

Medicare Prescription Drug, Improvement, and Modernization Act of 2003

[Public Law 108-173]

[As Amended Through P.L. 116-260, Enacted December 27, 2020]

Currency: This publication is a compilation of the text of Public Law 108-173. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at <https://www.govinfo.gov/app/collection/comps>

Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).

AN ACT To amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, 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; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO BIPA AND SECRETARY; TABLE OF CONTENTS.

(a) **[42 U.S.C. 1305 note]** SHORT TITLE.—This Act may be cited as the “Medicare Prescription Drug, Improvement, and Modernization Act of 2003”.

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in division A of this Act an amendment is expressed in 1301terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(c) **[42 U.S.C. 1301 note]** BIPA; SECRETARY.—In this Act:

(1) BIPA.—The term “BIPA” means the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106-554.

(2) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

(d) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

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TITLE IV—RURAL PROVISIONS

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SEC. 410A. [42 U.S.C. 1395ww note] RURAL COMMUNITY HOSPITAL DEMONSTRATION PROGRAM.

(a) ESTABLISHMENT OF RURAL COMMUNITY HOSPITAL (RCH) DEMONSTRATION PROGRAM.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall establish a demonstration program to test the feasibility and advisability of the establishment of rural community hospitals (as defined in subsection (f)(1)) to furnish covered inpatient hospital services (as defined in subsection (f)(2)) to medicare beneficiaries.

(2) DEMONSTRATION AREAS.—The program shall be conducted in rural areas selected by the Secretary in States with low population densities, as determined by the Secretary.

(3) APPLICATION.—Each rural community hospital that is located in a demonstration area selected under paragraph (2) that desires to participate in the demonstration program under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(4) SELECTION OF HOSPITALS.—The Secretary shall select from among rural community hospitals submitting applications under paragraph (3) not more than 15 of such hospitals to participate in the demonstration program under this section.

(5) DURATION.—The Secretary shall conduct the demonstration program under this section for a 5-year period (in this section referred to as the “initial 5-year period”) and, as provided in subsection (g), for the 15-year extension period.

(6) IMPLEMENTATION.—The Secretary shall implement the demonstration program not later than January 1, 2005, but may not implement the program before October 1, 2004.

(b) PAYMENT.—

(1) IN GENERAL.—The amount of payment under the demonstration program for covered inpatient hospital services furnished in a rural community hospital, other than such services furnished in a psychiatric or rehabilitation unit of the hospital which is a distinct part, is—

(A) for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration program, the reasonable costs of providing such services; and

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(B) for discharges occurring in a subsequent cost reporting period under the demonstration program, the lesser of—

- (i) the reasonable costs of providing such services in the cost reporting period involved; or
- (ii) the target amount (as defined in paragraph (2)), applicable to the cost reporting period involved.

(2) TARGET AMOUNT.—For purposes of paragraph (1)(B)(ii), the term “target amount” means, with respect to a rural community hospital for a particular 12-month cost reporting period—

(A) in the case of the second such cost reporting period for which this subsection is in effect, the reasonable costs of providing such covered inpatient hospital services as determined under paragraph (1)(A), and

(B) in the case of a later cost reporting period, the target amount for the preceding 12-month cost reporting period,

increased by the applicable percentage increase (under clause (i) of section 1886(b)(3)(B) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B))) in the market basket percentage increase (as defined in clause (iii) of such section) for that particular cost reporting period.

(c) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer from the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i) of such funds as are necessary for the costs of carrying out the demonstration program under this section.

(2) BUDGET NEUTRALITY.—In conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.

(d) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) as may be necessary for the purpose of carrying out the demonstration program under this section.

(e) REPORT.—Not later than August 1, 2018, the Secretary shall submit to Congress a report on the demonstration program under this section, together with recommendations for such legislation and administrative action as the Secretary determines to be appropriate.

(f) DEFINITIONS.—In this section:

(1) RURAL COMMUNITY HOSPITAL DEFINED.—

(A) IN GENERAL.—The term “rural community hospital” means a hospital (as defined in section 1861(e) of the Social Security Act (42 U.S.C. 1395x(e))) that—

- (i) is located in a rural area (as defined in section 1886(d)(2)(D) of such Act (42 U.S.C. 1395ww(d)(2)(D))) or treated as being so located pursuant to section 1886(d)(8)(E) of such Act (42 U.S.C. 1395ww(d)(8)(E));

(ii) subject to subparagraph (B), has fewer than 51 acute care inpatient beds, as reported in its most recent cost report;

(iii) makes available 24-hour emergency care services; and

(iv) is not eligible for designation, or has not been designated, as a critical access hospital under section 1820 of the Social Security Act (42 U.S.C. 1395i–4).

(B) TREATMENT OF PSYCHIATRIC AND REHABILITATION UNITS.—For purposes of subparagraph (A)(ii), beds in a psychiatric or rehabilitation unit of the hospital which is a distinct part of the hospital shall not be counted.

(2) COVERED INPATIENT HOSPITAL SERVICES.—The term “covered inpatient hospital services” means inpatient hospital services, and includes extended care services furnished under an agreement under section 1883 of the Social Security Act (42 U.S.C. 1395tt).

(g) FIFTEEN-YEAR EXTENSION OF DEMONSTRATION PROGRAM.—

(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, the Secretary shall conduct the demonstration program under this section for an additional 15-year period (in this section referred to as the “15-year extension period”) that begins on the date immediately following the last day of the initial 5-year period under subsection (a)(5).

(2) EXPANSION OF DEMONSTRATION STATES.—Notwithstanding subsection (a)(2), during the 15-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary under such subsection to 20. In determining which States to include in such expansion, the Secretary shall use the same criteria and data that the Secretary used to determine the States under such subsection for purposes of the initial 5-year period.

(3) INCREASE IN MAXIMUM NUMBER OF HOSPITALS PARTICIPATING IN THE DEMONSTRATION PROGRAM.—Notwithstanding subsection (a)(4), during the 15-year extension period, not more than 30 rural community hospitals may participate in the demonstration program under this section.

(4) HOSPITALS PARTICIPATING IN THE DEMONSTRATION PROGRAM DURING THE INITIAL 5-YEAR PERIOD.—In the case of a rural community hospital that is participating in the demonstration program under this section as of the last day of the initial 5-year period, the Secretary—

(A) shall provide for the continued participation of such rural community hospital in the demonstration program during the 15-year extension period unless the rural community hospital makes an election, in such form and manner as the Secretary may specify, to discontinue such participation; and

(B) in calculating the amount of payment under subsection (b) to the rural community hospital for covered inpatient hospital services furnished by the hospital during each 5-year period in such 15-year extension period, shall substitute, under paragraph (1)(A) of such subsection—

(i) the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of each applicable 5-year period in the 15-year extension period, for
(ii) the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration program.

(5) OTHER HOSPITALS IN DEMONSTRATION PROGRAM.—

(A) CURES ACT EXTENSION.—During the second 5 years of the 15-year extension period, the Secretary shall apply the provisions of paragraph (4) to rural community hospitals that are not described in paragraph (4) but are participating in the demonstration program under this section as of December 30, 2014, in a similar manner as such provisions apply to rural community hospitals described in paragraph (4).

(B) ADDITIONAL EXTENSION.—During the third 5 years of the 15-year extension period, the Secretary shall apply the provisions of paragraph (4) to rural community hospitals that are not described in paragraph (4) but are participating in the demonstration program under this section as of December 30, 2019, in a similar manner as such provisions apply to rural community hospitals described in paragraph (4).

(6) EXPANSION OF DEMONSTRATION PROGRAM TO RURAL AREAS IN ANY STATE.—

(A) IN GENERAL.—The Secretary shall, notwithstanding subsection (a)(2) or paragraph (2) of this subsection, not later than April 12, 2017, issue a solicitation for applications to select up to the maximum number of additional rural community hospitals located in any State to participate in the demonstration program under this section for the second 5 years of the 15-year extension period without exceeding the limitation under paragraph (3) of this subsection.

(B) PRIORITY.—In determining which rural community hospitals that submitted an application pursuant to the solicitation under subparagraph (A) to select for participation in the demonstration program, the Secretary—

(i) shall give priority to rural community hospitals located in one of the 20 States with the lowest population densities (as determined by the Secretary using the 2015 Statistical Abstract of the United States); and

(ii) may consider—

(I) closures of hospitals located in rural areas in the State in which the rural community hospital is located during the 5-year period immediately preceding the date of the enactment of this paragraph; and

(II) the population density of the State in which the rural community hospital is located.

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TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

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Subtitle B—Federal Trade Commission Review¹

SEC. 1111. DEFINITIONS.

In this subtitle:

(1) ANDA.—The term “ANDA” means an abbreviated drug application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act.

(2) ASSISTANT ATTORNEY GENERAL.—The term “Assistant Attorney General” means the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice.

(3) BIOSIMILAR BIOLOGICAL PRODUCT.—The term “biosimilar biological product” means a biological product for which a biosimilar biological product application under section 351(k) of the Public Health Service Act is approved.

(4) BIOSIMILAR BIOLOGICAL PRODUCT APPLICANT.—The term “biosimilar biological product applicant” means a person who has filed or received approval for a biosimilar biological product application under section 351(k) of the Public Health Service Act.

(5) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.—The term “biosimilar biological product application” means an application under section 351(k) of the Public Health Service Act for licensure of a biological product as biosimilar to, or interchangeable with, a reference product.

(6) BRAND NAME DRUG.—The term “brand name drug” means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, including an application referred to in section 505(b)(2) of such Act, or a biological product for which an application is approved under section 351(a) of the Public Health Service Act.

(7) BRAND NAME DRUG COMPANY.—The term “brand name drug company” means the party that holds the approved application referred to in paragraph (6) for a brand name drug that is a listed drug in an ANDA or a reference product in a biosimilar biological product application, or a party that is the owner of a patent for which information is submitted for such drug under subsection (b) or (c) of section 505 of the Federal Food, Drug, and Cosmetic Act or the owner, or exclusive li-

¹ Subtitle B of title XI of Public Law 108-173 (117 Stat. 2461; 21 U.S.C. 355 note).

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icensee, of a patent included in a list provided under section 351(l)(3) of the Public Health Service Act.

(8) COMMISSION.—The term “Commission” means the Federal Trade Commission.

(9) GENERIC DRUG.—The term “generic drug” means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act is approved.

(10) GENERIC DRUG APPLICANT.—The term “generic drug applicant” means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act.

(11) LISTED DRUG.—The term “listed drug” means a brand name drug that is listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act.

(12) REFERENCE PRODUCT.—The term “reference product” has the meaning given such term in section 351(i) of the Public Health Service Act.

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act or a biosimilar biological product applicant who has submitted a biosimilar biological product application and a brand name drug company that enter into an agreement described in paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA or the biosimilar biological product that is the subject of the biosimilar biological product application, as applicable.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between a generic drug applicant or a biosimilar biological product applicant and a brand name drug company is an agreement regarding—

(A) the manufacture, marketing, or sale of the brand name drug that is the listed drug in the ANDA or the reference product in the biosimilar biological product application involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted or of the biosimilar biological product for which the biosimilar biological product application was submitted; or

(C) as applicable—

(i) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same listed drug; or

(ii) any of the time periods referred to in section 351(k)(6) of the Public Health Service Act as such period applies to such biosimilar biological product application or to any other biosimilar biological product application based on the same reference product.

(b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLICANT OR BIOSIMILAR BIOLOGICAL PRODUCT APPLICANT.—

(1) REQUIREMENT.—

(A) **GENERIC DRUGS.**—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

(B) **BIOSIMILAR BIOLOGICAL PRODUCTS.**—A biosimilar biological product applicant that has submitted a biosimilar biological product application that references a reference product and another biosimilar biological product applicant that has submitted a biosimilar biological product application that references the same reference product shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the biosimilar biological products for which such biosimilar biological product applications were submitted.

(2) **SUBJECT MATTER OF AGREEMENT.**—An agreement described in this paragraph is, as applicable, an agreement between 2 or more generic drug applicants regarding the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to the ANDAs with which the agreement is concerned,² an agreement between 2 or more biosimilar biological product applicants regarding a time period referred to in section 351(k)(6) of the Public Health Service Act as it applies to the biosimilar biological product, or an agreement between 2 or more biosimilar biological product applicants regarding the manufacture, marketing, or sale of a biosimilar biological product.

(c) FILING.—

(1) **AGREEMENT.**—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that such parties are not required to file an agreement that solely concerns—

- (A) purchase orders for raw material supplies;
- (B) equipment and facility contracts;
- (C) employment or consulting contracts; or
- (D) packaging and labeling contracts.

(2) **OTHER AGREEMENTS.**—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any agreements between the parties that are not described in such subsections and are con-

²Two commas in paragraph (2) are so in law.

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tingent upon, provide a contingent condition for, were entered into within 30 days of, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) DESCRIPTION.—In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

SEC. 1113. FILING DEADLINES.

Any filing required under section 1112 shall be filed with the Assistant Attorney General and the Commission not later than 10 business days after the date the agreements are executed.

SEC. 1114. DISCLOSURE EXEMPTION.

Any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this subtitle shall be exempt from disclosure under section 552 of title 5, United States Code, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.

SEC. 1115. ENFORCEMENT.

(a) CIVIL PENALTY.—Any brand name drug company, generic drug applicant, or biosimilar biological product applicant which fails to comply with any provision of this subtitle shall be liable for a civil penalty of not more than \$11,000, for each day during which such entity is in violation of this subtitle. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) COMPLIANCE AND EQUITABLE RELIEF.—If any brand name drug company, generic drug applicant, or biosimilar biological product applicant fails to comply with any provision of this subtitle, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General or the Commission.

SEC. 1116. RULEMAKING.

The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5, United States Code, consistent with the purposes of this subtitle—

- (1) may define the terms used in this subtitle;
- (2) may exempt classes of persons or agreements from the requirements of this subtitle; and
- (3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this subtitle.

SEC. 1117. SAVINGS CLAUSE.

Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or

the Commission to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant or a biosimilar biological product applicant, any agreement between generic drug applicants, or any agreement between biosimilar biological product applicants, under any other provision of law, nor shall any filing under this subtitle constitute or create a presumption of any violation of any competition laws.

SEC. 1118. EFFECTIVE DATE.

This subtitle shall—

- (1) take effect 30 days after the date of the enactment of this Act; and
- (2) shall apply to agreements described in section 1112 that are entered into 30 days after the date of the enactment of this Act.

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