

118TH CONGRESS
1ST SESSION

H. R. 1199

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

FEBRUARY 27, 2023

Mr. DUNN of Florida (for himself, Mr. MURPHY, Mr. PETERS, Ms. SEWELL, Mrs. TRAHAN, Ms. BLUNT ROCHESTER, Mrs. MILLER-MEEKS, Mr. AUCHINCLOSS, Mr. TONKO, Mr. JOYCE of Pennsylvania, Mrs. WATSON COLEMAN, Ms. KUSTER, Mr. PAPPAS, Mr. RESCHENTHALER, Mr. MCGOVERN, and Mr. BUCSHON) 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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Facilitating Innovative
3 Nuclear Diagnostics Act of 2023”.

4 **SEC. 2. SEPARATE PAYMENT FOR CERTAIN DIAGNOSTIC**
5 **RADIOPHARMACEUTICALS.**

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

9 “(H) SEPARATE PAYMENT FOR CERTAIN
10 DIAGNOSTIC RADIOPHARMACEUTICALS.—

11 “(i) IN GENERAL.—Notwithstanding
12 any other provision of this subsection, with
13 respect to services furnished on or after
14 January 1, 2024, the Secretary shall not
15 package, and shall make a separate pay-
16 ment as specified in clause (ii) for a diag-
17 nostic radiopharmaceutical (as defined in
18 clause (v)) with an estimated mean per day
19 product cost equal to or exceeding the
20 threshold specified in clause (iii).

21 “(ii) SEPARATE PAYMENT.—For pur-
22 poses of clause (i), the separate payment
23 specified in this subclause for a diagnostic
24 radiopharmaceutical described in clause (i)
25 shall be equal to—

1 “(I) the average sales price for
2 the drug established under section
3 1847A, to the extent the average sales
4 price is available, as calculated and
5 adjusted by the Secretary to the ex-
6 tent such adjustment is adopted for
7 other specified covered outpatient
8 drugs under paragraph (14)(A); or

9 “(II) if the data necessary to cal-
10 culate the average sales price for the
11 drug in the year under the section
12 and paragraph specified in subclause
13 (I) is not available, the wholesale ac-
14 quisition cost (as defined in subsection
15 1847A(c)(6)(B)), as calculated and
16 adjusted by the Secretary to the ex-
17 tent such adjustment is adopted for
18 other specified covered outpatient
19 drugs under paragraph (14)(A), or, if
20 the wholesale acquisition cost is not
21 available, the mean unit cost data de-
22 rived from hospital claims data.

23 Nothing in this subparagraph shall be con-
24 strued as affecting eligibility of diagnostic

1 radiopharmaceuticals for pass-through pay-
2 ments under paragraph (6).

3 “(iii) THRESHOLD.—For purposes of
4 this subparagraph, the threshold specified
5 in this clause—

6 “(I) for 2024, is \$500; and

7 “(II) for a subsequent year, is
8 the amount specified in this clause for
9 the preceding year increased by the
10 OPD fee schedule increase factor
11 under paragraph (3)(C)(iv) for the
12 year.

13 “(iv) BUDGET NEUTRALITY.—The
14 Secretary shall make such adjustments as
15 are necessary under paragraph (9)(B) to
16 ensure that the amount of expenditures
17 under this subsection for a year with appli-
18 cation of this subparagraph is equal to the
19 amount of expenditures that would be
20 made under this subsection for such year
21 without application of this subparagraph.

22 “(v) DEFINITION OF DIAGNOSTIC
23 RADIOPHARMACEUTICAL.—For purposes of
24 this subparagraph, the term ‘diagnostic
25 radiopharmaceutical’ means a drug or bio-

1 logical that is described in section 315.2(a)
2 of title 21, Code of Federal Regulations, or
3 any successor regulation, and is approved
4 by the Food and Drug Administration on
5 or after January 1, 2008.”.

6 (b) NO IMPACT ON COPAYMENT.—Section
7 1833(t)(8)(E) of the Social Security Act (42 U.S.C.
8 1395l(t)(8)(E)) is amended—

9 (1) in the heading, by inserting “AND SEPA-
10 RATE PAYMENTS FOR CERTAIN DIAGNOSTIC RADIO-
11 PHARMACEUTICALS” after “PASS-THROUGH ADJUST-
12 MENTS”; and

13 (2) by inserting “and paragraph (16)(H)” after
14 “such adjustments”).

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