Title: To amend titles XVIII and XIX of the Social Security Act to prevent and mitigate generic prescription drug shortages.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Drug Shortage Prevention and Mitigation Act".

SEC. 2. MEDICARE DRUG SHORTAGE PREVENTION AND MITIGATION PROGRAM.

Part E of title XVIII of the Social Security Act (42 U.S.C. 1395x et seq.) is amended by adding at the end the following new section:

"SEC. 1899C. MEDICARE DRUG SHORTAGE PREVENTION AND MITIGATION PROGRAM.

"(a) Establishment.—Not later than [January 1, 2027], the Secretary shall establish a Drug Shortage Prevention and Mitigation Program (in this section referred to as the 'program'). Under the program, the Secretary shall—

"(1) enter into agreements, as described in subsection (b), for purposes of carrying out relevant activities under this section;

"(2) determine amounts for the prevention and mitigation incentive payments described in subsection (c) and make such payments to payment-eligible providers (as defined in subsection (b)(3)(A)), in accordance with the methodologies established under subsection (c);

"(3) issue technical guidance and provide outreach, education, and technical assistance to relevant providers of services and suppliers, as determined appropriate by the Secretary, to facilitate participation in the program and compliance with program requirements, including with respect to the standards and measures described in subsection (d); and

"(4) carry out compliance monitoring, oversight, and enforcement activities, in accordance with subsection (e).

"(b) Program Participation and Design.—

"(1) APPLICATION PROCESS FOR PROGRAM PARTICIPANTS.—

"(A) IN GENERAL.—The Secretary shall establish an application process, pursuant to subparagraph (B), for purposes of determining entities or consortia of entities, as applicable, that are qualified to serve as program participants with respect to a given program year.

"(B) APPLICATION PROCESS REQUIREMENTS.—Prior to a program year (in a form and manner, and at a time, specified by the Secretary), the Secretary shall solicit and

review applications from potential program participants.

"(C) APPLICATION CONTENTS.—

"(i) INITIAL APPLICATION.—

"(I) IN GENERAL.—With respect to a given program year, an applicant that did not serve as a program participant during the previous program year shall submit an initial application, using a standardized template developed and published by the Secretary.

"(II) REQUIREMENTS.—Such application shall include, as determined appropriate by the Secretary—

"(aa) a description of each applicable generic for which such applicant intends to participate in such program;

"(bb) a description of any advanced standards described under subsection (d)(4) or buffer inventory standards described under subsection (d)(5) that such applicant can meet for each such generic;

"(cc) a description supported by documentation and evidence of how such applicant is capable of completing program functions; and

"(dd) any other information determined appropriate by the Secretary for purposes of carrying out the program.

"(ii) ABRIDGED APPLICATION FOR SUBSEQUENT YEARS.—With respect to a given program year, for an applicant serving as a program participant for the year prior to such program year, such applicant may submit an abridged application, pursuant to a standardized template developed and published by the Secretary, which shall include changes or additions to the information submitted by such applicant in such applicant's initial application or previous abridged applications, in addition to any other information and documentation determined necessary and appropriate by the Secretary with respect to such subsequent program year.

"(iii) ATTESTATION.—The applications described in clauses (i) and (ii) shall include an attestation from such applicant to the Secretary that any information submitted in such application is true, complete, and factual to the best of the knowledge of such applicant.

"(2) PROGRAM PARTICIPANTS.—

"(A) PROGRAM PARTICIPANT DEFINED.—For purposes of this section, the term 'program participant' means, with respect to a given program year, an entity, or consortium of entities, that—

"(i) submits an application under paragraph (1)(C), with respect to a given program year;

"(ii) enters into a Program Participation Agreement under subparagraph (C) and is listed by the Secretary under subparagraph (D); and

"(iii) complies with all requirements of such Program Participation Agreement and any other requirements determined necessary and appropriate by the

Secretary to carry out the program under this section.

"(B) DETERMINATION AND NOTIFICATION.—Based on the applications submitted under paragraph (1), the Secretary shall determine whether each applicant for a given program year meets the requirements to be a program participant for such year. The Secretary shall notify each such applicant of such determination and offer a Program Participation Agreement, as described in subparagraph (C), for such program year.

"(C) PROGRAM PARTICIPATION AGREEMENT.—From the time of an offer made under subparagraph (B) with respect to a given program year, an applicant shall have [15 days] to enter into a Program Participation Agreement, under which such applicant shall agree to the following terms and conditions (in a form and manner, and at a time, specified by the Secretary):

"(i) Each program participant shall provide to the Secretary, by not later than [October 1, 2026, in the case of a participant with respect to the first program year] and by October 1 of each subsequent year, a list of each payment-eligible provider that has entered into a Program Provider Agreement with such participant for the next program year and a list of each applicable generic subject to such agreement for such program year.

"(ii) For each Program Provider Agreement with a payment-eligible provider specified under clause (i), such program participant shall—

"(I) provide timely notification to the Secretary of any updates to the information provided pursuant to clause (i); and

"(II) provide timely notification to the Secretary of any violation of the terms of such agreement by such provider, including a description of any corrective actions undertaken by such participant or provider to remedy or otherwise address such violation.

"(iii) Such program participant shall comply with periodic audits and other oversight and enforcement activities and requirements, as described in subsection (e).

"(iv) Such program participant shall provide the Secretary with—

"(I) a list of manufacturers with which such participant has entered into a Manufacturer Reliability Agreement (as described in paragraph (4)(C));

"(II) the summary information described under paragraph (4)(C)(v) for each such manufacturer; and

"(III) timely notification of manufacturer violations of terms or conditions of any such Manufacturer Reliability Agreement, as well as a summary of corrective actions undertaken by any such manufacturer and by such participant to remedy any such violations.

"(v) Such program participant shall attest that any information submitted to a payment-eligible provider, a manufacturer, or the Secretary related to the program is, to the best of its knowledge, true, complete, and factual.

"(vi) Such program participant shall comply with all relevant reporting and

other programmatic requirements under this section and provide any additional information that the Secretary determines is necessary to calculate and make prevention and mitigation incentive payments to providers, pursuant to subsection (c).

"(vii) Such program participant shall comply with the processes for agreement modifications, suspensions, and terminations described under paragraph (5)(C).

"(viii) Such program participant shall attest that any information submitted pursuant to [the Program Participant Agreement/this section] is true, complete, and factual to the best of the knowledge of such participant.

"(ix) Any other terms and conditions determined appropriate by the Secretary for purposes of carrying out the program under this section.

"(D) PROGRAM PARTICIPANT LIST.—Not later than [January 1, 2026], and by January 1 of each subsequent year, the Secretary shall publish, maintain, and update, as applicable, on a publicly available internet website of the Centers for Medicare & Medicaid Services, a list of each program participant that has entered a Program Participation Agreement with respect to at least 1 applicable generic for a program year. Such list shall be integrated and accessible with respect to other program information published by the Secretary pursuant to subsection (e) and shall include, for each such participant—

"(i) the name, relevant contact information, and date of initial entrance into a Program Participation Agreement for such participant;

"(ii) a list of all applicable generics, identified by the generic or non-proprietary name, covered by the agreement specified under clause (i);

"(iii) for each such generic, a list of all advanced and buffer inventory standards, as described under subsection (d), that such agreement is expected to meet for such program year; and

"(iv) any other information determined appropriate by the Secretary for purposes of carrying out the program under this section.

"(3) PAYMENT-ELIGIBLE PROVIDERS.—

"(A) PAYMENT-ELIGIBLE PROVIDER DEFINED.—For purposes of this section, the term 'payment-eligible provider' means, with respect to a given program year, a provider of services (as defined in section 1861(u)) or supplier (as defined in section 1861(d)) that—

"(i) furnishes items and services inclusive of applicable generics to beneficiaries under this title as part of the ordinary course of items and services furnished by such provider of services or supplier;

"(ii) enters into, and has in effect, at least 1 Program Provider Agreement with a program participant under this section (or, in the case of a provider of services or supplier electing to participate directly in the program pursuant to subparagraph (C), has in effect a Direct Program Participation Agreement with the Secretary); and

"(iii) complies with—

"(I) all requirements of such Program Provider Agreement (or Direct Program Participation Agreement, as applicable);

"(II) the reporting requirements described in subparagraph (F), certification requirements described in subparagraph (G), and attestation requirements described in subparagraph (H); and

"(III) any other requirements determined necessary and appropriate by the Secretary for purposes of carrying out the program under this section.

"(B) PROGRAM PROVIDER AGREEMENTS.—With respect to a given program year, in order to be eligible to receive any payments specified under subsection (c), a payment-eligible provider shall, unless electing to participate directly in the program pursuant to subparagraph (C), enter into at least 1 Program Provider Agreement with a program participant for at least 1 applicable generic for such program year (at a time, and in a form and manner, specified by the Secretary). Such payment-eligible provider and program participant shall comply with all terms under such Program Provider Agreement, which shall include the following:

"(i) Such agreement shall specify a list of each applicable generic covered by such agreement for which such provider intends to meet all core standards and, as applicable, any advanced or buffer inventory standards specified under subsection (d) for such program year.

"(ii) Such program participant or provider shall comply with the processes for agreement modifications, suspensions, and terminations described under paragraph (5)(C).

"(iii) Such provider shall comply with any audits or other enforcement or oversight activities undertaken pursuant to subsection (e).

"(iv) Such provider shall comply with reporting and recordkeeping requirements as described in subparagraph (G) in addition to reporting any other information required by the Secretary for purposes of determining eligibility or amounts for any payments under subsection (c) and for monitoring compliance.

"(v) Such program participant shall provide the following information and notifications to such provider, to the extent applicable:

"(I) A list of manufacturers with which such participant has entered into a Manufacturer Reliability Agreement (as described in paragraph (4)(C)) with respect to an applicable generic covered by any Program Provider Agreement in effect between such participant and such provider.

"(II) Timely notification of manufacturer violations of terms or conditions of any such Manufacturer Reliability Agreement, as well as a summary of corrective actions undertaken by any such manufacturer and by such participant to remedy any such violations.

"(III) The summary information described under paragraph (4)(C)(v) for each manufacturer listed under subclause (I).

"(IV) Advance notice of any modification or termination of such Program Participation Agreement for such participant with the Secretary for such program year.

"(V) Timely notification of any violations by such participant of such Program Participation Agreement, as identified by the Secretary, and any corrective actions undertaken by such participant to remedy such violations.

"(VI) Timely notification of any advanced notice and the quarterly reports related to on-time deliveries provided by primary and secondary suppliers pursuant to subparagraphs (B)(v) and (C)(vii) of subsection (d)(3).

"(vi) Such agreement shall not—

"(I) prohibit, or have the effect of prohibiting, such provider from entering into contracts or agreements with other program participants with respect to applicable generics not listed under clause (i); or

"(II) require such provider to enter into an exclusive contract or agreement with such program participant with respect to such provider's participation in the program.

"(vii) Such provider and such program participant shall certify that all information submitted between the parties to such agreement or to the Secretary pursuant to such agreement, is true, complete, and factual, to the best of the knowledge of such provider or program participant.

"(viii) Any other terms and conditions determined necessary and appropriate by the Secretary for purposes of carrying out the program under this section.

"(C) DIRECT PROGRAM PARTICIPATION AGREEMENTS.—

"(i) IN GENERAL.—A payment-eligible provider may, as an alternative to or in addition to entering into a Program Provider Agreement with a program participant—

"(I) apply to participate directly in the program through the application process specified under paragraph (1), with modifications and adaptations, as needed, to collect the information necessary for the Secretary to make a determination with respect to whether such provider may participate directly in the program; and

"(II) subject to the determination under subclause (I), enter into a Direct Program Participation Agreement with the Secretary for purposes of participating in the program.

"(ii) DIRECT PROGRAM PARTICIPATION AGREEMENT.—Such Direct Program Participation Agreement shall include all relevant and applicable components and information specified under a Program Participation Agreement described in paragraph (2)(C) and under a Program Provider Agreement described in subparagraph (B) of this paragraph, modified and adapted as determined necessary and appropriate by the Secretary to carry out the purposes of the program.

"(D) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as requiring a payment-eligible provider to participate in the program through a single Program Provider Agreement or Direct Program Participant Agreement with respect to all applicable generics for which such provider elects to participate in the program.

"(E) INITIATION OF PROGRAM PROVIDER AGREEMENT.—A payment-eligible provider shall enter into a Program Provider Agreement before October 1 in the year before the relevant program year. Where such agreement is terminated or suspended, such payment-eligible provider may enter into a new Program Provider Agreement for such program year, subject to timely notification requirements as determined by the Secretary.

"(F) REPORTING AND RECORDKEEPING REQUIREMENTS.—Pursuant to the agreements described in subparagraphs (B) and (C), payment-eligible providers shall submit, at least annually, to the program participant with which such provider has entered into a Program Provider Agreement (as applicable) and to the Secretary (in a form and manner, and at a time, specified by the Secretary) data and information, with respect to each applicable generic for which such provider has entered into such agreement, on—

"(i) the total committed volume by such provider for such applicable generic for the relevant program year pursuant to a contract or agreement with a primary supplier under subsection (d)(3)(B) and a secondary supplier under subsection (d)(3)(C);

"(ii) the total number of units of such applicable generic that such provider purchased from any manufacturer or other entity during the relevant program year;

"(iii) the number of units of such applicable generic broken down by purchases from primary suppliers, secondary suppliers, and other manufacturers and entities during the relevant program year;

["(iv) the number of units of such applicable generic that such provider administered during the relevant program year;]

"(v) total buffer inventory for such applicable generic such provider agreed to purchase pursuant to a contract or agreement under subsection (d)(3)(B) for the relevant program year expressed as a number of units, as applicable;

"(vi) the amount under clause (v), expressed as a number of months' supply based on the annual inventory amount reported by such provider under clause (ii), as applicable;

"(vii) off-contract purchases, expressed as a number of units purchased, with respect to such applicable generic during the relevant program year;

"(viii) certifications by such provider, as applicable, with respect to any off-contract purchases of such applicable generic reported under clause (vii) that met the terms of the exception specified under subsection (d)(3)(B)(ii)(I) during the relevant program year and the number of units of such applicable generic purchased pursuant to such certification; and

"(ix) for the first year of program participation, reasonable estimates of total

standard inventory of such applicable generic based on purchases by such provider from any manufacturer during previous calendar years, based on a methodology and documentation of past purchases, as determined by the Secretary.

"(G) PRICING STABILITY CERTIFICATIONS.—A payment-eligible provider shall submit an annual Pricing Stability Certification to the Secretary, in a time, form and manner determined by the Secretary, certifying that such provider will not seek or accept any additional rebates, discounts, or other price concessions from applicable manufacturers beyond any rebates, discounts, or other price concessions agreed to in contracts under subparagraph (B)(iii) or (C)(v) of subsection (d)(3) on units of applicable generics for which such provider receives payments under subsection (c), including discounts under section 340B of the Public Health Service Act.

"(H) ATTESTATIONS OF COMPLIANCE.—A payment-eligible provider shall submit attestations to the Secretary, in a time, form and manner determined by the Secretary, that such provider is compliant with any standards under paragraphs (2) through (5) of subsection (d) for which such provider intends to receive an incentive payment under subsection (c) with respect to an applicable generic for the program year.

"(4) APPLICABLE GENERIC MANUFACTURERS.—

"(A) APPLICABLE GENERIC MANUFACTURER DEFINED.—For purposes of this section, the term 'applicable generic manufacturer' means a manufacturer that, with respect to a given program year—

"(i) manufactures at least 1 applicable generic, as defined in subparagraph (B), during such program year;

"(ii) has in effect a Manufacturer Reliability Agreement, as described in subparagraph (C), with at least 1 program participant or payment-eligible provider during such program year;

"(iii) adheres to the terms of all such Manufacturer Reliability Agreements and meets any other requirements determined necessary and appropriate by the Secretary to carry out the program under this section; and

"(iv) reports an average sales price for any applicable generic manufactured by such manufacturer in accordance with paragraphs (1) through (3) of section 1847A(c), subject to all oversight and enforcement provisions applicable to such section, by no later than [January 1, 2025] for generics approved and marketed by the date of enactment of this section and at a time determined by the Secretary for generics approved and marketed thereafter.

"(B) APPLICABLE GENERIC DEFINED.—

"(i) IN GENERAL.—For purposes of this section, the term 'applicable generic' means a multiple source drug (as defined in section 1847A(c)(6)(C)(i)) that is manufactured by an applicable generic manufacturer and is furnished under part A or part B of this title (or, in the case of a multiple source drug approved or licensed by the Food and Drug Administration for at least one pediatric indication, is furnished under title XIX of this Act) and—

"(I) is not a private label drug unless—

"(aa) the entity marketing or distributing such private label drug discloses to program participants and payment-eligible providers the price at which such entity purchased such drug from the manufacturer or entity affiliated with such manufacturer;

"(bb) the price charged by such entity to any payment-eligible provider for such drug is no more than [10] percent higher than the purchase price described in item (aa); and

"(cc) the contract or agreement for such private label drug between any program participant, affiliate, or provider and the manufacturer of such drug complies with the core standards described in subparagraph (B) or (C) of subsection (d)(3), as applicable;

"(II) for program years beginning with [2027], is an injectable or infused drug [that is not usually self-administered]; and

["(III) for program years beginning with [2030], is either—]

["(aa) a drug described in subclause (II); or]

["(bb) a drug determined by the Secretary, in consultation with the Commissioner of the Food and Drug Administration and relevant stakeholders, as appropriate, to be at a heightened risk of supply disruption or shortage (as defined under section 506C(h)(2) of the Federal Food, Drug, and Cosmetic Act.]

["(ii) FACTORS FOR CONSIDERATION.—In making a determination under clause (i)(III)(bb), the Secretary, in consultation with the Commissioner, shall consider the following factors:]

["(I) The inclusion of such drug on the drug shortage list established under section 506E(a) of the Federal Food, Drug, and Cosmetic Act multiple times in recent years or for a substantial duration of time during such years.]

["(II) Manufacturer notifications related to such drug made pursuant to section 506C(a) of the Federal Food, Drug, and Cosmetic Act in recent months or years.]

["(III) Any other factor determined relevant and appropriate by the Secretary.]

"(iii) AGGREGATION.—For purposes of this section, the Secretary shall treat all strengths, dosage forms, package sizes, and package types of a multiple-source drug with the same established (generic) name, in the aggregate, as a single applicable generic.

"(C) MANUFACTURER RELIABILITY AGREEMENTS.—Each applicable generic manufacturer participating in the program under this section shall, with respect to any volume of any applicable generic supplied by such manufacturer pursuant to such program, enter into and comply with the terms of a Manufacturer Reliability Agreement with each program participant (and, in the case of a payment-eligible

provider participation through a Direct Program Participation Agreement, each such provider, as applicable). For purposes only of this subparagraph, 'program participant', as used in this subparagraph, refers to both program participants (as described in paragraph (2)) and payment-eligible providers electing to enter into Direct Program Participation Agreements. The terms and conditions of any Manufacturer Reliability Agreement shall include the following:

"(i) Any manufacturer entering such agreement shall provide a description to such participant, upon entering into such agreement, of how and why such manufacturer meets or has the capacity and capabilities needed to enable providers to meet, as applicable, relevant standards established under subsection (d) with respect to each applicable generic covered by such agreement, as demonstrated through the provision (to any program participant subject to such agreement) of supporting information, evidence, and documentation determined necessary and appropriate by the Secretary.

"(ii) Such manufacturer shall provide to such participant, as a condition for entering such agreement, the relevant supply chain, compliance, and quality information specified under subparagraph (D) with respect to each applicable generic subject to such agreement.

"(iii) Such manufacturer shall provide timely notification to such participant of any updates or changes in the relevant supply chain, compliance, and quality information described in clause (ii) with respect to each applicable generic covered under such agreement, including in the case where the Secretary modifies requirements for such information and such modifications require updates to remain in compliance.

"(iv) Such manufacturer shall provide information and timely updates related to any drug product quality initiatives identified by the Secretary for such applicable generic in which such manufacturer has engaged or is currently engaged, including any documentation, ratings, or other materials relevant to assessing the scope and nature of the engagement of such manufacturer in such initiative for such generic.

"(v) With respect to such information and updates specified under clauses (ii), (iii) and (iv), such manufacturer shall provide summary information to the program participant that such program participant can share with payment-eligible providers, in accordance with a standardized template developed by the Secretary, in a form and manner, and at a time, specified by the Secretary and in accordance with appropriate protections for proprietary information established by the Secretary.

"(vi) With respect to each applicable generic subject to such agreement, such manufacturer shall attest that such manufacturer shall comply with legal and regulatory requirements, to the extent applicable to such generics, related to redundancy risk management plans, as described under section 506C(j) of the Federal Food, Drug, and Cosmetic Act, current Good Manufacturing Practices, and notification requirements under section 506C(a) of the Federal Food, Drug, and Cosmetic Act.

"(vii) Such manufacturer shall provide timely notification to such program participant under such agreement and to the Secretary of any violation by such manufacturer of any such agreement, or of an alleged violation of such agreement by such participant or by a payment-eligible provider covered under such agreement, along with supporting documentation.

"(viii) Such manufacturer shall comply with periodic audits and other oversight and enforcement activities and requirements, as described in subsection (e).

"(ix) Such program participant and manufacturer shall comply with the processes for agreement modifications, suspensions, and terminations described under paragraph (5)(C).

"(x) With respect to any information transmitted or otherwise submitted pursuant to this subparagraph, such manufacturer shall certify that all such information is accurate, complete, and factual, to the best of the knowledge, belief, and understanding of such manufacturer.

"(xi) Any other requirements determined necessary and appropriate by the Secretary.

"(D) INTERAGENCY COORDINATION.—The Secretary shall consult and coordinate with the Administrator and the Commissioner to carry out the following activities and take the following actions:

"(i) DEVELOPING STANDARDS FOR SUPPLY CHAIN, COMPLIANCE, AND QUALITY INFORMATION.—The Secretary shall consult with the Commissioner, as well as with stakeholders, as applicable, in advance of any applications or submissions under this section, to develop, establish, and publish explicit standards for the supply chain, compliance, and quality information submitted by applicable generic manufacturers pursuant to subparagraph (C)(ii). Such standards shall ensure, as determined appropriate by the Secretary, the information submitted pursuant to this subparagraph (accounting for redactions or revisions related to proprietary[, confidential, or commercially sensitive information, or national security interests)] includes the following:

"(I) Information related to compliance, inspection findings (as reflected on FDA Form 483 or a successor document), enforcement action and pre-enforcement (or non-enforcement) action history related to such manufacturer and such applicable generic, including with respect to drug establishments owned or utilized by such manufacturer, as well as other establishments and facilities with which such manufacturer has contracted or entered into a comparable business arrangement related to the sourcing, supply, manufacture, preparation, propagation, compounding, or processing of such drug (including any ingredients or excipients for such applicable generic) under title 21 of the United States Code, or any corresponding regulations.

"(II)(aa) Geographic information, subject to item (bb), to the extent that any disclosure of such information does not result in the disclosure of proprietary information or trade secrets, with respect to establishments that

store finished dosage forms of applicable generics or actively engage in, are expected to engage in, or previously engaged in any of the processes described in subclause (I) with respect to such applicable generic, inclusive of any active pharmaceutical ingredients, other generic drug components, or containers for such generic, as applicable.

"(bb) The geographic information required to be submitted by an applicable generic manufacturer to a program participant under this subclause shall be sufficiently detailed for such participant to differentiate between sources, suppliers, and establishments, including for active pharmaceutical ingredients, for the primary supplier of such generic for such provider, relative to any secondary supplier with which such participant may elect to contract for such generic and for such participant to identify whether an establishment is located in a region of interest (as defined in section 510(h)(7) of the Federal Food, Drug, and Cosmetic Act).

"(III) A list of all entities with a contract, or other comparable arrangement, in effect with such manufacturer with respect to storage of finished dosage forms or any of the processes described in subclause (I), as applicable, in relation to such applicable generic.

"(IV) To the extent applicable, any redundancy risk management plan submitted by such manufacturer for such generic pursuant to section 506C(j) of the Federal Food, Drug, and Cosmetic Act within the most recent 5-year period.

"(V) A list of notifications submitted by such manufacturer for such generic pursuant to section 506C(a) of the Federal Food, Drug, and Cosmetic Act.

"(VI) A list of all instances and durations for which such generic has been placed on the drug shortage list established under section 506E(a) of the Federal Food, Drug, and Cosmetic Act over the course of the most recent 5-year period, along with an explanation of the underlying cause of any such listing and any corrective actions undertaken by such manufacturer to address the relevant disruption or shortage risk.

"(VII) Any other information the Secretary determines appropriate to help program participants and providers assess manufacturer quality and reliability.

"(ii) INFORMATION SHARING AND EXCHANGE.—The Secretary shall, as determined appropriate, take actions to facilitate and expedite the exchange of relevant information among the Department of Health and Human Services, the Centers for Medicare & Medicaid Services, and the Food and Drug Administration, including by—

"(I) providing for routine updates and notifications by the Secretary to the Commissioner with respect to relevant components of this program, including upon identification of any violations of any requirements under this section;

"(II) expanding upon or enhancing, to the extent appropriate and practicable, information provided by the Secretary to the Administrator pursuant to section 506E(d) of the Federal Food, Drug, and Cosmetic Act with respect to drugs currently in shortage;

"(III) providing for the prompt and routine provision of relevant information by the Secretary to the Administrator, including with respect to notifications made pursuant to subsection (a) of section 506C of the Federal Food, Drug, and Cosmetic Act, along with plans submitted pursuant to subsection (j) of such section, and compliance history for manufacturers and firms with which such manufacturers contract under the Federal Food, Drug, and Cosmetic Act; and

"(IV) consulting at least annually on potential regulatory or subregulatory modifications to such program, and holding periodic, joint public meetings on prevention and mitigation of drug shortages.

"(5) CLARIFICATIONS, STANDARDS, AND PROCESSES FOR AGREEMENTS.—

"(A) CLARIFICATION ON NATURE OF AGREEMENTS.—The agreements described in paragraphs (2)(C), (3)(B), (3)(C)(ii), and (4)(C) shall have the force of a binding contract.

"(B) DURATION OF AGREEMENTS.—The Secretary shall establish a process to allow the parties to agreements described in paragraphs (2)(C), (3)(B), (3)(C)(ii), and (4)(C) to enter into such agreements for a term of multiple program years. Under such process, the Secretary shall specify how such agreements will be updated based on the contents of abridged applications under paragraph (1)(C)(ii) and modifications, suspensions, and terminations under subparagraph (C), as applicable.

"(C) MODIFICATIONS, SUSPENSIONS, AND TERMINATIONS.—The Secretary shall establish processes with respect to modifications, suspensions, and terminations of the agreements described in paragraphs (2)(C), (3)(B), (3)(C)(ii), and (4)(C). Such processes shall include the following:

"(i) Processes the parties to such agreements shall follow in order to make material modifications to such agreements, including requirements to provide advance notice of intent to make such material modifications to other parties to the agreement and to the Secretary in a form and manner, and at a time, specified by the Secretary.

"(ii) Processes the parties to such agreements shall follow in order to voluntarily terminate an agreement, including—

"(I) requirements to provide advance notice of intent to voluntarily terminate such agreement to other parties to the agreement and to the Secretary in a form and manner, and at a time, specified by the Secretary; and

"(II) as determined necessary by the Secretary, requirements for the party electing to terminate such agreement to develop a transition plan outlining the steps that such party will take to minimize disruption for other parties to

the agreement.

"(iii) Processes for mandatory termination or suspension of such agreements in the event of a violation of such agreement by one of the parties to such agreement, including—

"(I) requirements for the Secretary to provide a notice of noncompliance to the party in violation of such agreement identifying any such violation and specifying a timeframe for remedying such violation and providing notification to the Secretary and other parties to the agreement about the actions taken to remedy such violation;

"(II) in the case where such party fails to remedy a violation and provide notification within the timeframe specified under subclause (I), requirements that such party submit to the Secretary and other parties to the agreement, as applicable, a corrective action plan;

"(III) in the case where such party fails to submit a corrective action plan as specified under subclause (II), or where the Secretary determines such party has failed to take adequate steps under such a plan, the Secretary may terminate or suspend all or part of such agreement in a form and manner, and at a time, specified by the Secretary;

"(IV) in the case where the Secretary determines such party has engaged in flagrant or repeated violations of such agreement, the Secretary may terminate or suspend all or part of such agreement in a form and manner, and at a time, specified by the Secretary, without first providing a timeframe for remedying such violation, as described in subclause (I), or requiring a corrective action plan, as described in subclause (II); and

"(V) in the case of flagrant or repeated violations as described under subclause (IV), the Secretary may also require such party to submit and comply with a remediation plan in order for such party to resume program participation.

"(iv) Processes to hold payment-eligible providers harmless for a period of not longer than [6 months] with respect to prevention and mitigation incentive payments received under subsection (c) where a modification, termination, or suspension described under this subparagraph—

"(I) is likely to reduce the amount of payment such provider receives under subsection (c); and

"(II) was not caused by the actions of such provider.

"(D) SIGNIFICANT HARDSHIP.—With respect to the terms of agreements established under paragraphs (2)(C), (3)(B), (3)(C)(ii), and (4)(C), the Secretary may grant temporary waivers or modifications of such terms in the event of significant hardship interfering with the ability of a relevant entity to comply with the requirements under this section, including a natural disaster, public health emergency, bankruptcy, or other unique or unexpected catastrophe or other similar situation.

"(6) OUTREACH AND TECHNICAL ASSISTANCE.—For purposes of facilitating program

participation and compliance under this section, the Secretary shall—

"(A) provide education and outreach to prospective payment-eligible providers, program participants, and applicable generic manufacturers, as applicable, to raise awareness, understanding, and clarity with respect to the program established under this section;

"(B) provide technical assistance to providers of services and suppliers, potential program participants, and manufacturers, as applicable, with respect to entering into agreements specified under this subsection and complying with all terms of such agreements, including with respect to the standards specified under subsection (d); and

"(C) publish and update, on an ongoing basis, as appropriate, materials using existing educational channels to provide a comprehensive understanding of each component of the program.

"(c) Prevention and Mitigation Incentive Payments.—

"(1) IN GENERAL.—Beginning with the first program year of the program established under this section, the Secretary shall—

"(A) calculate and make, on a quarterly basis, lump-sum prevention and mitigation incentive payments related to core standards and advanced standards measures, as applicable, to payment-eligible providers, in accordance with paragraph (2);

"(B) as applicable, calculate and make additional annual lump-sum payments related to buffer inventory standards, in accordance with paragraph (3); and

"(C) as applicable, calculate and make bonus payments related to outcomes measures, in accordance with paragraph (4).

"(2) PAYMENTS RELATED TO CORE STANDARDS AND ADVANCED STANDARDS.—

"(A) CALCULATION OF PAYMENTS FOR A PROGRAM QUARTER.—

"(i) IN GENERAL.—With respect to each quarter of a program year during which a payment-eligible provider meets each core standard specified in subsection (d)(3) with respect to an applicable generic under the program, the Secretary shall calculate a prevention and mitigation incentive payment for such provider for such quarter in an amount equal to—

"(I) the total committed volume for the quarter for such applicable generic for such provider, multiplied by

"(II) the payment factor applicable to such generic for such provider, as specified under clause (ii).

"(ii) PAYMENT FACTOR.—For purposes of this subparagraph, with respect to a payment-eligible provider and applicable generic for a quarter as described in clause (i), the payment factor shall be an amount equal to—

"(I) the applicable incentive percentage for such generic, as described in clause (iii)(I), multiplied by

"(II) the applicable pricing input for such generic for such program year, as described in clause (iii)(II).

"(iii) INPUTS FOR FACTORS FOR CALCULATION.—

"(I) APPLICABLE INCENTIVE PERCENTAGE.—With respect to an applicable generic subject to the program for a payment-eligible provider, for purposes of calculating the payment factor under clause (ii) for a program quarter, the applicable percentage shall be a percentage equal to the sum of—

"(aa) where such provider has met all core standards under subsection (d)(3) with respect to such generic, the base applicable incentive percentage that corresponds with such generic under the methodology described in subparagraph (B)(ii); and

"(bb) where such provider has met at least one advanced standard under subsection (d)(4) with respect to such generic an additional [two] percentage points for each such advanced standard met by such provider with respect to such generic.

"(II) APPLICABLE PRICING INPUT.—With respect to an applicable generic, for purposes of calculating the payment factor under clause (ii), the applicable pricing input shall be—

"(aa) for the first quarter of program year [2027], the average of the quarterly average sales prices for such generic described in section 1847A(c) for the most recent 4 quarters for which such data is available (or, if such data is available for such generic for fewer than 4 full quarters, the average of the quarterly average sales prices for such generic for any quarters for which such data is available), subject to the aggregation rule specified under subclause (III) and the special rule specified under subclause (IV), as applicable;

"(bb) for the second program quarter, the amount specified under item (aa), increased (or reduced, if applicable) based on the percentage by which the Producer Price Index for Pharmaceuticals (or successor index), as computed by the Bureau of Labor Statistics, increased (or decreased, if applicable) over the period between the end of the last of the four quarters described under item (aa) and the most recent date for which data for such index is available; and

"(cc) for each subsequent program quarter, the amount determined for the previous quarter, increased (or reduced, if applicable) based on the percentage change in the index specified under item (bb) between the date used to adjust the amount for such previous quarter based on such index and the most recent date for which data for such index is available.

"(III) AGGREGATION RULE FOR CALCULATIONS FOR APPLICABLE GENERICS WITH MULTIPLE AVERAGE SALES PRICES.—For purposes of the calculations specified under subclause (II)(aa), with respect to an applicable generic that has multiple average sales prices for a given quarter, the Secretary shall calculate the volume-weighted average of all such average sales prices for such generic for each such quarter.

"(IV) SPECIAL RULE FOR CERTAIN APPLICABLE GENERICS WITH INSUFFICIENT AVERAGE SALES PRICE DATA.—With respect to an applicable generic for which insufficient average sales price data is available for the Secretary to make the calculations under subclause (II), the Secretary shall establish an alternative methodology (or multiple alternative methodologies to account for different circumstances) for determining the applicable pricing input for such generic for each program quarter during which such generic is an applicable generic.

"(B) METHODOLOGY FOR ASSIGNING BASE APPLICABLE INCENTIVE PERCENTAGES TO APPLICABLE GENERICS FOR MEETING CORE STANDARDS.—With respect to an applicable generic for a program quarter, the Secretary shall, based on the applicable pricing input for such generic for such quarter, assign such generic to a base applicable incentive percentage for such quarter, for purposes of calculating the percentage amount under subparagraph (A)(iii)(I)(aa) (notwithstanding any additional percentage points for meeting any advanced standard), in accordance with the following methodology:

"(i) The Secretary shall establish a series of cost bands aggregating assignment of applicable generics with applicable pricing inputs within the same range of costs, such that each band corresponds with a different base applicable incentive percentage, with higher percentages for cost bands with lower pricing inputs, subject to clause (iii).

"(ii) No base applicable incentive percentage assigned to an applicable generic shall be lower than [5 percent] or higher than [25 percent], except that a unique base applicable incentive percentage under clause (iii) may exceed or be lower than these thresholds.

"(iii) The Secretary may assign an applicable generic to a unique base applicable incentive percentage that is higher or lower than the base applicable incentive percentage under the cost band to which such generic would otherwise be assigned under clause (i) under the following circumstances:

"(I) When such generic is subject to persistent shortages or threat of shortage over a period of multiple years, as determined by the Secretary.

"(II) When such generic is commonly used by providers of services or suppliers to treat the same disease or condition for similarly situated patients as another applicable generic that references a different listed drug under an application approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act, as determined by the Secretary, and such generics would otherwise be subject to different cost bands under clause (i).

"(III) When the Secretary determines that a base applicable incentive percentage of [5] percent provides an excessive incentive for providers to achieve the standards described under subsection (d).

"(IV) Any other circumstances the Secretary determines appropriate to prevent and mitigate shortages or prevent abuse of payment incentives under this subsection.

"(iv) The Secretary may update the base applicable incentive percentages or

unique base applicable incentive percentages for applicable generics, as determined appropriate by the Secretary, including with respect to any applicable pricing input bands specified under clause (ii), along with the pricing input band to which any applicable generic is assigned.

"(v) Beginning with respect to the first calendar quarter of [2026], the Secretary shall publish (and update, at least once each calendar quarter), on a publicly available internet website of the Centers for Medicare & Medicaid Services, the applicable pricing input and base applicable incentive percentage or unique base applicable incentive percentage for each applicable generic, as updated at least once every calendar quarter.

"(3) PAYMENTS RELATED TO BUFFER INVENTORY STANDARDS.—

"(A) CALCULATION OF PAYMENTS FOR A PROGRAM YEAR.—Beginning with program year [2029], with respect to each program year during which a payment-eligible provider meets a buffer inventory standard specified in subsection (d)(5) with respect to an applicable generic under the program, the Secretary shall calculate and provide an additional lump-sum payment for such provider for such program year in an amount equal to—

"(i) the total buffer inventory for such generic, up to a 6-month supply, multiplied by

"(ii)(I) [150 percent of] the average applicable incentive percentage or the average unique applicable incentive percentage for such program year as described in paragraph (2)(A)(iii)(I), as applicable, multiplied by

"(II) the average applicable pricing input for such generic for such program year described in paragraph (2)(A)(iii)(II).

"(4) PAYMENTS RELATED TO OUTCOME MEASURES.—

"(A) IN GENERAL.—Beginning with program year [2029], for purposes of calculating and making payments to payment-eligible providers based on performance on outcome measures relative to their peer groups under the outcomes measures specified under subsection (d)(6), the Secretary shall allocate the funding available for each such year under subparagraph (B) in accordance with a methodology developed by the Secretary that rewards at least the [top 30 percent] of highest ranked providers across all the outcome measures listed in subsection (d)(6)(B) in aggregate.

"(B) OUTCOME MEASURE FUNDING.—The funding available, with respect to each program year, for purposes of providing payments for the purposes specified under subparagraph (A), shall be—

"(i) [$__; and]

"(ii) [$__].

"(5) AUTHORITY TO RECONCILE AND ADJUST PAYMENTS.—Based on the data reported under subsection (b)(3)(F) and using a methodology established by the Secretary, the Secretary shall reconcile or adjust payments under this subsection for a payment-eligible provider to account for cases where—

"(A) off-contract purchases or other factors reduce volume purchased from primary or secondary suppliers below the total committed volume of an applicable generic for such provider during the relevant program year;

"(B) off-contract purchases or other factors reduce volume purchased from primary or secondary suppliers below total buffer inventory of an applicable generic for such provider during the relevant program year; and

"(C) an advanced standard is met by either the primary supplier or secondary supplier of an applicable generic for such provider, but not both.

"(d) Program Standards and Measures for Determining Incentive Payment Eligibility and Amounts.—

"(1) IN GENERAL.—Any payment-eligible provider shall, with respect to any applicable generic subject to a Program Provider Agreement to which such provider is a party for the relevant program year, comply with and meet the standards and measures established under this subsection in order for such provider to be eligible for payments corresponding to such standards and measures, as specified under subsection (c).

"(2) MINIMUM COMMITTED VOLUME.—In order to become eligible for any payment under subsection (c), with respect to any applicable generic, a payment-eligible provider shall commit and subject at least the minimum committed volume of such generic for a given program year to the core standards described in paragraph (3).

"(3) CORE STANDARDS.—

"(A) IN GENERAL.—A payment-eligible provider shall enter into contracts or agreements that enable such provider to meet the core standards specified under this paragraph with respect to the total committed volume of an applicable generic subject to a Program Provider Agreement or Direct Program Participation Agreement of such provider for the relevant program year in order to be eligible for and receive any payment under subsection (c) for such program year related to such volume.

"(B) CORE STANDARDS FOR CONTRACTS OR AGREEMENTS WITH PRIMARY SUPPLIERS.—The core standards specified under this paragraph shall require that such provider purchase a majority of total committed volume of an applicable generic for a program year from a primary supplier that has in effect a relevant Manufacturer Reliability Agreement for such generic (either with such provider or with such program participant, as applicable), under contracts or agreements that meet the following terms and conditions:

"(i) Such contract or agreement shall be for a duration of—

"(I) in the case of a contract or agreement entered into prior to or during program year [2027 or 2028], at least 2 years; and

"(II) in the case of a contract or agreement entered into during program year [2029] or a subsequent program year, at least 3 years.

"(ii) Such contract or agreement shall prohibit off-contract purchases by such provider that reduce the total committed volume of the applicable generic, except as follows:

"(I) Such contract or agreement shall permit the payment-eligible provider to make off-contract purchases of an applicable generic that would reduce the total committed volume of such applicable generic for the program year only in the case where such provider cannot continue to furnish such generic in sufficient quantities without taking such actions. If utilizing the exception under the preceding sentence, the payment-eligible provider shall maintain, as part of the reporting and recordkeeping requirements described under subsection (b)(3)(F), a certification to the Secretary that both the primary supplier for such generic under this subparagraph and, if applicable, the secondary supplier for such generic under subparagraph (C), were unable to provide sufficient supply of such generic to meet the needs of such provider.

"(II) Such contract or agreement shall permit the payment-eligible provider to make purchases of a separate drug or biological product in lieu of an applicable generic covered under such contract or agreement if such separate drug or product offers a meaningful clinical advantage or other benefit, subject to terms specified under such contract or agreement.

"(iii) The price agreed to in such contract or agreement may not be reduced through rebates, discounts, price concessions, fees, or other forms of remuneration paid by such supplier for the duration of the contract, except for—

"(I) bona fide service fees charged by the program participant to the supplier for services performed for the supplier by the program participant; and

"(II) reasonable fees charged by the program participant to the supplier for failure to meet on-time delivery standards described in clause (v) when such failure is the fault of the supplier.

"(iv) Such contract or agreement shall permit upward price adjustments by the supplier, subject to standards and limitations determined appropriate by the Secretary, for such applicable generic in the event of a natural disaster or other severe supply chain disruption that significantly affects the supply of such applicable generic or the supply of generic drug components of such applicable generic and is not caused by such supplier failing an inspection conducted pursuant to section 510 or 704 of the Federal Food, Drug, and Cosmetic Act, and enforcement actions related to such provisions under such Act;.

"(v) Such contract or agreement shall include uniform standards developed by the Secretary related to on-time deliveries for purchase orders of applicable generics from such supplier. Such supplier shall provide advance notice to program participants and providers with which such supplier has entered into a Manufacturer Reliability Agreement of inability or anticipated inability to meet such on-time delivery standards and quarterly reports on the percentage of deliveries that met such standards.

"(vi) Such contract or agreement shall include an attestation by each party to such contract or agreement that all information used to establish the terms and conditions of such contract or agreement, and all information shared or submitted

pursuant to such contract or agreement, is, to the best of the knowledge, belief, and understanding of the relevant party, true, factual, and complete.

"(C) CORE STANDARDS FOR CONTRACTS WITH SECONDARY SUPPLIERS.—Unless there [is/are only 1/2 or fewer] manufacturer[s] that produce[s] and market[s] an applicable generic, the core standards specified under this paragraph shall require, subject to exceptions for good cause, as determined appropriate by the Secretary (such as for substantial price differences between applicable generic manufacturers for the same product, natural disasters affecting 1 or more applicable manufacturers, or economic hardship on the part of such provider), that such provider enter into and have in effect a contract or agreement with a secondary supplier of an applicable generic that has in effect a relevant Manufacturer Reliability Agreement for such generic (either with such provider or with such program participant, as applicable) with respect to a program year that is separate and distinct from the contract or agreement described in subparagraph (B) and meets the following terms and conditions:

"(i) Such contract or agreement shall require that the supplier has, and certifies to having, sources and suppliers for active pharmaceutical ingredients [and other generic drug components of such generic] that are different from the sources and suppliers of the primary supplier described in subparagraph (B), except in the case where only 1 facility or drug establishment provides a given function or component for such generic, such that redundancy for such source, function, or supplier would be practically unfeasible.

"(ii) Such contract or agreement shall require that the supplier submit a contingency plan to such provider (or to such participant, acting on behalf of such provider, as applicable) that describes the capacity and capabilities of such supplier and how such supplier intends to meet the purchasing needs of such provider with respect to the applicable volume of such generic, in the event where a supply chain disruption or other exigent circumstances preclude the primary supplier described in subparagraph (B) from meeting such needs.

"(iii) Such contract or agreement shall require that the payment-eligible provider (or such participant acting on behalf of such provider) purchase a minimum of [10] percent of total committed volume of the applicable generic from such secondary supplier.

"(iv) Such contract or agreement shall require that the payment-eligible provider (or such participant acting on behalf of such provider) attempt to purchase any remaining total committed volume or buffer inventory, as applicable, of the applicable generic through the contract or agreement with the secondary supplier under this subparagraph in the event that such provider is unable to procure sufficient volume from the primary supplier pursuant to the contract or agreement described under subparagraph (B) before such provider makes an off-contract purchase.

"(v) Such contract or agreement shall include, with respect to secondary suppliers, the provisions described in subparagraphs (B)(iii), (B)(iv), (B)(v), and (B)(vi).

"(4) ADVANCED STANDARDS.—Beginning in program year [2029], a payment-eligible provider may, in order to become eligible for and receive certain payments under subsection (c), meet 1 or more of the following advanced standards with respect to the total committed volume of an applicable generic during a program year.

"(A) ADVANCED MANUFACTURING STANDARD.—A payment-eligible provider meets the advanced manufacturing standard specified in this subparagraph, with respect to an applicable generic, if the primary supplier or secondary supplier of such generic for such provider uses, for a substantial portion of the manufacture of such generic, a method of manufacturing, or a combination of manufacturing methods, that has been designated as an advanced manufacturing technology, pursuant to section 560L of the Federal Food, Drug, and Cosmetic Act, or that otherwise meets the criteria specified under subsection (b) of such section, as determined appropriate by the Secretary, in consultation with the Commissioner. For purposes of this subparagraph, the term 'substantial portion' means, with respect to an applicable generic manufacturer, that the manufacturer uses such technology for the production of such generic, or of certain components of such generic, in a manner that—

"(i) is not de minimis, as determined by the Secretary, in consultation with the Commissioner; and

"(ii) demonstrably, and by a more than de minimis amount, increases the capacity of such supplier to produce such generic or reduces the time otherwise needed to manufacture such generic, and increases the reliability and predictability of the supply of such generic.

"(B) DOMESTIC MANUFACTURING STANDARD.—A payment-eligible provider meets the domestic manufacturing standard if an applicable generic purchased from a primary or secondary supplier meets the following requirements:

"(i) The finished-dosage form for such generic is produced at a drug establishment located in the United States.

"(ii) No generic drug component of such generic is sourced or produced at a foreign establishment located in a region of interest (as defined in section 510(h)(7) of the Federal Food, Drug, and Cosmetic Act), except in the case where such location is necessary, as determined by the Secretary, to access certain raw materials or other ingredients or generic drug components included in such generic.

"(iii) Active pharmaceutical ingredients for such generic meet minimum domestic sourcing standards from countries that are members the Organization for Economic Cooperation and Development established and promulgated by the Secretary, in consultation with other Federal agencies and with relevant stakeholders.

"(5) BUFFER INVENTORY STANDARDS.—Beginning in program year [2029], a payment-eligible provider may, in order to become eligible for and receive certain payments under subsection (c), meet 1 of the following buffer inventory standards with respect to an applicable generic during a program year.

"(A) ENHANCED BUFFER INVENTORY STANDARD.—

"(i) IN GENERAL.—A payment-eligible provider described in clause (iii) meets the enhanced buffer inventory standard specified in this subparagraph, with respect to an applicable generic, if a contract or agreement with a primary supplier under paragraph (3)(B) includes a requirement that such provider purchase an enhanced buffer supply (as specified in clause (ii)) of the applicable generic and store such supply either through direct storage and maintenance by such provider or, alternatively, through procurement and storage by a third-party entity acting on behalf of such provider, with such buffer supply contractually committed to such provider, in accordance with subparagraph (D).

"(ii) ENHANCED BUFFER SUPPLY.—For purposes of this subparagraph, the term 'enhanced buffer supply' means, with respect to a payment-eligible provider and an applicable generic, a 6-month minimum supply calculated based on the total standard inventory of such applicable generic for such provider, subject to any adjustment made pursuant to subparagraph (E).

"(iii) ELIGIBLE PROVIDERS.—Not later than [January 1, 2028], the Secretary shall determine which payment-eligible providers are eligible for prevention and mitigation payment incentives under subsection (c) for the enhanced buffer inventory standard described in this subparagraph. Eligible providers under this clause shall—

"(I) be included in peer groups as established by the Secretary under paragraph (6)(C)(iii) that represent providers with large size and scale relative to other payment-eligible providers and serve a relatively large number of beneficiaries; and

"(II) not be eligible for prevention and mitigation payments described under subsection (c) related to the customary buffer inventory standard described under subparagraph (B).

"(B) CUSTOMARY BUFFER INVENTORY STANDARD.—

"(i) IN GENERAL.—A payment-eligible provider described in clause (iii) meets the buffer inventory standard specified in this subparagraph, with respect to an applicable generic, if the contract or agreement with a primary supplier under paragraph (3)(B) includes a requirement that the provider subject to such contract or agreement purchase a customary buffer supply (as specified in clause (ii)) of the applicable generic and store such supply either through direct storage and maintenance by such provider or, alternatively, through procurement and storage by a third-party entity acting on behalf of such provider, with such buffer supply contractually committed to such provider, subject to subparagraph (D).

"(ii) CUSTOMARY BUFFER SUPPLY.—For purposes of this subparagraph, the term 'customary buffer supply' means, with respect to a payment-eligible provider and an applicable generic, a 3-month minimum supply based on such provider's historical inventory of such applicable generic, subject to any adjustment made pursuant to subparagraph (E).

"(iii) ELIGIBLE PROVIDERS.—Payment-eligible providers that are not eligible providers under subparagraph (A)(iii) shall be eligible for prevention and

mitigation incentive payments under subsection (c) related to the customary buffer inventory standard described in this subparagraph.

"(C) ANTI-HOARDING MEASURES.—With respect to buffer inventory purchased or procured under this paragraph, the Secretary shall establish an anti-hoarding standard, which shall be a limitation on the maximum supply of an applicable generic that a provider may secure and hold under the standard established in this subparagraph. Payment-eligible providers that violate such standard with respect to total buffer supply shall not be eligible for payments under subsection (c)(3).

"(D) THIRD-PARTY STORAGE.—In the case where a payment-eligible provider meets a buffer inventory standard under this paragraph by contracting with a third-party entity to store and hold the buffer supply of an applicable generic on behalf of such provider—

"(i) such third-party entity must provide a description, including supporting documentation and evidence as determined by the Secretary, that such entity would have the capacity necessary to provide such supply to such provider on a timely basis, subject to standards determined appropriate by the Secretary; and

"(ii) in no case shall a third-party entity specified under this clause hold or store such buffer supply in a location outside of the United States.

"(E) ADJUSTMENTS TO BUFFER SUPPLY THRESHOLD.—The Secretary may, as determined necessary and appropriate by the Secretary to prevent and mitigate drug shortages, make adjustments to the 6-month supply threshold under subparagraph (A)(ii) and the 3-month supply threshold under subparagraph (B)(ii) to—

"(i) adjust such thresholds upward or downward for certain peer groups as described in paragraph (6)(C)(iii) or types of payment-eligible providers, such as for physician practices not owned by a hospital, for providers that furnish items and services under this title in rural areas, or for other entities for which such thresholds would impose substantial administrative or cost burdens;

"(ii) adjust such thresholds downward [or temporarily suspend payments under subsection (c)] with respect to a specific applicable generic (or a specific type of applicable generic) in the case where such threshold [or incentive] poses a reasonable risk of increasing demand for such generic in a manner that causes or worsens supply chain disruptions or shortages, as determined by the Secretary, in consultation with the Commissioner and with relevant stakeholders; or

"(iii) adjust such threshold downward where the typical expiration date for the relevant applicable generic may limit how much volume of such generic a provider should reasonably hold in inventory, as determined by the Secretary.

"(6) OUTCOME MEASURES.—

"(A) IN GENERAL.—Beginning in program year [2029], a payment-eligible provider may be subject to payment adjustments under subsection (c) on the basis of the relative performance of such provider on the outcome measures specified under subparagraph (B).

"(B) ESTABLISHMENT OF OUTCOME MEASURES.—The Secretary shall establish

outcome measures for purposes of measuring the aggregate performance of payment-eligible providers relative to their peer group at preventing and mitigating shortages of applicable generics during a program year. The Secretary [may/shall] develop outcome measures that evaluate the following:

"(i) The extent to which such provider, or a third-party entity acting on behalf of such provider, physically maintained sufficient inventory of applicable generics for which a notification of a discontinuance or interruption was submitted to the Secretary pursuant to section 506C of the Federal Food, Drug, and Cosmetic Act during the program year.

"(ii) The portion of total inventory such provider purchased from manufacturers that are primary or secondary suppliers of such provider met on-time delivery standards, did not experience preventable shortages during the program year, complied with the attestations described under subsection (b)(4)(C)(vi), [or met other related reliability standards related established by the Secretary through rulemaking].

"(iii) Any other outcome measure that evaluates the extent to which a provider prevented or mitigated shortages during the program year based on the purchasing or inventory management practices of such provider.

"(C) PARTICIPATION AND PARAMETERS FOR EVALUATION.—

"(i) IN GENERAL.—The Secretary shall conduct evaluations of the performance of a payment-eligible provider under the program based on the outcome measures described in subparagraph (B) pursuant to this paragraph on an annual basis, with respect to each program year beginning with program year [2029], based on information and data reported by program participants and payment-eligible providers, as applicable, in accordance with requirements determined necessary and appropriate by the Secretary for purposes of carrying out this paragraph.

"(ii) THRESHOLD FOR PARTICIPATION.—In order to be eligible for payments under subsection (c) related to the outcome measures specified in subparagraph (B), a payment-eligible provider shall, either directly or through a program participant acting on behalf of such provider, comply with all data submission and reporting requirements established by the Secretary for purposes of carrying out this paragraph for all outcomes measures under subparagraph (B) and meet any other requirements established by the Secretary.

"(iii) PEER GROUPS.—For purposes of conducting assessments and evaluations of the performance of payment-eligible providers relative to the outcome measures specified in subparagraph (B), the Secretary shall, not later than the beginning of program year [2027], establish and publish peer groups to differentiate among different types and features of payment-eligible providers. In establishing such peer groups, the Secretary shall consult with stakeholders and shall consider any factors determined appropriate by the Secretary, including geographic location and features of such location, category or type of provider of services or supplier, size and scale, affiliation with a large health system or other large health care entity, number of beneficiaries served, and types of items or

services furnished under this title.

"(iv) EVALUATION.—In evaluating the performance of payment-eligible providers based on the outcome measures described in subparagraph (B), the Secretary shall—

"(I) with respect to each peer group established under clause (iii), rank the quantitative performance of all payment-eligible providers that meet the criteria specified under clause (ii) and fit within the scope of such group, evaluating relative performance on such measures on the basis of either all applicable generics relevant to each outcomes measure or, to the extent appropriate and feasible, a selective subset of applicable generics;

"(II) in a form and manner, and at a time, specified by the Secretary, notify each payment-eligible provider described in subclause (I) of their ranking for each outcome measure under such subclause; and

"(III) publish, on a publicly accessible internet website of the Centers for Medicare & Medicaid Services, a summary of the results of such evaluations, disaggregated by peer group.

"(e) Program Oversight, Enforcement, and Accountability.—

"(1) AUDITS.—

"(A) AGREEMENTS.—The Secretary shall conduct periodic audits of Program Participation Agreements, Direct Program Participation Agreements, Program Provider Agreements, and Manufacturer Reliability Agreements under this section, of the information submitted and records maintained in relation to such agreements, and of any other information required to be reported or maintained under this section, in order to assess the accuracy of all such information, as well as to monitor and ensure compliance with the requirements of this section.

"(B) USE OF VENDOR.—The Secretary may contract with a vendor to carry out any of the audits under this paragraph.

"(2) ENFORCEMENT ACTIONS.—

"(A) INTERMEDIATE SANCTIONS.—With respect to violations of a Program Provider Agreement or Direct Program Participation Agreement by a payment-eligible provider, the Secretary may impose, as determined appropriate, intermediate sanctions in accordance with this title, and may require the timely submission of a corrective action plan, as determined appropriate by the Secretary.

"(B) CIVIL MONETARY PENALTIES.—

"(i) IN GENERAL.—The Secretary may impose a civil monetary penalty on a payment-eligible provider in the case where the Secretary determines that intermediate sanctions under subparagraph (A) do not result in the required remediation actions on the part of such provider, or in the case where such a provider commits, once or on a repeat or flagrant basis, 1 or more of the following actions:

"(I) Willful, deliberate, or repeated failure by such provider to comply

with the standards for modifying, suspending, or terminating agreements under subsection (b)(5)(C).

"(II) Willful, deliberate, or otherwise egregious submission of inaccurate and material information or other documents (such as information conflicting with other such documents).

"(III) Refusal to comply with any audit conducted by the Secretary under paragraph (1).

"(IV) A relatively high rate of failure, as determined by the Secretary, for such payment-eligible provider to meet the core standards under subsection (d) after entering into one or more such agreements.

"(ii) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(3) PUBLIC REPORTING RELATED TO THE PROGRAM.—The Secretary shall publish, update, and maintain on an ongoing basis on a publicly available internet website of the Centers for Medicare & Medicaid Services, along with consumer-friendly accompanying explanations and descriptions, to the extent feasible and practicable, the following information with respect to the program established under this section, coordinated and integrated with the information on program participants published under subsection (b)(2)(D):

"(A) FOR PROGRAM PARTICIPANTS.—With respect to each program participant with a Program Participation Agreement currently or previously in effect with the Secretary under subsection (b)(2)(C) (or, as applicable, subject to such adaptations and modifications as the Secretary determines necessary and appropriate, a payment-eligible provider with a Direct Program Participation Agreement currently or previously in effect, hereafter in this subparagraph included in the terms 'program participant' and 'Program Participation Agreement', respectively), for each such agreement, both in the aggregate and by each applicable generic covered under such agreement the following:

"(i) Summary information related to terminations, suspensions, and modifications of agreements under subsection (b) to which such program participant is a party, including a complete listing of all mandatory terminations and suspensions.

"(ii) Data and information, as determined appropriate by the Secretary, on the extent to which payment-eligible providers that have entered into contracts or agreements under subsection (b) with such program participant that met, with respect to each payment quarter specified under subsection (c)—

"(I) all core standards in effect for such program year, as specified under subsection (d)(3);

"(II) each advanced standard in effect for such program year, as specified under subsection (d)(4); and

["(III) buffer inventory standards in effect for such program year, as

specified under subsection (d)(5).]

"(iii) The findings of any audits of such program participant pursuant to paragraph (1) of this subsection.

"(B) FOR PAYMENT-ELIGIBLE PROVIDERS.—With respect to each payment-eligible provider that has or previously had a Program Provider Agreement in effect under subsection (b)(2)(C) (or, if applicable, a Direct Program Participation Agreement under subsection (b)(3)(C)), the following information, both in the aggregate and disaggregated by such agreements and applicable generics:

"(i) Summary information related to terminations, suspensions, and modifications of agreements under subsection (b) to which such provider is a party, including a complete listing of all mandatory terminations and suspensions.

"(ii) The findings of any audits of such provider pursuant to paragraph (1).

"(iii) Any enforcement actions undertaken with respect to such provider under paragraph (2).

"(iv) Any non- or pre-enforcement actions undertaken with respect to such provider, such as through warning letters or other forms of notification.

"(C) FOR APPLICABLE GENERIC MANUFACTURERS.—With respect to applicable generic manufacturers, the following information:

"(i) A list of all applicable generic manufacturers for each applicable generic.

"(ii) High-level information, with no risk of disclosure of proprietary information [or trade secrets], based on the information provided pursuant to subsection (b)(4)(C)(ii).

"(iii) Summary information related to terminations, suspensions, and modifications of agreements under subsection (b) to which such manufacturer is a party, including a complete listing of all mandatory terminations and suspensions.

"(iv) The findings of any audits of such manufacturer pursuant to paragraph (1).

"(4) NON-DUPLICATION AND STREAMLINING IMPLEMENTATION.—The Secretary shall establish procedures to streamline any information submission requirements under this subsection in order to prevent duplication of requirements with other reporting requirements under this title.

"(5) SIGNIFICANT HARDSHIP.—The Secretary may waive or reduce penalties for violations of the requirements under this section, as determined appropriate by the Secretary, in the event of significant hardship interfering with the ability of an entity to comply with the requirements under this section, including in the case of a natural disaster, public health emergency, bankruptcy, or other unique or unexpected catastrophe or other similar situation.

"(6) REPORTING OF ALLEGED VIOLATIONS.—The Secretary shall make available and maintain a mechanism for providers, program participants, manufacturers, and other stakeholders subject to or with knowledge of an agreement under this section to report on a

confidential basis alleged violations of the requirements under this section.

"(f) Definitions.—In this section:

"(1) ACTIVE PHARMACEUTICAL INGREDIENT.—The term 'active pharmaceutical ingredient' has the meaning given to such term in section 744A(2) of the Federal Food, Drug, and Cosmetic Act.

"(2) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Centers for Medicare & Medicaid Services.

"(3) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled by, or related under a common ownership structure with a program participant, or that acts as a contractor or agent to such program participant, insofar as such contractor or agent markets or distributes a private label drug.

"(4) BONA FIDE SERVICE FEE.—The term 'bona fide service fee' means a fee that is reflective of the fair market value (as specified by the Secretary) for a bona fide, itemized service actually performed on behalf of an entity, that the entity would otherwise perform (or contract for) in the absence of the service arrangement and that is not passed on in whole or in part to a client or customer, whether or not the entity takes title to the drug.

"(5) COMMISSIONER.—The term 'Commissioner' means the Commissioner of the Food and Drug Administration.

"(6) CORRECTIVE ACTION PLAN.—The term 'corrective action plan' means a document submitted using a standardized template developed and published by the Secretary that is completed and signed by an entity subject to an agreement under subsection (b) that specifies the actions such entity has taken and plans to take to remedy program violations.

"(7) DRUG PRODUCT QUALITY INITIATIVES.—The term 'drug product quality initiatives' means public or private sector programs that evaluate, test, or otherwise assess manufacturer quality management practices, prescription drug supply chain reliability, or drug product quality.

"(8) GENERIC DRUG COMPONENT.—The term 'generic drug component' means active pharmaceutical ingredients, excipients, or other substances that are ingredients of generic drugs.

"(9) MANUFACTURER.—The term 'manufacturer' has the meaning given that term under section 1860D–14C(g)(5).

"(10) MATERIAL MODIFICATION.—The term 'material modification' means a change to an agreement described under subsection (b) that is likely to reduce payments made under subsection (c) to a payment-eligible provider.

"(11) MINIMUM COMMITTED VOLUME.—

"(A) IN GENERAL.—The term 'minimum committed volume' means, with respect to a payment-eligible provider and an applicable generic, the applicable minimum percentage (as defined in subparagraph (B)) of the total standard inventory for such provider for such generic for a given program year.

"(B) APPLICABLE MINIMUM PERCENTAGE.—

"(i) IN GENERAL.—Subject to clause (ii), the term 'applicable minimum percentage' means, with respect to a payment-eligible provider and an applicable generic—

"(I) for program years [2027 and 2028], [40 percent];

"(II) for program years [2029 through 2031], [60 percent]; and

"(III) for program year [2032 and each subsequent program year], [75 percent].

"(ii) CONTROLLED SUBSTANCES.—The Secretary may set a lower minimum committed volume than the amounts specified under clause (i) for applicable generics that are controlled substances if the Secretary determines that a lower minimum committed volume would help prevent diversion of such generic or facilitate compliance with Federal law.

"(C) CLARIFICATION ON VOLUME CALCULATIONS.—The Secretary, in consultation with relevant stakeholders, shall specify appropriate methodologies and volume metrics for calculating the volume and inventory of an applicable generic for purposes of this section, including with respect to appropriate metrics for determining the scope of a single unit of an applicable generic.

"(12) OFF-CONTRACT PURCHASE.—The term 'off-contract purchase' means a purchase of an applicable generic by a payment-eligible provider that is subject to a Program Provider Agreement or Direct Program Participation Agreement of such provider from a manufacturer other than the primary supplier or a secondary supplier of such provider for such applicable generic pursuant to the contracts or agreements described under subsection (d)(3).

"(13) PRIMARY SUPPLIER.—The term 'primary supplier' means an applicable generic manufacturer that has entered into a contract or agreement for an applicable generic pursuant to subsection (d)(3)(B) with a payment-eligible provider from which such payment-eligible provider agrees to purchase the majority of total committed volume of such applicable generic for a program year.

"(14) PRIVATE LABEL DRUG.—The term 'private label drug' means a drug that is marketed or distributed under a distinct trade name by an entity that does not participate in the manufacture or processing of such drug.

"(15) REMEDIATION PLAN.—The term 'remediation plan' means a document submitted using a standardized template developed and published by the Secretary that is completed and signed by a potential program participant seeking the Secretary's approval to become a program participant that specifies the actions such potential program participant has taken and plans to take to address past Program Participation Agreement violations.

"(16) SECONDARY SUPPLIER.—The term 'secondary supplier' means an applicable generic manufacturer that has entered into a contract or agreement pursuant to subsection (d)(3)(C) with a payment-eligible provider that is distinct from the manufacturer that is the primary supplier for such provider from which such payment-eligible provider agrees to purchase any remaining total committed volume not committed to the primary supplier of such applicable generic for a program year.

"(17) TOTAL BUFFER INVENTORY.—The term 'total buffer inventory' means the estimated number of units of an applicable generic held in buffer inventory by a provider over a year-long period calculated based on a methodology developed by the Secretary using data submitted by such provider under subsection (b)(3)(F).

"(18) TOTAL COMMITTED VOLUME.—The term 'total committed volume' means, with respect to a payment eligible provider and an applicable generic, the percentage of the total purchasing volume (calculated in terms of units of such generic) of the provider for such generic for a given program year that such provider agrees to purchase from a primary supplier or a secondary supplier pursuant to a contract or agreement under subsection (d)(3), excluding any volume of such applicable generic dedicated to buffer inventory.

"(19) TOTAL STANDARD INVENTORY.—The term 'total standard inventory' means the estimated number of units of an applicable generic, excluding any units included in total buffer inventory, that a payment-eligible provider administers over a year-long period calculated based on a methodology developed by the Secretary using data submitted by such provider under subsection (b)(3)(F).

"(g) Program Reports, Studies, and Evaluations.—

"(1) INITIAL STUDY AND REPORT.—

"(A) STUDY.—The Comptroller General of the United States (in this subsection referred to as the 'Comptroller General') shall conduct a study on the effects of the implementation of the program. Such study shall include an analysis of the following:

"(i) Trends, changes, and the frequency with which applicable generics subject to the program—

"(I) appeared on the drug shortage list established under section 506E(a) of the Federal Food, Drug, and Cosmetic Act, drug shortage lists maintained by the American Society of Health-System Pharmacists, or drug shortage lists maintained by other organizations, as determined appropriate by the Comptroller General; or

"(II) were subject to notifications under section 506C(a) of the Federal Food, Drug, and Cosmetic Act.

"(ii) Trends and changes in the amounts paid to manufacturers for applicable generics before and after implementation of the program.

"(iii) Hospital and provider participation in the program and findings from stakeholder surveys or interviews on the greatest incentives and barriers to program participation.

"(iv) Participation in the program by manufacturers, wholesalers, group purchasing organizations, and other entities and findings from stakeholder surveys or interviews on the greatest incentives and barriers to program participation.

"(v) How the program could be improved to address loopholes, further prevent and mitigate prescription drug shortages, or improve program efficiency.

"(vi) Other items determined appropriate by the Comptroller General.

"(B) REPORT.—Not later than [January 1, 2031], the Comptroller General shall publish a report on the study conducted under subparagraph (A).

"(2) SUBSEQUENT STUDIES AND REPORTS.—The Comptroller General may, as determined appropriate, conduct subsequent studies and produce subsequent reports with respect to the ongoing implementation and effects of the program.

"(h) Implementation.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any money in the Treasury not otherwise appropriated, $[XXX] for fiscal year [2025], to remain available until expended, for purposes of carrying out this section.".

SEC. 3. REBATES FOR GENERIC COVERED OUTPATIENT DRUGS UNDER MEDICAID.

(a) Limitation on Covered Outpatient Drugs; Determination of Amount of Rebate.—Section 1927(c)(3) of the Social Security Act (42 U.S.C. 1396r–8(c)(3)) is amended—

(1) in subparagraph (B)—

(A) in clause (ii), by striking "and" after the semicolon;

(B) in clause (iii)—

(i) by inserting "and before _____," after "2009,"; and

(ii) by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following:

"(iv) after [_____], is [___] percent."; and

(2) in subparagraph (C)—

(A) in clause (i)—

(i) by striking "covered outpatient drug other than a single source drug or an innovator multiple source drug of a manufacturer" and inserting "covered outpatient drug described in clause (v)"; and

(ii) by striking "clause (ii)" and inserting "clauses (ii) and (vii)"; and

(B) in clause (iii), in the matter preceding subclause (I), by inserting "described in clause (v)" after "covered outpatient drug"; and

(C) by adding at the end the following new clauses:

"(v) APPLICATION TO CERTAIN COVERED OUTPATIENT DRUGS.—The additional rebate described in this subparagraph shall only apply to a covered outpatient drug that—

"(I) is not a single source drug or innovator multiple source drug;

"(II) is a drug approved under an abbreviated new drug application under section 505(j) of the Federal Food, Drug, and Cosmetic Act, in the case where—

"(aa) the reference listed drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, including any 'authorized generic drug' (as that term is defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act), is not being marketed, as identified in the Food and Drug Administration's National Drug Code Directory;

"(bb) there is no other drug approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act that is rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations') and that is being marketed, as identified in the Food and Drug Administration's National Drug Code Directory;

"(cc) the manufacturer is not a 'first applicant' during the '180-day exclusivity period', as those terms are defined in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act; and

"(dd) the manufacturer is not a 'first approved applicant' for a competitive generic therapy, as that term is defined in section 505(j)(5)(B)(v) of the Federal Food, Drug, and Cosmetic Act; and

"(III) with respect to the rebate period involved, has an average annual total cost under this title per individual who uses such drug (as determined by the Secretary using the most recent data available or, if data is not available, as estimated by the Secretary) that is equal to or greater than the amount specified for the rebate period in clause (vi).

"(vi) AMOUNT SPECIFIED.—

"(I) IN GENERAL.—For purposes of clause (v)(III), the amount specified in this clause for a rebate period shall, subject to subclause (II), be equal to—

"(aa) for rebate periods beginning in calendar year [2027], $100; and

"(bb) for rebate periods beginning in a subsequent calendar year, $100, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for January of such calendar year exceeds such index for January of [2027].

"(II) ROUNDING.—Any amount determined under subclause (I) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

"(vii) REDUCTION OR WAIVER FOR GENERIC DRUG SHORTAGES AND SEVERE SUPPLY CHAIN DISRUPTIONS.—The Secretary shall reduce or waive the amount of any rebate increase applicable under clause (i) for a rebate period with respect to each dosage form and strength of a covered outpatient drug described in clause (v) and a calendar quarter—

"(I) in the case of such a drug that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act at any point during the calendar quarter;

"(II) in the case of such a drug when the Secretary determines there is a

severe supply chain disruption during the calendar quarter, such as that caused by a natural disaster or other unique or unexpected event; and

"(III) in the case of such a drug if the Secretary determines that without such reduction or waiver, the drug is likely to be described as in shortage on such shortage list during a subsequent calendar quarter.".

(b) Effective Date.—The amendments made by this section shall take effect on [January 1, 2027], and shall apply to rebate periods beginning on or after such date.