**SECTION 1. SHORT TITLE.**

**This Act may be cited as the "Drug Shortage Compounding Patient Access Act of 2025.**

**SEC. 2. PHARMACY COMPOUNDING.**

**COMPOUNDING FOR URGENT ADMINISTRATION TO PATIENTS.—SECTION 503A(a) OF THE Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a(a)) is amended--**

21 U.S. Code § 353a - Pharmacy compounding

**~~(A)~~(a) In general**
Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

**(1)** is by—

**(A)** a licensed pharmacist in a State licensed pharmacy or a Federal facility, or~~or~~

**(B)** a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; ~~or~~

**(2)**

**(A)** is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

**(B)** is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

**(i)** the licensed pharmacist or licensed physician; and

**(ii)**

**( I )** such individual patient for whom the prescription order will be provided; or

**( I I )** the physician or other licensed practitioner who will write such prescription order~~.~~ ;or

**(III)** notwithstanding the requirement in the matter preceding paragraph (1) that the drug product is compounded for an identified individual patient based on a valid prescription order or notation described in such matter, is by a licensed pharmacist or licensed physician and the compounded drug product is compounded for distribution in limited quantities to a licensed prescriber for urgent administration to a patient in a hospital or other clinical setting, provided that all of the following are met:

A. The drug product appeared on the drug shortage list in effect under section 506E at any time during the 60-day period ending on the date of the compounding, distribution, or dispensing of the drug product.

~~E.~~B.

The licensed prescriber certifies by notation on the order to the compounding pharmacist or physician that the licensed prescriber has made reasonable attempts to obtain, and has not been able to obtain, to address the urgent medical need a drug product that is compounded~~ing~~ by an outsourcing facility in accordance with section 503B with the same active ingredient and the same route of administration.

C.

The compounded drug product is labeled with a beyond-use-date in accordance with applicable United States Pharmacopeia standards.

D.

~~F.~~

~~G.~~ The licensed pharmacist or licensed physician marks the packaging of the compounded drug product with text-

i. ~~I~~indicating that the drug product is provided to the hospital or other clinical setting only for urgent administration to a patient; and

ii. ~~R~~requesting that the hospital or other clinical setting provide to the compounding pharmacist or physician the records that identify the patient or

patients to whom the drug products were administered within-

I. 7 days of each such patient receiving such medication; or

II. 7 days of each such patient being discharged.

~~H.~~ E. Upon receipt of records requested pursuant to subparagraph (D)(ii), the licensed pharmacist or licensed physician ensures that the patient information in such records is linked with the respective order.

~~(H)~~F.The licensed pharmacist or licensed physician reports adverse events associated with the compounded drug product as soon as possible by no later than 15 days after becoming aware of such events to the MedWatch Adverse Event Reporting program of the Food and Drug Administration (or any successor program).~~".~~

**(b) Compounded drug**

**(1) Licensed pharmacist and licensed physician**
A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

**(A)** compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

**(i)** that—

**(I)** comply with the standards of an applicable United States Pharmacopoeia or ~~National Formulary monograph~~ National Formulary drug or dietary supplement monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

**(II)** if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

**(III)** if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

**(ii)** that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

**(iii)** that are accompanied by valid certificates of analysis for each bulk drug substance;

**(B)** compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

**(C)** does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

**(D)** does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

**(2) Definition**
For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include

(A) a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product~~.~~; or

(B) a drug product that meets each of the following conditions:

i. At any time during the 60-day period ending on the date of the compounding, distribution, or dispensing, the drug product appeared on the drug shortage list in effect under section 506E.

ii. If the drug product is not compounded for an identified individual patient based on a valid prescription order or notation, notwithstanding such requirement in the matter preceding paragraph (1) of subsection (a), the drug product—

I. ~~I~~is labeled in accordance subparagraphs (C) and (D) of subsection (a)(3); and

II. ~~I~~is documented by the compounding pharmacist or physician in accordance with subparagraphs (E) and (F) of subsection (a)(3).

**(3) Drug product**

A drug product may be compounded under subsection (a) only if—

**(A)** such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

**(B)** such drug product is labeled as follows: "This medication has been compounded for dispensing to an individual patient and has not been approved by the Food and Drug Administration." ~~such drug product is compounded in a State—~~

~~**(i)** that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or~~

~~**(ii)** that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.~~

~~The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).~~

**(c)Regulations**

**(1) In general**
The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

**(2)Limiting compounding**
The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

**(d) Application**
This section shall not apply to—

**(1)** compounded positron emission tomography drugs as defined in section 321(ii) of this title; or

**(2)** radiopharmaceuticals.

**(e) "Compounding" defined**
As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(June 25, 1938, ch. 675, § 503A, as added Pub. L. 105–115, title I, § 127(a), Nov. 21, 1997, 111 Stat. 2328; amended Pub. L. 113–54, title I, § 106(a), Nov. 27, 2013, 127 Stat. 598.)

## SEC. 3. MITIGATING DRUG SHORTAGES THROUGH IMPROVED REPORTING

Section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amended---

21 U.S. Code § 356c - Discontinuance or interruption in the production of or surge in demand for life-saving drugs

**(a ) In general**

A manufacturer of a drug—

**(1)** that is—

**(A)** life-supporting;

**(B)** life-sustaining; or

**(C)** intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery or any such drug that is critical to the public health during a public health emergency declared by the Secretary under section 247d of title 42; and

**(2)** that is not a radio pharmaceutical drug product or any other product as designated by the Secretary,

shall notify the Secretary, in accordance with subsection (b), of a permanent discontinuance in the manufacture of the drug ~~or an interruption of the manufacture of the drug~~ , an interruption of the manufacture of the drug, or a surge in demand for the drug that is likely to lead to a meaningful disruption in the supply of that drug in the United States, or a permanent discontinuance in the manufacture of an active pharmaceutical ingredient or an interruption in the manufacture of the active pharmaceutical ingredient of such drug that is likely to lead to a meaningful disruption in the supply of the active pharmaceutical ingredient of such drug, and the reasons for ~~such discontinuance or interruption~~ such discontinuance, interruption, or surge in demand. Notification under this subsection shall include disclosure of reasons for ~~the discontinuation or interruption~~ the discontinuation, interruption, or surge in demand, and if applicable, an active pharmaceutical ingredient is a reason for, or risk factor in, ~~such discontinuation or interruption, the source~~ such discontinuation, interruption, or surge in demand, the source of the active pharmaceutical ingredient and any alternative sources for the active pharmaceutical ingredient known by the manufacturer; whether any associated device used for preparation or administration included in the drug is a reason for, or a risk factor in, ~~such discontinuation or interruption; the expected duration of the interruption;~~ such discontinuation, interruption, or surge in demand; the expected duration

of the interruption or surge in demand and such other information as the Secretary may require.

**(b) Timing**

A notice required under subsection (a) shall be submitted to the Secretary—

**(1)** ~~at least 6 months prior to the date of the discontinuance or interruption; or~~in the case of a notice of a discontinuance or interruption in the manufacture of a drug—

(A) at least 6 months prior to the date of the discontinuance or interruption; or

(B) if compliance with subparagraph (A) is not possible, as soon as practicable; or

**(2)** ~~if compliance with paragraph (1) is not possible, as soon as practicable.~~in the case of a notice of a surge in demand for a drug, as soon as practicable.

**(c) Distribution**

To the maximum extent practicable, the Secretary shall distribute, through such means as the Secretary deems appropriate, information on the ~~discontinuance or interruption~~ discontinuance, interruption, or surge in demand of the manufacture of the drugs described in subsection (a) to appropriate organizations, including physician, health provider, and patient organizations, and outsourcing facilities (as defined in section 503B(d) as described in section 356e of this title.

**(d) Confidentiality**

Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

**(e) Coordination with Attorney General**

Not later than 30 days after the receipt of a notification described in subsection (a), the Secretary shall—

**(1)** determine whether the notification pertains to a controlled substance subject to a production quota under section 826 of this title; and

**(2)** if necessary, as determined by the Secretary—

**(A)** notify the Attorney General that the Secretary has received such a notification;

**(B)** request that the Attorney General increase the aggregate and individual production quotas under section 826 of this title applicable to such controlled substance and any ingredient therein to a level the Secretary deems necessary to address a shortage of a controlled substance based on the best available market data; and

**(C)** if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide to the Secretary a written response detailing the basis for the Attorney General's determination.

The Secretary shall make the written response provided under subparagraph (C) available to the public on the Internet Web site of the Food and Drug Administration.

**(f) Failure to meet requirements**

If a person fails to submit information required under subsection (a) in accordance with subsection (b)—

**(1)** the Secretary shall issue a letter to such person informing such person of such failure;

**(2)** not later than 30 calendar days after the issuance of a letter under paragraph (1), the person who receives such letter shall submit to the Secretary a written response to such letter setting forth the basis for noncompliance and providing information required under subsection (a); and

**(3)** not later than 45 calendar days after the issuance of a letter under paragraph (1), the Secretary shall make such letter and any response to such letter under paragraph (2) available to the public on the Internet Web site of the Food and Drug Administration, with appropriate redactions made to protect information described in subsection (d), except that, if the Secretary determines that the letter under paragraph (1) was issued in error or, after review of such response, the person had a reasonable basis for not notifying as required under subsection (a), the requirements of this paragraph shall not apply.

**(g) Expedited inspections and reviews**

If, based on notifications described in subsection (a) or any other relevant information, the Secretary concludes that there is, or is likely to be, a drug shortage of a drug described in subsection (a), the Secretary shall, as appropriate—

**(1)** prioritize and expedite the review of a supplement to a new drug application submitted under section 355(b) of this title, an abbreviated new drug application submitted under section 355(j) of this title, or a supplement to such an application submitted under section 355(j) of this title, that could help mitigate or prevent such shortage; or

**(2)** prioritize and expedite an inspection or reinspection of an establishment that could help mitigate or prevent such drug shortage.

**(h) Definitions**

For purposes of this section—

**(1)** the term "drug"—

**(A)** means a drug (as defined in section 321(g) of this title) that is intended for human use ~~and that is subject to section 353(b)(1) of this title~~ or the active pharmaceutical ingredient of such a drug; and

**(B)** does not include biological products (as defined in section 262 of title 42), unless otherwise provided by the Secretary in the regulations promulgated under subsection (i);

**(2)** the term "drug shortage" or "shortage", with respect to a drug, means a period of time ~~when~~ with the demand or projected demand for the drug within the United States exceeds the supply of the drug~~; and~~, taking into consideration—

**(A)** how the drug is prepared or dispensed, including the route of administration and dosage form; and

**(B)** information reported by manufacturers, health care professionals, and patients;

**(3 )** the term "meaningful disruption"—

**(A)** means a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product; and

**(B)** does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time~~.~~; and

(4) the term "surge" means an increase in demand or projected demand for a drug that the manufacturer likely will be unable to meet without meaningful shortfall or delay.

**(i) Regulations**

**(1) In general**

Not later than 18 months after July 9, 2012, the Secretary shall adopt a final regulation implementing this section.

**(2) Contents**

Such regulation shall define, for purposes of this section, the terms "life-supporting", "life-sustaining", and "intended for use in the prevention or treatment of a debilitating disease or condition".

**(3) Inclusion of biological products**

**(A) In general**

The Secretary may by regulation apply this section to biological products (as defined in section 262 of title 42), including plasma products derived from human plasma protein and their recombinant analogs, if the Secretary determines such inclusion would benefit the public health. Such regulation shall take into account any supply reporting programs and shall aim to reduce duplicative notification.

**(B) Rule for vaccines**

If the Secretary applies this section to vaccines pursuant to subparagraph (A), the Secretary shall—

**(i)** consider whether the notification requirement under subsection (a) may be satisfied by submitting a notification to the Centers for Disease Control and Prevention under the vaccine shortage notification program of such Centers; and

**(ii)** explain the determination made by the Secretary under clause (i) in the regulation.

**(4) Procedure**

In promulgating a regulation implementing this section, the Secretary shall—

**(A)** issue a notice of proposed rulemaking that includes the proposed regulation;

**(B)** provide a period of not less than 60 days for comments on the proposed regulation; and

**(C)** publish the final regulation not less than 30 days before the regulation's effective date.

**(5) Restrictions**

Notwithstanding any other provision of Federal law, in implementing this section, the Secretary shall only promulgate regulations as described in paragraph (4).

**(j) Risk management plans**

Each manufacturer of a drug described in subsection (a) or of any active pharmaceutical ingredient or any associated medical device used for preparation or administration included in the drug, shall develop, maintain, and implement, as appropriate, a redundancy risk management plan that identifies and evaluates risks to the supply of the drug, as applicable, for each establishment in which such drug or active pharmaceutical ingredient of such drug is manufactured. A risk management plan under this section shall be subject to inspection and copying by the Secretary pursuant to an inspection or a request under section 374(a)(4) of this title.

(June 25, 1938, ch. 675, § 506C, as added Pub. L. 105–115, title I, § 131(a), Nov. 21, 1997, 111 Stat. 2332; amended Pub. L. 112–144, title X, § 1001(a), July 9, 2012, 126 Stat. 1099; Pub. L. 114–255, div. A, title III, § 3101(a)(2)(E), Dec. 13, 2016, 130 Stat. 1153; Pub. L. 116–136, div. A, title III, §§ 3111–3112(b), Mar. 27, 2020, 134 Stat. 361, 362; Pub. L. 117–328, div. FF, title II, § 2515(a)(1), (b)(1), Dec. 29, 2022, 136 Stat. 5806.)

## SEC. 4. OUTSOURCING FACILITY COMPOUNDING

**Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353b) is amended—**

21 U.S. Code § 353b - Outsourcing facilities

**(a) In general**

Sections 352(f)(1), 355, and 360eee–1 of this title shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

**(1) Registration and reporting**

The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).

**(2) Bulk drug substances**
The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless—

**(A)**
**(i)** the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by—

**(I)** publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

**(II)** providing a period of not less than 60 calendar days for comment on the notice; and

**(III)** publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

**(ii)** the drug compounded from such bulk drug substance ~~appears~~appeared on the drug shortage list in effect under section 356e of this title ~~at the time of~~ at any time during the 180-day period ending on the date of compounding, distribution, and dispensing;

**(B)** if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

**(C)** the bulk drug substances are each manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

**(D)** the bulk drug substances are each accompanied by a valid certificate of analysis.

**(3) Ingredients (other than bulk drug substances)**
If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply with the standards of the

applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph if any.

**(4)Drugs withdrawn or removed because unsafe or not effective**
The drug does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

**(5)Essentially a copy of an approved drug**
The drug is not essentially a copy of one or more approved drugs.

**(6)Drugs presenting demonstrable difficulties for compounding**
The drug—

> **(A)** is not identified (directly or as part of a category of drugs) on a list published by the Secretary, through the process described in subsection (c), of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or
>
> **(B)** is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

**(7) Elements to assure safe use**
In the case of a drug that is compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 355–1 of this title, or from a bulk drug substance that is a component of such drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that such facility will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

**(8) Prohibition on wholesaling**
The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 353(b)(1) of this title.

**(9) Fees**
The drug is compounded in an outsourcing facility that has paid all fees owed by such facility pursuant to section 379j–62 of this title.

**(10) Labeling of drugs**

**(A) Label**

The label of the drug includes—

**(**i) the statement "This is a compounded drug." or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

**(ii)** the name, address, and phone number of the applicable outsourcing facility; and

**(iii)** with respect to the drug—

**(I)** the lot or batch number;

**(II)** the established name of the drug;

**(III)** the dosage form and strength;

**(IV)** the statement of quantity or volume, as appropriate;

**(V)** the date that the drug was compounded;

**(VI)** the expiration date;

**(VII)** storage and handling instructions;

**(VIII)** the National Drug Code number, if available~~;~~and ;

~~**(IX)** the statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only"; and~~

**(IX)** subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

**(B) Container**

The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include—

**(i)** the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

**(ii)** the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088 (or any successor Internet Web site or phone number); and

**(iii)** directions for use, including, as appropriate, dosage and administration.

**(C) Additional information**
The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

**(11) Outsourcing facility requirement**
The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section.

**(b) Registration of outsourcing facilities and reporting of drugs**

**(1 ) Registration of outsourcing facilities**

**(A) Annual registration**
Upon electing and in order to become an outsourcing facility, and during the period beginning on October 1 and ending on December 31 of each year thereafter, a facility—

**(i)** shall register with the Secretary its name, place of business, and unique facility identifier (which shall conform to the requirements for the unique facility identifier established under section 360 of this title), and a point of contact email address; and

**(ii)** shall indicate whether the outsourcing facility intends to compound a drug that appears on the list in effect under section 356e of this title during the subsequent calendar year.

**(B )Availability of registration for inspection; list**

**(i) Registrations**
The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this paragraph.

**(ii) List**
The Secretary shall make available on the public Internet Web site of the Food and Drug Administration a list of the name of each facility registered under this subsection as an outsourcing facility, the State in which

each such facility is located, whether the facility compounds from bulk drug substances, and whether any such compounding from bulk drug substances is for sterile or nonsterile drugs.

**(2) Drug reporting by outsourcing facilities**

**(A) In general**
Upon initially registering as an outsourcing facility, once during the month of June of each year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph

(1) shall submit to the Secretary a report—

**(i)** identifying the drugs compounded by such outsourcing facility during the previous 6-month period; and

**(ii)** with respect to each drug identified under clause (i), providing the active ingredient, the source of such active ingredient, the National Drug Code number of the source drug or bulk active ingredient, if available, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of individual units produced, and the National Drug Code number of the final product, if assigned.

**(B) Form**
Each report under subparagraph (A) shall be prepared in such form and manner as the Secretary may prescribe by regulation or guidance.

**(C) Confidentiality**
Reports submitted under this paragraph shall be exempt from inspection under paragraph (1)(B)(i), unless the Secretary finds that such an exemption would be inconsistent with the protection of the public health.

**(3) Electronic registration and reporting**
Registrations and drug reporting under this subsection (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting waiver.

**(4) Risk-based inspection frequency**

**(A) In general**
Outsourcing facilities—

**(i)** shall be subject to inspection pursuant to section 374 of this title; and

**(ii)** shall not be eligible for the exemption under section 374(a)(2)(A) of this title.

**(B) Risk-based schedule**
The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

**(C) Risk factors**
In establishing the risk-based schedule, the Secretary shall inspect outsourcing facilities according to the known safety risks of such outsourcing facilities, which shall be based on the following factors:

**(i)** The compliance history of the outsourcing facility.

**(ii)** The record, history, and nature of recalls linked to the outsourcing facility.

**(iii)** The inherent risk of the drugs compounded at the outsourcing facility.

**(iv)** The inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected pursuant to section 374 of this title within the last 4 years.

**(v)** Whether the outsourcing facility has registered under this paragraph as an entity that intends to compound a drug that appears on the list in effect under section 356e of this title.

**(vi)** Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

**(5) Adverse event reporting**
Outsourcing facilities shall submit adverse event reports to the Secretary in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).

**(c) Regulations**

**(1) In general**
The Secretary shall implement the list described in subsection (a)(6) through regulations.

**(2) Advisory committee on compounding**

Before issuing regulations to implement subsection (a)(6), the Secretary shall convene and consult an advisory committee on compounding. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations.

**(3) Interim list**

**(A) In general**
Before the effective date of the regulations finalized to implement subsection (a)(6), the Secretary may designate drugs, categories of drugs, or conditions as described such [1] subsection by—

**(i)** publishing a notice of such substances, drugs, categories of drugs, or conditions proposed for designation, including the rationale for such designation, in the Federal Register;

**(ii)** providing a period of not less than 60 calendar days for comment on the notice; and

**(iii)** publishing a notice in the Federal Register designating such drugs, categories of drugs, or conditions.

**(B) Sunset of notice**
Any notice provided under subparagraph (A) shall not be effective after the earlier of—

**(i)** the date that is 5 years after November 27, 2013; or

**(ii)** the effective date of the final regulations issued to implement subsection (a)(6).

**(4) Updates**
The Secretary shall review, and update as necessary, the regulations containing the lists of drugs, categories of drugs, or conditions described in subsection (a)(6) regularly, but not less than once every 4 years. Nothing in the previous sentence prohibits submissions to the Secretary, before or during any 4-year period described in such sentence, requesting updates to such lists.

(d) LIST OF IDENTIFIED BULK DRUG SUBSTANCES.—The Secretary shall make publicly available annual updates on the evaluation of bulk drug substances for purposes of the list maintained under subsection (a)(2)(A)(i).

**(~~e~~d) [2] DEFINITIONS**

In this section:

**(1)** The term "compounding" includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

**(2)**The term "essentially a copy of an approved drug" means—

**(A)** a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 353(b) of this title and not subject to approval in an application submitted under section 355 of this title, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing; or

**(B)** a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 353(b) of this title and not subject to approval in an application submitted under section 355 of this title, unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

**(3)** The term "approved drug" means a drug that is approved under section 355 of this title and does not appear on the list described in subsection (a)(4) of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

**(4)**

**(A)** The term "outsourcing facility" means a facility at one geographic location or address that—

**(i)** is engaged in the compounding of sterile drugs;

**(ii)** has elected to register as an outsourcing facility; and

**(iii)** complies with all of the requirements of this section.

**(B)** An outsourcing facility is not required to be a licensed pharmacy.

**(C)** An outsourcing facility may or may not obtain prescriptions for identified individual patients.

**(5)** The term "sterile drug" means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law.

**(fd)[2] OBLIGATION TO PAY FEES**

Payment of the fee under section 379j–62 of this title, as described in subsection (a)(9), shall not relieve an outsourcing facility that is licensed as a pharmacy in any State that requires pharmacy licensing fees of its obligation to pay such State fees.

(June 25, 1938, ch. 675, § 503B, as added Pub. L. 113–54, title I, § 102(a)(2), Nov. 27, 2013, 127 Stat. 588.)

## SEC. 5. CLARIFYING PROVISIONS; LABELING REQUIREMENT.

Section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) is amended—

(These proposed changes are inserted above)