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118TH CONGRESS
1ST SESSION

H. R. 6094

To amend titles XVIII and XIX of the Social Security Act and title XXVII of the Public Health Service Act to refine the set of information sources for determining coverage of certain drugs and biologicals used in the treatment or management of a rare disease or condition, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 26, 2023

Ms. MATSUI (for herself, Mr. DUNN of Florida, Mr. THOMPSON of California, and Mr. KELLY of Pennsylvania) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 titles XVIII and XIX of the Social Security Act and title XXVII of the Public Health Service Act to refine the set of information sources for determining coverage of certain drugs and biologicals used in the treatment or management of a rare disease or condition, 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 ''Providing Realistic Opportunity To Equal and Comparable Treatment for Rare Act'' or the ''PROTECT Rare Act''.

SEC. 2. COVERAGE OF CERTAIN DRUGS USED IN TREATMENT OR MANAGEMENT OF RARE DISEASE OR CONDITION.

(a) MEDICARE.—

(1) IN GENERAL.—Section 1861(t)(2) of the Social Security Act (42 U.S.C. 1395x(t)(2)) is amended—

(A) in subparagraph (A), by inserting after ''regimen'' the following: '', or in the treatment or management of a disease or condition affecting 200,000 or fewer individuals in the United States,''; and

(B) in subparagraph (B)(ii)—

(i) in subclause (I), by striking '', or'' at the end and inserting a semicolon;

(ii) in subclause (II), by striking the period at the end and inserting ''; or''; and

(iii) by adding at the end the following new subclause:

''(III) in the case of a drug that is used in the treatment or management of a disease or condition affect-

ing 200,000 or fewer individuals in the United States, such use is supported by peer-reviewed medical literature, including clinical guidelines, and is not reviewed unfavorably in the compendia described in section 1927(g)(1)(B)(i), or listed as a contraindication in the FDA-approved labeling.''.

(2) MEDICALLY ACCEPTED USES OF COVERED PART D DRUGS IN TREATING RARE CONDITIONS.—Section 1860D–2(e)(4)(A) of the Social Security Act (42 U.S.C. 1395w–102(e)(4)(A)) is amended—

(A) in clause (i)(II), by striking ''and'';

(B) by redesignating clause (ii) as clause (iii); and

(C) by inserting after clause (i)(II) the following new clause:

''(ii) in the case of a covered part D drug used in the treatment or management of a disease or condition affecting 200,000 or fewer individuals in the United States, in section 1861(t)(2)(B); and''.

(3) EFFECTIVE DATE.—The amendments made by this subsection apply with respect to items and

services furnished on or after the date that is 30 days after the date of the enactment of this Act.

(b) MEDICAID.—

(1) IN GENERAL.—Section 1927(k)(6) of the Social Security Act (42 U.S.C. 1396r–8(k)(6)) is amended to read as follows:

"(6) MEDICALLY ACCEPTED INDICATION.—The term 'medically accepted indication' means any use for a covered drug—

"(A) which is approved under the Federal Food, Drug, and Cosmetic Act;

"(B) which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i); or

"(C) in the case of a drug used to treat or manage a disease or condition affecting 200,000 or fewer individuals in the United States—

"(i) the use of such drug is supported by peer-reviewed medical literature, including clinical guidelines; and

"(ii) is not reviewed unfavorably in the compendia described in subsection

(g)(1)(B)(i), or listed as a contraindication in the FDA-approved labeling.''.

(2) CONFORMING AMENDMENT.—Section 1927(d)(4)(C) of the Social Security Act (42 U.S.C. 1396r–8(d)(4)(C)) is amended by striking ''compendia'' and inserting ''sources''.

(3) EFFECTIVE DATE.—The amendments made by this subsection apply with respect to covered outpatient drugs furnished on or after the date that is 30 days after the date of the enactment of this Act.

(c) PRIVATE HEALTH INSURANCE.—

(1) IN GENERAL.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–19) is amended by adding at the end the following new section:

''SEC. 2730. EXPEDITED PROCESSES FOR REVIEW ASSOCIATED WITH CERTAIN DRUGS USED IN TREATMENT OR MANAGEMENT OF A RARE DISEASE OR CONDITION.

''A group health plan or a health insurance issuer offering group or individual health insurance coverage shall provide a mechanism for expedited formulary exception, reconsideration, and appeal of any denial of coverage for a drug or biological—

''(1) approved by the Food and Drug Administration;

''(2) for which the use is related to treatment or management of a disease or condition affecting 200,000 or fewer individuals in the United States; and

''(3) the use of which is supported by the FDA-approved label or peer-reviewed literature, including clinical guidelines, and that is not reviewed unfavorably in the compendia described in section 1927(g)(1)(B)(i)) of the Social Security Act or listed as a contraindication in the FDA-approved labeling.''.

(2) EFFECTIVE DATE.—The amendment made by this subsection applies with respect to plan years beginning on or after the date that is 30 days after the date of the enactment of this Act.

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