Signed into law by President Obama on November 27, 2013

Text of Compounding Quality Act

TITLE I--DRUG COMPOUNDING
SEC. 101. SHORT TITLE.
This Act may be cited as the ``Compounding Quality Act''.
SEC. 102. VOLUNTARY OUTSOURCING FACILITIES.
(a) In General.--Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended--
(1) by redesignating section 503B as section 503C; and
(2) by inserting after section 503A the following new section:
``SEC. 503B. OUTSOURCING FACILITIES.
``(a) In General.--Sections 502(f)(1), 505, and 582 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 on the drug shortage list in effect under section 506E at the time 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 510 (including a

foreign establishment that is registered under section 510(i)); 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 505-1, 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 503(b)(1).

``(9) Fees.--The drug is compounded in an outsourcing facility that has paid all fees owed by such facility pursuant to section 744K.
``(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;
``(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
``(X) 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 510), 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 506E 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 704; and
``(ii) shall not be eligible for the exemption under section 704(a)(2)(A).
``(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 704 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 506E.
``(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 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 the date of enactment of the Compounding Quality Act; 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) 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 503(b) and not subject to approval in an application submitted under section 505, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E 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 503(b) and not subject to approval in an application submitted under section 505, 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 505 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.".
``(d) Obligation to Pay Fees.--Payment of the fee under section 744K, 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.".
(b) Fees.--Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by adding at the end the following:
``PART 9--FEES RELATING TO OUTSOURCING FACILITIES
``SEC. 744J. DEFINITIONS.
``In this part:
``(1) The term `affiliate' has the meaning given such term in section 735(11).

``(2) The term `gross annual sales' means the total worldwide gross annual sales, in United States dollars, for an outsourcing facility, including the sales of all the affiliates of the outsourcing facility.
``(3) The term `outsourcing facility' has the meaning given to such term in section 503B(d)(4).
``(4) The term `reinspection' means, with respect to an outsourcing facility, 1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified noncompliance materially related to an applicable requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.
``SEC. 744K. AUTHORITY TO ASSESS AND USE OUTSOURCING FACILITY FEES.
``(a) Establishment and Reinspection Fees.--
``(1) In general.--For fiscal year 2015 and each subsequent fiscal year, the Secretary shall, in accordance with this subsection, assess and collect--
``(A) an annual establishment fee from each outsourcing facility; and
``(B) a reinspection fee from each outsourcing facility subject to a reinspection in such fiscal year.
``(2) Multiple reinspections.--An outsourcing facility subject to multiple reinspections in a fiscal year shall be subject to a reinspection fee for each reinspection.
``(b) Establishment and Reinspection Fee Setting.--The Secretary shall--
``(1) establish the amount of the establishment fee and reinspection fee to be collected under this section for each fiscal year based on the methodology described in subsection (c); and
``(2) publish such fee amounts in a Federal Register notice not later than 60 calendar days before the start of each such year.
``(c) Amount of Establishment Fee and Reinspection Fee.--
``(1) In general.--For each outsourcing facility in a fiscal year--
``(A) except as provided in paragraph (4), the amount of the annual establishment fee under subsection (b) shall be equal to the sum of--
``(i) $15,000, multiplied by the inflation adjustment factor described in paragraph (2); plus
``(ii) the small business adjustment factor described in paragraph (3); and
``(B) the amount of any reinspection fee (if applicable) under subsection (b) shall be equal to $15,000, multiplied by the inflation adjustment factor described in paragraph (2).
``(2) Inflation adjustment factor.--
``(A) In general.--For fiscal year 2015 and subsequent

fiscal years, the fee amounts established in paragraph (1) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of--

``(i) 1;

``(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years; plus

``(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (U.S. City Average; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years.

``(B) Compounded basis.--The adjustment made each fiscal year under subparagraph (A) shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under subparagraph (A).

``(3) Small business adjustment factor.--The small business adjustment factor described in this paragraph shall be an amount established by the Secretary for each fiscal year based on the Secretary's estimate of--

``(A) the number of small businesses that will pay a reduced establishment fee for such fiscal year; and

``(B) the adjustment to the establishment fee necessary to achieve total fees equaling the total fees that the Secretary would have collected if no entity qualified for the small business exception in paragraph (4).

``(4) Exception for small businesses.--

``(A) In general.--In the case of an outsourcing facility with gross annual sales of $1,000,000 or less in the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which the fees under this section are assessed, the amount of the establishment fee under subsection (b) for a fiscal year shall be equal to \1/3\ of the amount calculated under paragraph (1)(A)(i) for such fiscal year.

``(B) Application.--To qualify for the exception under this

paragraph, a small business shall submit to the Secretary a written request for such exception, in a format specified by the Secretary in guidance, certifying its gross annual sales for the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which fees under this subsection are assessed. Any such application shall be submitted to the Secretary not later than April 30 of such immediately preceding fiscal year.

``(5) Crediting of fees.--In establishing the small business adjustment factor under paragraph (3) for a fiscal year, the Secretary shall--

``(A) provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of the small business adjustment factor for such previous fiscal year; and

``(B) consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

``(d) Use of Fees.--The Secretary shall make all of the fees collected pursuant to subparagraphs (A) and (B) of subsection (a)(1) available solely to pay for the costs of oversight of outsourcing facilities.

``(e) Supplement Not Supplant.--Funds received by the Secretary pursuant to this section shall be used to supplement and not supplant any other Federal funds available to carry out the activities described in this section.

``(f) Crediting and Availability of Fees.--Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the purpose of paying the costs of oversight of outsourcing facilities.

``(g) Collection of Fees.--

``(1) Establishment fee.--An outsourcing facility shall remit the establishment fee due under this section in a fiscal year when submitting a registration pursuant to section 503B(b) for such fiscal year.

``(2) Reinspection fee.--The Secretary shall specify in the Federal Register notice described in subsection (b)(2) the manner in which reinspection fees assessed under this section shall be collected and the timeline for payment of such fees. Such a fee shall be collected after the Secretary has conducted a reinspection

of the outsourcing facility involved.
``(3) Effect of failure to pay fees.--
``(A) Registration.--An outsourcing facility shall not be considered registered under section 503B(b) in a fiscal year until the date that the outsourcing facility remits the establishment fee under this subsection for such fiscal year.
``(B) Misbranding.--All drugs manufactured, prepared, propagated, compounded, or processed by an outsourcing facility for which any establishment fee or reinspection fee has not been paid, as required by this section, shall be deemed misbranded under section 502 until the fees owed for such outsourcing facility under this section have been paid.
``(4) Collection of unpaid fees.--In any case where the Secretary does not receive payment of a fee assessed under this section within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.
``(h) Annual Report to Congress.--Not later than 120 calendar days after each fiscal year in which fees are assessed and collected under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to include a description of fees assessed and collected for such year, a summary description of entities paying the fees, a description of the hiring and placement of new staff, a description of the use of fee resources to support inspecting outsourcing facilities, and the number of inspections and reinspections of such facilities performed each year.
``(i) Authorization of Appropriations.--For fiscal year 2014 and each subsequent fiscal year, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.".
SEC. 103. PENALTIES.
(a) Prohibited Acts.--Section 301 (21 U.S.C. 331) is amended by adding at the end the following:
``(ccc)(1) The resale of a compounded drug that is labeled `not for resale' in accordance with section 503B.
``(2) With respect to a drug to be compounded pursuant to section 503A or 503B, the intentional falsification of a prescription, as applicable.
``(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 503B.".
(b) Misbranded Drugs.--Section 502 (21 U.S.C. 352) is amended by adding at the end the following:
``(bb) If the advertising or promotion of a compounded drug is

false or misleading in any particular.".
SEC. 104. REGULATIONS.
In promulgating any regulations to implement this title (and the amendments made by this title), the Secretary of Health and Human Services shall--
(1) issue a notice of proposed rulemaking that includes the proposed regulation;
(2) provide a period of not less than 60 calendar days for comments on the proposed regulation; and
(3) publish the final regulation not more than 18 months following publication of the proposed rule and not less than 30 calendar days before the effective date of such final regulation.
SEC. 105. ENHANCED COMMUNICATION.
(a) Submissions From State Boards of Pharmacy.--In a manner specified by the Secretary of Health and Human Services (referred to in this section as the ``Secretary''), the Secretary shall receive submissions from State boards of pharmacy--
(1) describing actions taken against compounding pharmacies, as described in subsection (b); or
(2) expressing concerns that a compounding pharmacy may be acting contrary to section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a).
(b) Content of Submissions From State Boards of Pharmacy.--An action referred to in subsection (a)(1) is, with respect to a pharmacy that compounds drugs, any of the following:
(1) The issuance of a warning letter, or the imposition of sanctions or penalties, by a State for violations of a State's pharmacy regulations pertaining to compounding.
(2) The suspension or revocation of a State-issued pharmacy license or registration for violations of a State's pharmacy regulations pertaining to compounding.
(3) The recall of a compounded drug due to concerns relating to the quality or purity of such drug.
(c) Consultation.--The Secretary shall implement subsection (a) in consultation with the National Association of Boards of Pharmacy.
(d) Notifying State Boards of Pharmacy.--The Secretary shall immediately notify State boards of pharmacy when--
(1) the Secretary receives a submission under subsection (a)(1); or
(2) the Secretary makes a determination that a pharmacy is acting contrary to section 503A of the Federal Food, Drug, and Cosmetic Act.
SEC. 106. SEVERABILITY.
(a) In General.--Section 503A (21 U.S.C. 353a) is amended--
(1) in subsection (a), in the matter preceding paragraph (1), by striking ``unsolicited";

(2) by striking subsection (c);
(3) by redesignating subsections (d) through (f) as subsections (c) through (e), respectively; and
(4) in subsection (b)(1)(A)(i)(III), by striking ``subsection (d)'' and inserting ``subsection (c)''.
(b) Severability.--If any provision of this Act (including the amendments made by this Act) is declared unconstitutional, or the applicability of this Act (including the amendments made by this Act) to any person or circumstance is held invalid, the constitutionality of the remainder of this Act (including the amendments made by this Act) and the applicability thereof to other persons and circumstances shall not be affected.
SEC. 107. GAO STUDY.
(a) Study.--Not later than 36 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on pharmacy compounding and the adequacy of State and Federal efforts to assure the safety of compounded drugs.
(b) Contents.--The report required under this section shall include--
(1) a review of pharmacy compounding in each State, and the settings in which such compounding occurs;
(2) a review of the State laws and policies governing pharmacy compounding, including enforcement of State laws and policies;
(3) an assessment of the available tools to permit purchasers of compounded drugs to determine the safety and quality of such drugs;
(4) an evaluation of the effectiveness of the communication among States and between States and the Food and Drug Administration regarding compounding; and
(5) an evaluation of the Food and Drug Administration's implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.