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118TH CONGRESS
1ST SESSION

H. R. 2408

To amend title XVIII of the Social Security Act to provide a review process for adverse national coverage determinations with respect to drug coverage under the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

MARCH 30, 2023

Ms. BARRAGÁN (for herself and Mr. JOYCE of Pennsylvania) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to provide a review process for adverse national coverage determinations with respect to drug coverage under the Medicare program.

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 ''Access to Innovative Treatments Act of 2023''.

SEC. 2. PROVIDING A REVIEW PROCESS FOR ADVERSE NATIONAL COVERAGE DETERMINATIONS WITH RESPECT TO DRUG COVERAGE UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Section 1862(l) of the Social Security Act (42 U.S.C. 1395y(l)) is amended—

(1) by redesignating paragraphs (5) and (6) as paragraphs (7) and (8), respectively; and

(2) by inserting after paragraph (4) the following new paragraphs:

''(5) REVIEW OF NATIONAL COVERAGE DETERMINATIONS FOR DRUGS AND BIOLOGICALS.—

''(A) IN GENERAL.—Subject to subparagraph (D), not later than 30 days after receiving a request for a review of a specified national coverage determination (as defined in subparagraph (E)), the Secretary shall initiate such a review in accordance with the provisions of this paragraph.

''(B) PUBLIC COMMENT PERIOD.—Beginning on the date of the initiation of a review of a specified national coverage determination under subparagraph (A), the Secretary shall provide for a 30-day public comment period as to whether such determination should be affirmed, reversed, or otherwise modified.

''(C) FINAL DECISION.—Not later than 30 days after the conclusion of the 30-day period described in subparagraph (B) with respect to a specified national coverage determination, the Secretary shall—

''(i) make a final decision as to whether such determination should be affirmed, reversed, or otherwise modified;

''(ii) include in such final decision summaries of the public comments received and responses to such comments;

''(iii) make available to the public the clinical evidence and other data used in making such decision when such decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

''(iv) in the case of a final decision under clause (i) to reverse or modify such determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change as applicable.

''(D) LIMITATION ON SUCCESSIVE REVIEWS.—Subparagraph (A) shall not apply with

respect to a request for a review of a specified national coverage determination if the Secretary has made a final decision with respect to a previous review of such determination under this paragraph during the 2-year period ending on the date of the receipt of such request. Nothing in the preceding sentence shall be construed to limit the authority of the Secretary to review or reconsider a national coverage determination if determined appropriate by the Secretary.

''(E) SPECIFIED NATIONAL COVERAGE DETERMINATION DEFINED.—In this paragraph, the term 'specified national coverage determination' means a national coverage determination made with respect to a drug or biological approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act under which coverage of such drug or biological under this title was denied or otherwise limited in a manner inconsistent with such approval or licensure.

''(6) PROHIBITION ON APPLICATION OF CERTAIN EXISTING NATIONAL COVERAGE DETERMINATIONS TO NEWLY APPROVED DRUGS AND

BIOLOGICALS.—The Secretary may not, with respect to a drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act or a biological licensed under section 351 of the Public Health Service Act, apply a national coverage determination that was made prior to the date of such approval or licensure (as applicable) to the extent that such application would result in a denial or other limit of coverage under this title for such drug or biological in a manner inconsistent with such approval or licensure.''.

(b) NONRELIANCE ON CERTAIN NCDS UNDER PART D.—Section 1860D–2(e)(3) of the Social Security Act (42 U.S.C. 1395w–102(e)(3)) is amended by adding at the end the following new sentence: ''In determining whether payment would not be made with respect to a covered part D drug if section 1862(a) applied to this part, a prescription drug plan or MA–PD plan may not base such determination on a national coverage determination made with respect to such drug if such determination is a specified national coverage determination (as defined in section 1862(l)(5)).''.

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