[DISCUSSION DRAFT]

118TH CONGRESS
1ST SESSION

H. R. _____

To address drug shortages, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

M__. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To address drug shortages, and for other purposes.

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 "_____ Act of 2023".

TITLE I—MEDICAID

SEC. 101. EXEMPTING CERTAIN SPECIFIED DRUGS FROM CERTAIN INCREASES IN REBATES PAID UNDER THE MEDICAID PROGRAM; REBATE CAP FOR CERTAIN DRUGS.

Section 1927(c)(3) of the Social Security Act (42 U.S.C. 1396r–8(c)(3)) is amended—

(1) in subparagraph (A), by striking ''subparagraph (C)'' and inserting ''subparagraphs (C) and (D)'';

(2) in subparagraph (C)—

(A) clause (i), by striking ''The amount'' and inserting ''Subject to clause (v) and subparagraph (D), the amount''; and

(B) by adding at the end the following new clause:

''(v) NONAPPLICATION OF INCREASE FOR SPECIFIED GENERIC DRUGS AND SPECIFIED INJECTABLE DRUGS.—

''(I) IN GENERAL.—No increase shall be made under this subparagraph with respect to the amount of the rebate otherwise specified in subparagraph (A) for a rebate period beginning on or after January 1, 2024,

for a dosage form and strength of a covered outpatient drug that is a specified generic drug or a specified injectable drug (as such terms are defined in subclause (II)).

''(II) DEFINITIONS.—In this clause:

''(aa) SPECIFIED GENERIC DRUG.—The term 'specified generic drug' means, with respect to a rebate period, a drug—

''(AA) 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 such period; or

''(BB) that the Secretary determines there is a severe supply chain disruption during such period, such as that caused by a natural disaster or other unique or unexpected event.

''(bb) SPECIFIED INJECTABLE DRUG.—The term 'specified injectable drug' means, with respect to a rebate period, a drug—

''(AA) that is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act for at least one indication for a serious disease or condition (as defined in section 312.300 of title 21, Code of Federal Regulations (or a successor regulation)); and

''(BB) with respect to which there is at least one other sterile injectable drug that is approved under such section 505(j) referring to the same listed drug (as such term is defined in such section 505(j)) and sold or marketed in the United States.''; and

(3) by adding at the end the following new subparagraph:

''(D) MAXIMUM REBATE AMOUNT.—In no case may the amount specified under this subsection with respect to each dosage form and strength of a multiple source drug (other than an innovator multiple source drug) for a rebate period beginning on or after January 1, 2024, exceed 100 percent of the average manufacturer price of the drug, if the drug is a specified generic drug (as defined in subparagraph (C)(3)(v)(II)(aa)) or a specified injectable drug (as defined in subparagraph (C)(3)(v)(II)(bb)).''.

TITLE II—340B PROGRAM

SEC. 201. EXEMPTING CERTAIN GENERIC INJECTABLE DRUGS FROM THE 340B DRUG DISCOUNT PROGRAM.

Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by adding at the end the following new subsection:

''(f) EXCLUSION OF CERTAIN GENERIC INJECTABLE DRUGS.—Beginning January 1, 2024, for purposes of this section, the term 'covered outpatient drug' shall not include a sterile injectable drug—

''(1) that is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act for at least one indication for a serious disease or condition (as defined in section 312.300 of title 21, Code of Federal Regulations (or a successor regulation)); and

''(2) with respect to which there is at least one other sterile injectable drug that is approved under such section 505(j) referring to the same listed drug (as such term is defined in such section 505(j)) and sold or marketed in the United States.''.

SEC. 202. GAO REPORT.

Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the role of the 340B drug discount program, and other Federal laws and programs that artificially keep the costs of generic drugs low, on access to such drugs and the frequency that such drugs are included on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e). Such report shall include—

(1) the number of covered outpatient drugs that have been subject to ''penny pricing'' under the 340B drug discount program as described in the final rule of the Health Resources and Services Ad-

ministration titled ''340B Drug Pricing Program Ceiling and Manufacturer Civil Monetary Penalties Regulation'' and published in the Federal Register on November 30, 2018 (83 Fed. Reg. 61563) since the finalization of such rule, and the number of such drugs with a ceiling price at $0.01 under the 340B drug discount program that have been in shortage at any point since 2017; and

(2) the number of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) that have had an average manufacturer price equal to $1 or less and have been in shortage at any point since 2014.

SEC. 203. HRSA GUIDANCE.

Not later than 18 months after the date of the enactment of this Act, the Administrator of the Health Resources and Services Administration shall issue guidance to covered entities under 340B of the Public Health Service Act (42 U.S.C. 256b) as to how such entities may transfer a drug described as in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e) to other covered entities if necessary in a manner consistent with the prohibition on the diversion of covered outpatient drugs, and

specify any reporting requirements for such entities with respect to such transfer.

TITLE III—MEDICARE

SEC. 301. REDUCING INFLATION REBATE AMOUNTS FOR CERTAIN SHORTAGE DRUGS SUBJECT TO REBATE WAIVERS UNDER THE MEDICARE PROGRAM.

(a) PART B INFLATION REBATES.—Section 1847A(i)(3)(G) of the Social Security Act (42 U.S.C. 1395w–3a(i)(3)(G)) is amended—

(1) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively, and adjusting the margins accordingly;

(2) by striking ''The Secretary'' and inserting the following:

''(i) IN GENERAL.—The Secretary''; and

(3) by adding at the end the following new clause:

''(ii) PHASE-OUT OF WAIVER OF REBATE AMOUNT.—

''(I) IN GENERAL.—In the case of a part B rebatable drug with respect to which the Secretary has waived, under clause (i), the entirety

of the amount under subparagraph (A) for a calendar quarter occurring on or after the date of the enactment of this clause, beginning with the first succeeding calendar quarter during which such drug is not eligible for a waiver or reduction under such clause, the Secretary shall reduce the amount under subparagraph (A) for such drug for such first succeeding quarter and the following 3 quarters by the percentage specified in subclause (II).

''(II) PERCENTAGE SPECIFIED.—For purposes of subclause (I), the percentage specified in this subclause is, with respect to a part B rebatable drug with respect to which the Secretary has waived, under clause (i), the entirety of the amount under subparagraph (A) for a calendar quarter, the following:

''(aa) For the first calendar quarter during which a reduction is required under subclause (I), 75 percent.

''(bb) For the second such calendar quarter, 50 percent.

''(cc) For the third such calendar quarter, 25 percent.

''(dd) For the fourth such calendar quarter, 10 percent.''.

(b) PART D INFLATION REBATES.—Section 1860D–14B(b)(1)(C) of the Social Security Act (42 U.S.C. 1395w–114b(b)(1)(C)) is amended—

(1) by redesignating clauses (i) through (iii) as subclauses (I) through (III), respectively, and adjusting the margins accordingly;

(2) by striking ''The Secretary'' and inserting the following:

''(i) IN GENERAL.—The Secretary''; and

(3) by adding at the end the following new clause:

''(ii) PHASE-OUT OF WAIVER OF REBATE AMOUNT.—In the case of a part D rebatable drug with respect to which the Secretary has waived, under clause (i), the entirety of the amount under subparagraph (A) for an applicable period occurring on or after the date of the enactment of this

clause, the Secretary shall reduce the amount under subparagraph (A) for such drug for the first succeeding applicable period during which such drug is not eligible for a waiver or reduction under such clause by 40 percent.''.

(c) PROHIBITION ON LENGTH OF DISRUPTION REQUIREMENT.—The Secretary of Health and Human Services may not require, as a condition of granting a waiver or reduction of a rebate amount with respect to a drug otherwise applicable under section 1847A(i) of the Social Security Act (42 U.S.C. 1395w–3a(i)) or section 1860D–14B of such Act (42 U.S.C. 1395–114b), that the supply chain disruption or shortage on which such waiver or reduction is based last for a certain number of days.

SEC. 302. STUDY ON MARKET-BASED PRICING FOR SHORTAGE DRUGS UNDER MEDICARE PART B.

Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall conduct a study and submit to Congress a report on payment under part B of the Medicare program for drugs, including generic sterile injectable drugs, that are included on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

356e) or are at risk of being included on such list. Such report shall include recommendations relating to changing payment under such part for such drugs such that such payment is based on such drugs' net prices when furnished under a group health plan or group or individual health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91)) to the extent the average sales price methodology does not currently capture such net prices.

SEC. 303. CMI MODEL ON ALTERNATIVE PAYMENT FOR GENERIC STERILE INJECTABLE DRUGS.

Section 1115A(b)(2) of title XI of the Social Security Act (42 U.S.C. 1315a(b)(2)) is amended—

(1) in subparagraph (A), in the third sentence, by inserting ", and shall include the model described in subparagraph (B)(xxviii)" before the period at the end; and

(2) in subparagraph (B), by adding at the end the following new clause:

"(xxviii) A model that provides, in no fewer than 3 and no more than 12 States, payment for sterile injectable drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act administered under part B of title XVIII based on

net prices for such drugs under group health plans and group or individual health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), or based on the wholesale acquisition costs of such drugs, in lieu of payment otherwise available for such drugs under such part.''.

SEC. 304. STUDY ON MEDICARE CODING FOR DRUGS IN SHORTAGE OR IN DANGER OF SHORTAGE.

Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall conduct a study and submit to Congress a report on coding policies with respect to generic drugs payable under part B of the Medicare program, including sterile injectable drugs. Such report shall-—

(1) include an analysis of the benefits and tradeoffs involved in using separate billing codes for unique drugs or combined billing codes for drugs and classes of drugs and how such coding policies may address drug supply and mitigate potential drug shortages; and

(2) include an analysis of options relating to multiple or tiered bundling options for drugs in am-

bulatory payment classification packages and how such coding policies could address drug shortages.

SEC. 305. HOSPITAL REPORTING OF GROUP PURCHASING ORGANIZATION REMUNERATION UNDER MEDICARE.

Section 1866(a)(1) of the Social Security Act (42 U.S.C. 1395cc(a)(1)) is amended—

(1) in subparagraph (X), by striking ''and'' at the end;

(2) in subparagraph (Y), by striking the period at the end and inserting '', and''; and

(3) by adding at the end the following new subparagraph:

''(Z) in the case of a hospital, with respect to cost reporting periods beginning after the date of the enactment of this subparagraph, to include on the cost report for such period any remuneration received from a group purchasing organization during such period, with a specification as to any such remuneration received during such period from such an organization that was under common ownership (as defined by the Secretary) with such hospital.''.

SEC. 306. STUDY ON FLAT FEE PAYMENT.

Not later than 2 years after enactment, the Medicare Payment Advisory Commission shall submit to Congress

recommendations for implementing flat fee-based add-on payments for physician administered drugs and biologicals reimbursed under Medicare part B. Such recommendations shall include—

(1) whether or not such a flat-fee based model can increase payments for relatively low-cost generic and biosimilar medications;

(2) an analysis of specifically how such flat fee-based model may impact utilization of generic and biosimilar medications;

(3) the extent to which average sales price accurately reflects purchasing price of drugs and biologicals by physicians and, to the extent applicable, recommendations for improving average sales price to mitigate any potential discrepancies; an

(4) specific recommendations for—

(A) ensuring physician specialty practices are held harmless in terms of overall reimbursement, including through adjustments to relative value units in the physician fee schedule to more accurately account for high overhead costs associated with certain medications;

(B) mitigating financial impact to small physician practices to the extent such practices

purchase medications at prices above average sales price; and

(C) updating the flat fee amount over time.

SEC. 307. CLARIFICATION OF MEDICARE AVERAGE SALES PRICE PAYMENT METHODOLOGY.

(a) IN GENERAL.—Section 1847A(c) of the Social Security Act (42 U.S.C. 1395w–3a(c)), as amended by section 102, is amended—

(1) in paragraph (3)(A), in the first sentence—

(A) by striking ''and rebates'' and inserting ''rebates''; and

(B) by inserting '', and fees (other than bona fide service fees)'' before the period at the end; and

(2) in paragraph (6), by adding at the end the following new subparagraph:

''(M) BONA FIDE SERVICE FEE.—The term 'bona fide service fee' means a fee paid by a manufacturer to an entity that—

''(i) represents fair market value for a bona fide, itemized service that—

''(I) is performed on behalf of the manufacturer; and

''(II) the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement;

''(ii) is not passed on, in whole or in part, to a client or customer of the entity, whether or not the entity takes title to the drug or biological;

''(iii) is a fixed payment and not based on a percentage of sales; and

''(iv) is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to drugs and biologicals furnished on or after the first day of the first calendar quarter that begins on or after the date that is 180 days after the date of the enactment of this Act.

TITLE IV—TRANSPARENCY

SEC. 401. GROUP PURCHASING ORGANIZATION REPORTING REQUIREMENT.

The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall revise section 1001.952(j) of title 42, Code of Federal Regulations, to

include a standard requiring a group purchasing organization to annually submit to the Secretary and to the Inspector General of the Department of Health and Human Services any written agreement or disclosure described in paragraph (1) or (2) of such section.

TITLE V—FOOD AND DRUG ADMINISTRATION

SEC. 501. NONCOMPLIANCE LETTERS RELATING TO VOLUME REPORTING.

Paragraph (3) of section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)) is amended—

(1) by moving the margins 2 ems to the left; and

(2) by adding at the end:

''(C)(i) Beginning 270 days after the date of enactment of this subparagraph, the Secretary shall issue a noncompliance letter to any person that fails to report as required by this paragraph—

''(I) informing such person of such failure; and

''(II) requiring such person to respond in writing within 45 calendar days of issuance of such letter.

''(ii) A response under clause (i)(II) may include the person's request for a deferral extension if applicable.

''(iii) Not later than 60 calendar days after issuing a letter pursuant to clause (i), the Secretary shall post

on the public website of the Food and Drug Administration such letter and any written response to such letter, with redactions for any trade secrets and confidential commercial information. If the Secretary determines that a letter was issued pursuant to clause (i) in error, the preceding sentence shall not apply.''.

SEC. 502. INCENTIVE FOR SHELF-LIFE EXTENSION STUDIES.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505G (21 U.S.C. 355h) the following:

''SEC. 505H. SHELF-LIFE EXTENSION STUDIES OF DRUGS.

''(a) MAXIMUM SHELF-LIFE EXTENSION STUDIES FOR NEW DRUGS.—The extensions of exclusivity described in subsection (c) apply with respect to a sterile, injectable drug if, prior to approval of an application that is submitted under section 505(b)(1) or 505(j)(1) for the drug for at least one indication for a serious disease or condition—

''(1) the Secretary makes a written request for shelf-life extension studies in accordance with subsection (d)(1);

''(2) the applicant agrees to the request;

''(3) such studies are completed within the timeframe specified in the request; and

''(4) the reports thereof are submitted and accepted in accordance with subsection (d)(2).

''(b) MAXIMUM SHELF-LIFE EXTENSION STUDIES FOR ALREADY-MARKETED DRUGS.—The extensions of exclusivity described in subsection (c) apply with respect to a sterile, injectable drug if, after approval of an application that is submitted under section 505(b)(1) or 505(j)(1) for the drug for at least one indication for a serious disease or condition—

''(1) the Secretary makes a written request to the holder of an approved application under section 505(b)(1) and 505(j)(1) for shelf-life extension studies in accordance with subsection (d)(1);

''(2) the holder agrees to the request;

''(3) such studies are completed within the timeframe specified in the request; and

''(4) the reports thereof are submitted and accepted in accordance with subsection (d)(2).

''(c) EXTENSIONS.—The extensions of exclusivity described in this subsection are the following:

''(1) The period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be 5 years and 1 month rather than 5 years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such

section to 4 years, to 48 months, and to 7 and one-half years are deemed to be 4 years and 1 month, 49 months, and 7 years and 7 months, respectively.

''(2) The 180-day period referred to in section 505(j)(5)(B)(iv) is extended by 30 days.

''(d) CONDUCT OF SHELF-LIFE EXTENSION STUDIES.—

''(1) REQUEST FOR STUDIES.—The Secretary may, after consultation with the sponsor of an application for an investigational new drug under section 505(i), the sponsor of an application for a new drug under section 505(b)(1), the sponsor of an abbreviated application for a new drug under 505(j)(1), or the holder of an approved application for a drug under section 505(b)(1) or 505(j)(1), issue to the sponsor or holder a written request under subsection (a) or (b) to conduct shelf-life extension studies for such drug. Any such request shall be in writing and include a timeframe for such studies.

''(2) MEETING THE STUDIES REQUIREMENT.—Not later than 180 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accept-

ing or rejecting the reports shall be to determine, within such 180-day period, whether—

''(A) the studies fairly respond to the written request under paragraph (1);

''(B) have been conducted in accordance with commonly accepted scientific principles and protocols; and

''(C) have been reported in accordance with the requirements of the Secretary for filing.

''(e) DEFINITIONS.—In this section:

''(1) The term 'serious disease or condition' has the meaning given to such term in section 312.300 of title 21, Code of Federal Regulations (or successor regulations).

''(2) The terms 'shelf-life studies' and 'studies' mean studies designed to result in data and information from any stage of development of the drug that are adequate to assess the stability of the drug to determine the longest supported expiration date.''.

SEC. 503. PROVIDING FOR A LAG PERIOD FOR OUTSOURCING FACILITIES TO COMPOUND AND DISTRIBUTE DRUGS IN SHORTAGE.

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

(1) by amending subsection (a)(2)(A)(ii) to read as follows:

''(ii) the drug compounded from such bulk drug substance appeared on the drug shortage list in effect under section 506E—

''(I) at the time of compounding or within the period of 30 days preceding such compounding; and

''(II) at the time of distribution and dispensing or within the period of 180 days preceding such distribution and dispensing;''; and

(2) in subsection (d)(2)(A), by striking ''under section 506E at the time of compounding, distribution, and dispensing; or'' and inserting the following: ''under section 506E—

''(i) at the time of compounding or within the period of 30 days preceding such compounding; and

''(ii) at the time of distribution and dispensing or within the period of 180 days preceding such distribution and dispensing; or''.

SEC. 504. ADDITIONAL INFORMATION ON GENERIC DRUG ACTIVE PHARMACEUTICAL INGREDIENTS.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)) is amended—

(1) in clause (vii), by striking ''and'' at the end;

(2) in clause (viii), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(ix) if the abbreviated application lists more than one manufacturer of an active pharmaceutical ingredient used for the manufacture, preparation, propagation, compounding, or processing of such drug—

''(I) information indicating if the sponsor relies or anticipates relying on any one manufacturer of such active pharmaceutical ingredient for more than 60 percent of the supply of such active pharmaceutical ingredient for the manufacture, preparation, propagation, compounding, or processing of such drug; and

''(II) if so, identify such manufacturer.''.

(b) ANNUAL REPORTING.—

(1) IN GENERAL.—Section 505(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)) is amended by adding at the end:

''(6) ANNUAL REPORTING ON API SOURCING.—The Secretary shall require each holder of an approved abbreviated application for a new drug under subsection (j) to submit an annual report under paragraph (1)—

''(A) indicating whether the holder relies or anticipates relying on any one manufacturer for more than 60 percent of the supply of any active pharmaceutical ingredient for the manufacture, preparation, propagation, compounding, or processing of such drug; and

''(B) if so, identify such manufacturer and the amount of such active pharmaceutical ingredient so relied upon or anticipated to be relied upon.''.

(2) TECHNICAL CORRECTIONS.—Section 505(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)) is amended by moving the margins of paragraphs (3), (4), and (5) 2 ems to the left.

SEC. 505. REPORTING ON USE OF NEW AUTHORITIES AND REQUIREMENTS WITH RESPECT TO DRUG SHORTAGES.

Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Com-

mittee on Energy and Commerce of the House of Representatives on—

(1) the extent to which the Secretary has implemented the authorities and requirements under sections 506C(g), 506C(j), 506E(d), 510(j)(3), and 704(b)(2) (21 U.S.C. 356c(g), 356c(j), 356e(d), 360(j)(3), 374(b)(2)) of the Federal Food, Drug, and Cosmetic Act, as amended by sections 3111 and 3112 of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136), including—

(A) specific examples of uses of such authorities and requirements; and

(B) an assessment of the extent to which such authorities and requirements have helped mitigate drug shortages; and

(2) the status of the guidance documents that the Secretary intends to issue with respect to reporting and risk management plan requirements applicable to manufacturers of drugs and active pharmaceutical ingredients, pursuant to the amendments made to section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) by subsections (a) and (b) of section 3112 of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136).

SEC. 506. NEW DOMESTIC FACILITY INSPECTION PILOT PROGRAM.

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended by inserting after section 704 of such Act (21 U.S.C. 374) the following:

"SEC. 704A. NEW DOMESTIC FACILITY INSPECTION PILOT PROGRAM.

''(a) IN GENERAL.—The Secretary shall conduct a pilot program under which the Secretary, upon the request of the owner or operator of a covered establishment, inspects the establishment prior to such establishment being included in an abbreviated new drug application under section 505(j).

''(b) COVERED ESTABLISHMENT DEFINITION.—In this section, the term 'covered establishment' means an establishment in any State that is registered under section 510(b) to engage in the manufacture, preparation, propagation, compounding, or processing of a sterile, injectable drug or drugs.

''(c) REQUIREMENTS.—To request that a facility be inspected pursuant to this section, the owner or operator of a covered establishment shall submit to the Secretary, in a form and manner determined by the Secretary, the following information:

''(1) Certification that the covered establishment is a qualified facility (as defined in section

117.3 of title 21, Code of Federal Regulations (or successor regulations)) and a quality management system for the covered establishment is in place.

''(2) A target date for filing an abbreviated new drug application under section 505(j) for the sterile, injectable drug or drugs to be manufactured, prepared, propagated, compounded, or processed at the covered establishment within one year after the request is made.

''(3) Certification that the covered establishment has not been inspected by the Food and Drug Administration.

''(d) RECEIPT OF INFORMATION.—The Secretary shall—

''(1) not later than 3 business days after receiving a request under subsection (b), acknowledge receipt of such request; and

''(2) not later than 30 days after receiving such request, indicate whether the request meets the requirements of subsection (b) or has any deficiencies.

''(e) INSPECTION SCHEDULE.—Not later than 90 days after the Secretary indicates that a request meets the requirements of subsection (b), the Secretary shall conduct an inspection of the covered establishment.

''(f) PILOT PROGRAM INITIATION.—Not later than 30 days after the date of enactment of this section, the Secretary shall initiate the pilot program under this section.

''(g) REPORT.—Not later than June 1, 2026, the Secretary shall submit to the Congress a report on inspections conducted pursuant to this section between January 1, 2024, and March 1, 2026, including—

''(1) the number of requests for such inspections;

''(2) the number of such requests found to have deficiencies;

''(3) the average number of days, the minimum number of days, and the maximum number of days it took the Secretary to conduct such an inspection; and

''(4) the number of States that have laws in effect requiring a pharmaceutical manufacturing facility in the State to be inspected by the Food and Drug Administration before the State will license the facility.

''(h) SUNSET.—This section shall cease to be effective on October 1, 2027.''.