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117TH CONGRESS
1ST SESSION

H. R. 4479

To amend title XVIII of the Social Security Act to ensure equitable payment for, and preserve Medicare beneficiary access to, diagnostic radiopharmaceuticals under the Medicare hospital outpatient prospective payment system.

IN THE HOUSE OF REPRESENTATIVES

JULY 16, 2021

Mr. PETERS (for himself, Mr. RUSH, Mr. DUNN, and Mr. MURPHY of North Carolina) 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 title XVIII of the Social Security Act to ensure equitable payment for, and preserve Medicare beneficiary access to, diagnostic radiopharmaceuticals under the Medicare hospital outpatient prospective payment system.

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 ''Facilitating Innovative Nuclear Diagnostics Act of 2021''.

SEC. 2. SEPARATE PAYMENT FOR CERTAIN DIAGNOSTIC RADIOPHARMACEUTICALS.

(a) IN GENERAL.—Section 1833(t)(16) of the Social Security Act (42 U.S.C. 1395(t)(16)) is amended by adding at the end the following new subparagraph:

''(G) SEPARATE PAYMENT FOR CERTAIN DIAGNOSTIC RADIOPHARMACEUTICALS.—

''(i) IN GENERAL.—Notwithstanding any other provision of this subsection, with respect to services furnished on or after January 1, 2022, the Secretary shall not package, and shall make a separate payment as specified in clause (ii) for a diagnostic radiopharmaceutical (as defined in clause (v)) with an estimated mean per day product cost equal to or exceeding the threshold specified in clause (iii).

''(ii) SEPARATE PAYMENT.—For purposes of clause (i), the separate payment specified in this subclause for a diagnostic radiopharmaceutical described in clause (i) shall be equal to—

''(I) the average sales price for the drug established under section 1847A, to the extent the average sales price is available, as calculated and

adjusted by the Secretary to the extent such adjustment is adopted for other specified covered outpatient drugs under paragraph (14)(A); or

''(II) if the data necessary to calculate the average sales price for the drug in the year under the section and paragraph specified in subclause (I) is not available, the wholesale acquisition cost (as defined in subsection 1847A(c)(6)(B)), as calculated and adjusted by the Secretary to the extent such adjustment is adopted for other specified covered outpatient drugs under paragraph (14)(A), or, if the wholesale acquisition cost is not available, the mean unit cost data derived from hospital claims data.

Nothing in this subparagraph shall be construed as affecting eligibility of diagnostic radiopharmaceuticals for pass-through payments under paragraph (6).

''(iii) THRESHOLD.—For purposes of this subparagraph, the threshold specified in this clause—

"(I) for 2022, is $500; and

"(II) for a subsequent year, is the amount specified in this clause for the preceding year increased by the OPD fee schedule increase factor under paragraph (3)(C)(iv) for the year.

"(iv) BUDGET NEUTRALITY.—The Secretary shall make such adjustments as are necessary under paragraph (9)(B) to ensure that the amount of expenditures under this subsection for a year with application of this subparagraph is equal to the amount of expenditures that would be made under this subsection for such year without application of this subparagraph.

"(v) DEFINITION OF DIAGNOSTIC RADIOPHARMACEUTICAL.—For purposes of this subparagraph, the term 'diagnostic radiopharmaceutical' means a drug or biological that is described in section 315.2(a) of title 21, Code of Federal Regulations, or any successor regulation, and is approved by the Food and Drug Administration on or after January 1, 2008.".

(b) NO IMPACT ON COPAYMENT.—Section 1833(t)(8)(E) of the Social Security Act (42 U.S.C. 1395l(t)(8)(E)) is amended—

(1) in the heading, by inserting ''AND SEPARATE PAYMENTS FOR CERTAIN DIAGNOSTIC RADIOPHARMACEUTICALS'' after ''PASS-THROUGH ADJUSTMENTS''; and

(2) by inserting ''and paragraph (16)(G)'' after ''such adjustments)''.

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