Abuse Act of 1986 (P.L. 99-570). This law amended the Controlled Substances Act to treat a controlled substance analogue (intended for human consumption) as a controlled substance under Schedule I.[68] Under this law, a controlled substance analogue is defined as a substance if

[64] 21 U.S.C. §829(e).

[65] 21 U.S.C. §831(h)(1).

[66] 21 U.S.C. §831(h)(2).

[67] An interim rule was published on April 6, 2009; see DEA, "Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008," 74 *Federal Register* 15603. For additional information about the special registration, see CRS Report R45240, *The Special Registration for Telemedicine: In Brief*.

[68] 21 U.S.C. §813.

> (i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;
>
> (ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or
>
> (iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.[69]

Of note, many of the synthetic cathinones marketed under household names such as "bath salts" or "plant food" are stamped with "not intended for human consumption." This action is intended to circumvent the Analogue Enforcement Act under the CSA.[70] One barrier to prosecuting individuals for violations relating to synthetic substances such as "bath salts" that are marketed as "not intended for human consumption" is proving that despite this labeling, these substances are indeed intended for consumption.

In addition, the Analogue Enforcement Act requires that a substance must be chemically similar to a controlled substance in order to be considered an analogue. The DEA has noted that the chemical structure of a substance can be manipulated such that it is not chemically similar to a controlled substance but still produces effects that are pharmacologically similar to a Schedule I or Schedule II controlled substance.[71] These manipulations can continuously occur to stay ahead of scientists and law enforcement.

The DEA has also pointed out several prosecutorial challenges for using the Analogue Enforcement Act to prevent drug use and abuse. These challenges include the following:

- Each case requires additional investigation to determine whether the substance in question was "intended for human consumption" and can therefore be considered an analogue.
- A forensic chemist can testify to laboratory analysis that would identify a controlled substance in a case; however, to establish that a substance is an analogue, additional testimony from experts in other disciplines is needed.
- In cases involving potential analogue substances, experts must establish that the substance has a substantially similar chemical structure (and pharmacological effect) to a Schedule I controlled substance. The threshold for "substantially similar" is subjective and may differ from expert to expert.

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[69] 21 U.S.C. §802(32)(A). For more information on which drugs or substances may be placed on Schedule II, see 21 U.S.C. §812(b)(2).

[70] Statement for the record of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the U.S. Congress, United States Senate Caucus on International Narcotics Control, *Dangerous Synthetic Drugs*, 113th Cong., 1st sess., September 25, 2013.

[71] Statement for the record of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the U.S. Congress, United States Senate Caucus on International Narcotics Control, *The Dangers of Synthetic Cannabinoids and Stimulants*, 112th Cong., 1st sess., April 6, 2011; Statement of the Honorable Michele Leonhart, Administrator, Drug Enforcement Administration before the United States House of Representatives Committee on Appropriations, Subcommittee on Commerce, Justice, Science, and Related Agencies, 113th Cong., 1st sess., April 12, 2013.

- Establishing a substance as an analogue in one case does not carry over to other cases. Each case involving the potential analogue substance must separately establish that the substance is indeed an analogue.[72]

Provision

Section 3241 amends the Analogue Enforcement Act (21 U.S.C. §813) by adding factors to consider in determining whether a controlled substance analogue was intended for human consumption. These factors include

- the marketing, advertising, and labeling of the substance;
- the known efficacy or usefulness of the substance for the marketed, advertised, or labeled purpose;
- the difference between the price at which the substance is sold and the price at which the substance it is purported to be or advertised as is normally sold;
- the diversion of the substance from legitimate channels and the clandestine importation, manufacture, or distribution of the substance;
- whether the defendant knew or should have known the substance was intended to be consumed by injection, inhalation, ingestion, or any other immediate means; and
- any controlled substance analogue that is manufactured, formulated, sold, distributed, or marketed with the intent to avoid the provisions of existing drug laws.

For purposes of §813, evidence that a substance was not marketed, advertised, or labeled for human consumption, by itself, is not sufficient to establish that the substance was *not* intended for human consumption.

Chapter 6—Access to Increased Drug Disposal

Sections 3252-3260. Definitions; Authority to Make Grants; Application; Use of Grant Funds; Eligibility for Grant; Duration of Grants; Accountability and Oversight; Duration of Program; and Authorization of Appropriations

Background

As mentioned earlier in this report, the Disposal Act[73] authorized the Attorney General, acting through the DEA Administrator, to issue regulations that permit members of the public to give their unwanted, unused, or expired prescription-controlled substance drugs (including opioid medications) to federally authorized entities for disposal in a manner that reduces their potential misuse and abuse.[74] The Disposal Act required the Attorney General, when developing these regulations, to "take into consideration the public health and safety, as well as the ease and cost of

[72] Ibid.

[73] P.L. 111-273, 124 Stat. 2858 (codified at 21 U.S.C. §822).

[74] 21 U.S.C. §822(g)(1)(B).

program implementation and participation by various communities."[75] The promulgated regulations provide for three secure collection and disposal options.[76] The first option is for federal, state, tribal, or local law enforcement agencies to organize periodic drug "take-back" events for ultimate users to get rid of their unused controlled substance pharmaceuticals.[77] Second, law enforcement entities and DEA-registered parties (referred to as "registrants" under the CSA)[78] that have received specific DEA approval to collect unwanted controlled substances for disposal purposes[79] may conduct "mail-back" programs that allow the public to send unwanted controlled substances to collectors via the mail.[80] The third option permits law enforcement agencies or authorized collectors to install and maintain secure collection receptacles at their DEA-registered location for ultimate users to deposit their controlled substance drugs.[81] Finally, the regulations require collectors to destroy controlled substances using certain methods and following certain procedures that render the collected controlled substances "non-retrievable."[82]

An October 2017 report by GAO revealed that approximately 3% of pharmacies and other DEA-registered entities eligible to collect unused prescription drugs for disposal have voluntarily sought DEA authorization to become registered collectors.[83] (The GAO report focused specifically on the use of collection receptacles and did not examine the other two methods of disposal available under the Disposal Act implementing regulations.)[84] According to the GAO, the relatively low rate of participation of eligible entities as authorized collectors could be attributed to the costs associated with purchasing, installing, and managing the disposal bins and some confusion over how to comply with the DEA regulations governing these activities.[85]

[75] 21 U.S.C. §822(g)(2).

[76] DEA, "Disposal of Controlled Substances," 79 *Federal Register* 53,520, September 9, 2014 (codified at 21 C.F.R. pt. 1317).

[77] 21 C.F.R. §1317.65(a). Private entities or community groups may also partner with law enforcement to hold community drug take-back events. Ibid.

[78] 21 C.F.R. §1300.02(b). As mentioned earlier in this report, the CSA requires certain persons who handle controlled substances to register with the DEA and comply with the terms and conditions of the registration. 21 U.S.C. §822(a).

[79] Eligible registrants who may seek DEA authorization to be collectors are manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies. 21 C.F.R. §1317.40(a).

[80] 21 C.F.R. §1317.70(a). The physical packages in which the drugs are shipped must comply with certain regulatory requirements (e.g., be tamper-resistant and have tracking numbers). 21 C.F.R. §1317.70(c).

[81] 21 C.F.R. §1317.75(a). Installation and maintenance of the collection receptacles must meet regulatory requirements specified in 21 C.F.R. §1317.75(d)-(g). A long-term care facility may also dispose of controlled substances on behalf of its residents (or former residents) by using on-site collection receptacles that are installed, managed, and maintained by authorized retail pharmacies or hospitals/clinics with an on-site pharmacy. 21 C.F.R. §1317.75(d)(2)(iii) and 21 C.F.R. §1317.80.

[82] 21 C.F.R. §1317.90 and 21 C.F.R. §1317.95. The regulations define "non-retrievable" to mean a controlled substance that has been permanently and irreversibly altered such that it is "unavailable and unusable for all practical purposes." 21 C.F.R. §1300.05.

[83] U.S. Government Accountability Office, Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs, GAO-18-25, October 2017, p. 7, https://www.gao.gov/assets/690/687719.pdf.

[84] Ibid., at p. 3.

[85] Ibid., at pp. 13-16.

Provisions

Section 3251 provides a short title for Chapter 6, the "Access to Increased Drug Disposal Act of 2018." Section 3252 defines particular terms used in this chapter, including defining the term "Attorney General" to mean "the Attorney General, acting through the Assistant Attorney General for the Office of Justice Programs" and the term "authorized collector" to mean "a narcotic treatment program, a hospital or clinic with an on-site pharmacy, a retail pharmacy, or a reverse distributor, that is authorized [by the DEA] as a collector." Section 3253 provides the Attorney General with authority to make grants to states in an effort to increase participation rates of eligible collectors as authorized collectors. A state applying for a Section 3253 grant award must submit certain information specified in Section 3254, including (1) designating a single state agency responsible for complying with the conditions of the grant, (2) describing a plan to increase the participation of eligible collectors as authorized collectors, and (3) explaining how the state will select eligible collectors to be served under the grant.

Section 3255 provides that a Section 3253 grant recipient (and any subrecipients of the grant) may use the grant funds only toward the costs associated with participating in authorized disposal activities. In accordance with Section 3256, the Attorney General shall award these grants to only five states, though at least three of these states must be "in the lowest quartile of States based on the participation rate of eligible collectors as authorized collectors, as determined by the Attorney General."[86] In addition, Section 3257 directs the Attorney General to establish the duration of these grants, while Section 3259 provides that the Section 3253 grant program is available for "each of the first 5 fiscal years beginning after the date of enactment of this Act."[87] Section 3258 requires a state receiving this grant award to submit a report to the Attorney General that contains (1) a list of the "ultimate recipients of the grant amounts," (2) a description of the state's activities supported by this grant funding, and (3) a discussion of "performance measures relating to the effectiveness of the grant, including changes in the participation rate of eligible collectors as authorized collectors."[88] Finally, Section 3260 provides an authorization of appropriations to the Attorney General of such sums as may be necessary for carrying out this chapter.

Chapter 7—Using Data to Prevent Opioid Diversion

Sections 3272-3274. Purpose; Amendments; and Report

Background

Manufacturers and distributors of Schedule I and II drugs must file reports[89] with the DEA through the Automated Reports and Consolidated Orders System (ARCOS),[90] which is an automated drug reporting system that allows the agency to "monitor[] the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level."[91] Certain narcotics listed in Schedules III and

[86] P.L. 115-271, §3256.

[87] P.L. 115-271, §§3257, 3259.

[88] P.L. 115-271, §3258 (1)-(3).

[89] 21 C.F.R. §§1304.31 and 1304.32.

[90] 21 C.F.R. §§1304.31-1304.33.

[91] Drug Enforcement Administration, Automation of Reports and Consolidated Orders System (ARCOS), https://www.deadiversion.usdoj.gov/arcos/index.html.

IV are also covered by the ARCOS reporting requirements.[92] According to the DEA, U.S. attorneys and DEA investigators may use ARCOS-controlled substances transaction information "to strengthen criminal cases in the courts."[93]

DEA, other federal agencies, and state and local investigative agencies use ARCOS information. Approximately 1,100 distributors and manufacturers report to ARCOS, and over 30 million transactions are reported to ARCOS each year.[94]

Provisions

Section 3272 states the purpose of Chapter 7, which is to provide drug manufacturers and distributors with access to anonymized information through ARCOS to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids and reduce diversion rates. It also states that nothing within the section should be construed to absolve a registrant from the responsibility to identify, stop, and report suspicious orders or maintain effective controls against diversion.

Section 3273 amends Section 307 of the CSA by requiring the Attorney General to make certain data available to registered manufacturers and distributors through the ARCOS system on a quarterly basis.[95] These data include the total number of registrants that distribute controlled substances to a pharmacy or practitioner registrant[96] and the total quantity and type of opioids[97] distributed to each pharmacy and practitioner registrant. Manufacturers and distributors are responsible for reviewing these data.

Section 3273 also requires the Attorney General to consider certain information made available under 21 U.S.C. §827(f)[98] when determining whether to initiate proceedings against a registered manufacturer or distributor based on the failure to maintain effective controls against diversion or noncompliance with other CSA statutory or regulatory requirements. It directs the Attorney General to prepare and make available, once every six months, a standardized report to state regulatory, licensing, attorneys general, and law enforcement agencies, containing descriptive and analytic information on the actual distribution patterns, as gathered through ARCOS. Data are to include detailed amounts, outliers, and trends of distributor and pharmacy registrants in such states for the controlled substances contained in Schedule II which the Attorney General has determined to have the highest abuse.

Section 3273 adds a new prohibited act to Section 402 of the CSA, which makes unlawful the failure of a registered manufacturer or distributor of opioids to review the most recent information, directly related to the customers of the manufacturer or distributor, made available by the Attorney General through ARCOS.[99] Except as provided in 21 U.S.C. §842(c)(1)(B)(ii), the maximum civil penalty for violating this new provision is $10,000.

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[92] 21 C.F.R. §1304.33(d).

[93] Drug Enforcement Administration, Automation of Reports and Consolidated Orders System (ARCOS), https://www.deadiversion.usdoj.gov/arcos/index.html.

[94] Ibid.

[95] 21 U.S.C. §827.

[96] These data are to be aggregated by the name and address of each pharmacy and practitioner registrant.

[97] These data must be listed by Administration Controlled Substances Code Number.

[98] As redesignated by Section 3273.

[99] 21 U.S.C. §842.

Under 21 U.S.C. §842(c)(1)(B)(ii), in the case of any violation described in 21 U.S.C. §842(c)(1)(B)(i) committed by a registered manufacturer or distributor of opioids and related to the reporting of suspicious orders for opioids, failing to maintain effective controls against diversion of opioids, or failing to review the most recent information made available by the Attorney General in accordance with Section 307(f) of the CSA, as added by this act, the maximum civil penalty is $100,000.

Section 3273 also specifies a maximum criminal fine of $500,000 for a violation committed by a registered manufacturer or distributor of opioids that relates to the reporting of suspicious orders for opioids, failing to maintain effective controls against diversion of opioids, or failing to review the most recent information made available by the Attorney General in accordance with Section 307(f).[100]

Section 3274 requires the Attorney General to submit to Congress within one year of enactment of this act a report that provides information about how the Attorney General is using data in ARCOS to identify and stop suspicious activity.

Chapter 8—Opioid Quota Reform

Section 3282. Strengthening Considerations for DEA Opioid Quotas

Background

The CSA includes a production quota system that requires the DEA to establish the total amount of each basic class of Schedule I and II controlled substances and certain listed chemicals[101] that may be manufactured in a given calendar year, in order "to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks."[102] The DEA establishes this quota, referred to as the aggregate production quota (APQ), for approximately 200 Schedule I and II controlled substances.[103] The DEA also assigns individual production quotas to controlled substance manufacturers that prevent the APQ from being exceeded.[104] The CSA allows registrants to apply for an increase in individual manufacturing quota if it is necessary "to meet ... estimated disposal, inventory, and other requirements during the remainder of that year."[105]

By regulation, the DEA Administrator must consider the following factors in making APQ determinations: (1) the total disposal of the controlled substance during the current and two preceding years; (2) trends in new disposal of the controlled substance; (3) total inventories (actual or estimated) of "the class and all substances manufactured from the class [of controlled substances listed in Schedule I or II]"; (4) projected demand for a particular controlled substance;

[100] Paragraphs (5), (10), or (17) of subsection (a) of 21 U.S.C. §842.

[101] These listed chemicals are ephedrine, pseudoephedrine, and phenylpropanolamine, which are ingredients commonly found in over-the-counter cold medicines that may be used in the production of methamphetamine and amphetamine. See Drug Enforcement Administration, *CMEA (Combat Methamphetamine Epidemic Act) Questions & Answers*, https://www.deadiversion.usdoj.gov/meth/q_a_cmea.htm.

[102] 21 U.S.C. §826(a).

[103] Statement for the record of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the U.S. Congress, United States Senate Caucus on International Narcotics Control, *Improving Management of the Controlled Substances Quota Process*, 114th Cong. 1st sess., May 5, 2015.

[104] 21 U.S.C. §826(b).

[105] See 21 U.S.C. §826(b) and (e).

and (5) other relevant factors affecting the use of controlled substances, including changes in the currently accepted medical use of a controlled substance, the economic and physical availability of the raw materials necessary to produce a controlled substance, and recent unforeseen emergencies (i.e., natural disasters).[106]

A registrant may not manufacture a Schedule I or II controlled substance or a specified listed chemical that is (1) not expressly authorized by his registration and by the individual quota assigned to him by the DEA, or (2) in excess of that quota.[107]

Provision

Section 3282 amends Section 306 of the CSA by adding to the DEA considerations for opioid quotas.[108] In establishing annual need, the Attorney General may, if the Attorney General determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance, establish an aggregate or individual production quota, or a procurement quota established by the Attorney General by regulation, in terms of pharmaceutical dosage forms[109] prepared from or containing the controlled substance.[110]

In establishing quotas for fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone (referred to as a "covered controlled substance"), the Attorney General will estimate the amount of diversion of the covered controlled substance that occurs in the United States. In estimating such diversion, the Attorney General must consider, in consultation with the HHS Secretary, information they determine to be reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States and whatever other sources of information the Attorney General determines reliable. After estimating the amount of diversion of a covered controlled substance, the Attorney General will make appropriate quota reductions from the quota the Attorney General would have otherwise established had such diversion not been considered.

For any year for which the approved APQ for a covered controlled substance is higher than the approved APQ for the covered controlled substance for the previous year, the Attorney General, in consultation with the HHS Secretary, will include in the final order an explanation of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.

Not later than one year after enactment of this act, the Attorney General must submit to Congress (1) an anonymized count of the total number of manufacturers issued individual manufacturing quotas that year for the covered controlled substance and (2) an anonymized count of how many such manufacturers were issued an approved manufacturing quota that was higher than the quota issued to that manufacturer for the covered controlled substance in the previous year.[111] Also within a year of enactment, the Attorney General must submit a report to Congress on how the Attorney General, when fixing and adjusting quotas for covered controlled substances, will take into consideration changes in the accepted medical use of the covered controlled substances and work with the HHS Secretary on methods to appropriately and anonymously estimate the type

[106] 21 C.F.R. §§1303.11(b)(1)-(5).

[107] 21 U.S.C. §§842(b).

[108] 21 U.S.C. §826.

[109] Also referred to as unit doses.

[110] As delegated to the DEA.

[111] Specified committees.

and amount of covered controlled substances that are submitted for collection from approved drug collection receptacles, mail-back programs, and take-back events.

Chapter 9—Preventing Drug Diversion

Section 3292. Improvements to Prevent Drug Diversion

Background

DEA regulations require manufacturers, distributors, and dispensers of controlled substances to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and to report to the local DEA Field Division Office "suspicious orders when discovered by the registrant."[112] DEA regulations describe "suspicious orders" as those that may include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[113] Suspicious orders could indicate that controlled substances are being diverted out of legitimate medical, scientific, or industrial channels for illegal purposes such as drug abuse and drug trafficking activities.[114] The CSA provides civil and criminal penalties for DEA registrants who refuse or negligently fail to report suspicious orders to the DEA.[115]

Provisions

Section 3291 provides a short title for Chapter 9, the "Preventing Drug Diversion Act of 2018."

Section 3292(a) adds a statutory definition of "suspicious order" to Section 102 of the CSA that essentially adopts the language of the existing regulatory definition.[116]

Section 3292(b) adds a new Section 312 to the CSA entitled "Suspicious Orders." This new CSA Section 312(a) requires a DEA registrant to take the same actions as DEA regulations currently mandate: (1) to design and operate a system (that is compliant with applicable federal and state privacy laws) that will alert the registrant of suspicious orders of controlled substances, and (2) upon discovering a suspicious order or series of orders, to inform the DEA Administrator and the Special Agent in Charge of the DEA Field Division Office.[117] New CSA Section 312(b)(1)

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[112] 21 C.F.R. §1301.74(b).

[113] Ibid. The U.S. Court of Appeals for the D.C. Circuit rejected a challenge claiming that the regulatory definition of suspicious orders provides "an exhaustive list of the characteristics that make an order for controlled substances suspicious." Masters Pharmaceutical, Inc. v. DEA, 861 F.3d 206, 220 (D.C. Cir. 2017). Instead, the federal appellate court noted that the regulation's listed characteristics are only illustrative examples and not an exhaustive list. Ibid., at 221.

[114] Ibid., at 211-12 ("Masters had an obligation to report to DEA suspicious orders for controlled substances and to take other precautions to ensure that those medications would not be diverted into illegal channels.").

[115] 21 U.S.C. §§842(a)(5), (c)(1)(B), (c)(2). In the past decade, the DEA has investigated several opioid drug distributors and manufacturers that failed to report suspicious orders or that filled suspicious orders for controlled substances. Several of these investigations resulted in civil penalty settlements and the companies agreeing to implement certain regulatory compliance measures. See e.g., Department of Justice, Office of Public Affairs, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs," press release, January 17, 2017, available at https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

[116] 21 U.S.C. §802.

[117] However, there are a few differences between the statutory requirements concerning suspicious orders under new CSA Section 312(a) and the existing regulatory requirements under 21 C.F.R. §1301.74(b). For example, the new statutory provision directs the registrant to notify the DEA Administrator in addition to the DEA Field Division Office

requires the Attorney General, within a year of the act's enactment, to establish a centralized database for storing suspicious orders reports; per Section 312(b)(2), if a registrant submits a suspicious order to this database, the registrant is considered to have complied with the notification requirement mentioned above. Under new CSA Section 312(c), the Attorney General must share information regarding suspicious orders for prescription controlled substances in a state with an entity designated by the governor or chief executive officer of that state.

Section 3292(c) requires the Attorney General, within a year of the act's enactment, to inform Congress about the reporting of suspicious orders under new CSA Section 312, including a description of the actions taken in response to the reports. This section also requires the Attorney General to submit additional reports to Congress about the number of suspicious orders in the previous year; such reports are to be filed annually until five years after the act's date of enactment. Finally, this section mandates that not later than a year after the act's enactment, the Comptroller General of the United States (head of the GAO), in consultation with the DEA Administrator, submit to Congress a report on the reporting of suspicious orders.

Title IV—Offsets

Section 4004. Modernizing the Reporting of Biological and Biosimilar Products

Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act; P.L. 98-417) created an abbreviated pathway for generic drugs, allowing a generic drug manufacturer to submit to FDA an abbreviated NDA (i.e., an ANDA), rather than a full NDA, demonstrating that the generic product is the same as the brand drug (i.e., the RLD).[118] By relying on FDA's previous determination that the RLD is safe and effective, the generic drug company can avoid replicating the expensive clinical trials already conducted by the brand company.[119] The generic drug applicant must, among other things, submit either a Section viii statement[120] or one of four certifications for every patent listed in the Orange Book[121] with respect to the RLD referenced in the ANDA:

- the brand company has not filed any patent information with respect to the RLD;
- the patent has expired;
- the date on which the patent will expire; or

about suspicious orders (the regulations specify only the latter as the point of contact) and requires the registrant to ensure that the system used to identify suspicious orders complies with federal and state privacy laws (the applicable regulations do not reference privacy laws). Compare P.L. 115-271, §3292 (adding §312(a)(2) to the CSA) with 21 C.F.R. §1301.74(b).

[118] The brand product is called the reference listed drug (RLD) because the generic product ANDA refers to the clinical data in the brand-name drug's NDA.

[119] CRS Report R44703, *Generic Drugs and GDUFA Reauthorization: In Brief*.

[120] 21 U.S.C. §355(j)(2)(A)(vii). A section viii statement should be filed when the generic applicant is seeking approval for a method-of-use not claimed by the listed patent.

[121] All approved drugs (brand and generic) are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (i.e., the "Orange Book"). The holder of an approved NDA, generally the brand drug company, must identify any patents covering its products, which are listed in the Orange Book (21 U.S.C. §355(b)(1)).

- the patent is invalid or will not be infringed by the drug for which the ANDA is submitted, as specified.

These are referred to as paragraph I, II, III, and IV certifications, respectively. The first generic drug company that files an ANDA with a paragraph IV certification is eligible to receive a 180-day period of exclusivity, which precludes FDA from approving another ANDA for the same product during that period of time.[122]

Since enactment of Hatch-Waxman, certain practices have emerged that may disrupt the law's intended balance between innovation and competition in the pharmaceutical industry.[123] One such practice involves pay-for-delay settlements pursuant to which a generic drug company agrees to neither challenge a brand company's patents nor sell a generic version of a patented RLD for a certain period of time in exchange for payment from the brand company. Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173) required drug companies to file such agreements with the Federal Trade Commission (FTC) and DOJ. More specifically, under MMA Section 1112(a), a generic drug company that submits an ANDA containing a paragraph IV certification and a brand drug company that enter into an agreement must each file the agreement with FTC and DOJ. Covered agreements are those regarding the manufacture, marketing, or sale of the RLD that is listed in the ANDA or the generic drug for which the ANDA was submitted, as well as agreements regarding the 180-day exclusivity period as it applies to the ANDA or to any other ANDA based on the same RLD.

Additionally, under MMA Section 1112(b), if two generic drug applicants each have submitted an ANDA containing a paragraph IV certification for the same RLD, and they have entered into an agreement regarding the 180-day exclusivity period, each applicant is required to file the agreement with FTC and DOJ. MMA Section 1112(c) requires drug companies also to file agreements not described in subsections (a) and (b) of Section 1112 if they are contingent upon, provide a contingent condition for, or are otherwise related to (a) or (b) agreements.

The Patient Right to Know Drug Prices Act (P.L. 115-263) amended MMA Title XI, expanding these reporting requirements to include agreements between biosimilar product applicants and brand companies, as well as agreements between two biosimilar product applicants.[124]

Provision

Section 4004 amends MMA Title XI, further expanding reporting requirements to include agreements between two *or more* generic drug applicants and between two *or more* biosimilar product applicants, as well as other agreements not described under subsections (a) and (b) of MMA Section 1112, but that were entered into within 30 days of (a) or (b) agreements. Section 4004 also makes numerous technical changes to MMA Title XI, as amended by P.L. 115-263. This section applies to taxable years beginning after December 31, 2018. The CBO estimates that

[122] 21 U.S.C. §355(j)(5)(B)(iv). For additional information about the Hatch-Waxman Act, see CRS Report R44643, *The Hatch-Waxman Act: A Primer* and CRS Report R44951, *Regulatory Exclusivity Reform in the 115th Congress*.

[123] FDA, "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments," 82 *Federal Register* 28493, June 22, 2017.

[124] A biological product, or biologic, is a medicine derived from a living organism. Because biologics feature a more complex structure than chemical drugs, it would be challenging for manufacturers of follow-on products to demonstrate sameness as required under Hatch-Waxman. In 2010, the Biologics Price Competition and Innovation Act (BPCIA) created an abbreviated licensure pathway for biological products that are demonstrated to be "highly similar" (biosimilar) to or "interchangeable" with an FDA-licensed biological product. For additional information, see CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*.

this provision would decrease direct spending outlays by $41 million from FY2019 through FY2028.[125]

[125] CBO, Estimated Direct Spending and Revenue Effects of H.R. 6, Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, September 27, 2018, https://www.cbo.gov/system/files?file=2018-09/hr6ConferenceSept27.pdf.

Appendix. FDA and Controlled Substances Provisions with Implementation Deadlines

The table below includes relevant provisions that include a required report, guidance, or other action, listed in order of section number.

Table A-1. Title III SUPPORT Act Provisions with Implementation Dates, Reporting Requirements, or Other Deadlines

Section Number	Title	Brief Description	Deadline
		Subtitle A—FDA Provisions	
Sec. 3001(a)	Clarifying FDA regulation of non-addictive pain products	The HHS Secretary, acting through the FDA Commissioner, is required to hold at least one public meeting with stakeholders to "address the challenges and barriers of developing non-addictive medical products intended to treat acute or chronic pain or addiction."	NLT 1 year after enactment
Sec. 3001(b)	Clarifying FDA regulation of non-addictive pain products	The HHS Secretary is required to update or issue at least one final guidance addressing the challenges of developing non-addictive medical products for treatment of pain or addiction, as specified.	Not less than[a] 1 year after the public meeting(s) in Sec. 3001(a)
Sec. 3002(c)	Evidence-based opioid analgesic prescribing guidelines and report	The FDA Commissioner is required to submit to Congress and post on the FDA website, a report on how FDA will use the guidelines to protect the public health and a description of the public health need with respect to each such indication-specific treatment guideline.	NLT 1 year after enactment or, if earlier, at the time the guidelines are finalized
Sec. 3014(c)	Strengthening FDA and CBP coordination and capacity	The HHS Secretary, in consultation with DHS and USPS, is required to report to Congress on the implementation of this section, "including a summary of progress made toward near-real-time information sharing and the interoperability of such technologies."	NLT 6 months after enactment
Sec. 3022(a)(2)	Restricting entrance of illicit drugs	The HHS Secretary, acting through the FDA Commissioner and in consultation with the DHS Secretary, is required to report to Congress on the implementation of this section.	NLT 9 months after enactment

Section Number	Title	Brief Description	Deadline
Sec. 3032(d)	Safety-enhancing packaging and disposal features	GAO is required to report to Congress on packaging and disposal technologies, as specified.	NLT 1 year after enactment
Sec. 3041(c)	Clarifying FDA postmarket authorities	The HHS Secretary is required to issue guidance regarding the circumstances under which FDA may require postmarket studies to assess the potential reduction in effectiveness of a drug, and how the FDA may apply this section to require postmarket studies or clinical trials and safety labeling changes.	Not less than[a] 1 year after enactment
Subtitle B—Controlled Substance Provisions			
Sec. 3201(e)	Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders	The HHS Secretary, in consultation with DEA, is required to submit a report that assesses the care provided by qualifying physicians treating more than 100 patients and qualifying other practitioners treating more than 30 patients, with appropriate recommendations based on the findings.	NLT 2 years after enactment
Sec. 3204(b)	Delivery of a controlled substance by a pharmacy to be administered by injection or implantation	GAO is required to study and submit a report to Congress on access to and potential diversion of controlled substances administered by injection or implantation.	NLT 2 years after enactment
Sec. 3212	Programs and materials for training on certain circumstances under which a pharmacist may decline to fill a prescription	The HHS Secretary shall develop and disseminate materials for pharmacists, providers, and patients on circumstances under which a pharmacist may decline to fill a prescription for a controlled substance, and other Federal requirements pertaining to declining to fill a prescription.	NLT 1 year after enactment
Sec. 3223	GAO study and report on hospice safe drug management	GAO is required to study and report to Congress on the requirements applicable to, and challenges of, hospice programs with regard to the management and disposal of controlled substances.	NLT 18 months after enactment

Section Number	Title	Brief Description	Deadline
Sec. 3232	Regulations relating to a special registration for telemedicine	The Attorney General, in consultation with the HHS Secretary, is required to promulgate final regulations specifying the limited circumstances in which a special registration for telemedicine may be issued and the procedure for obtaining the registration.	NLT 1 year after enactment
Sec. 3274	Report	The Attorney General is required to submit to Congress a report that provides information about how the Attorney General is using data in ARCOS to identify and stop suspicious activity.	NLT 1 year after enactment
Sec. 3282(a)	Strengthening considerations for DEA opioid quotas	The Attorney General is required to submit to Congress (1) an anonymized count of the total number of manufacturers issued individual manufacturing quotas that year for the covered controlled substance and (2) an anonymized count of how many such manufacturers were issued an approved manufacturing quota that was higher than the quota issued to that manufacturer for the covered controlled substance in the previous year.	NLT 1 year after enactment
Sec. 3282(a)	Strengthening considerations for DEA opioid quotas.	The Attorney General is required to submit to Congress a report on how the Attorney General, when fixing and adjusting quotas for covered controlled substances, will take into consideration changes in the accepted medical use of the covered controlled substances and work with the HHS Secretary on methods to appropriately and anonymously estimate the type and amount of covered controlled substances that are submitted for collection from approved drug collection receptacles, mail-back programs, and take-back events.	NLT 1 year after enactment
Sec. 3292(b)	Improvements to prevent drug diversion	The Attorney General is required to establish a centralized database for collecting reports of suspicious orders.	NLT 1 year after enactment

Section Number	Title	Brief Description	Deadline
Sec. 3292(c)(2)	Improvements to prevent drug diversion	The Attorney General is required to submit a report to Congress about the reporting of suspicious orders under new CSA Section 312, including a description of the actions taken in response to the reports.	NLT 1 year after enactment
Sec. 3292(c)(3)	Improvements to prevent drug diversion	The Attorney General is required to submit additional reports to Congress about the number of suspicious orders in the previous year, a summary of actions taken in response, and a description of the information shared with States based on such reports.	NLT 1 year after enactment and annually thereafter until five years after enactment
Sec. 3292(c)(4)	Improvements to prevent drug diversion	GAO, in consultation with the DEA Administrator, is required to submit to Congress a report on the reporting of suspicious orders, as specified.	NLT 1 year after enactment

Source: CRS identified implementation deadlines by searching the text of P.L. 115-271 for the phrase "not later than" and sorting through the results to identify relevant deadlines. CRS also identified and added a few deadlines according to analyst discretion that had not been returned when searching the phrase "not later than."

Notes: NLT= Not later than.

a. For the guidance documents required by Sections 3001(b) and 3041(c), the deadline in statute appears as "not less than one year after."

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