

117TH CONGRESS
1ST SESSION

S. 2609

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 SENATE OF THE UNITED STATES

AUGUST 4, 2021

Mrs. BLACKBURN (for herself and Ms. BALDWIN) introduced the following bill;
which was read twice and referred to the Committee on Finance

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Facilitating Innovative
5 Nuclear Diagnostics Act of 2021”.

1 **SEC. 2. SEPARATE PAYMENT FOR CERTAIN DIAGNOSTIC**
2 **RADIOPHARMACEUTICALS.**

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

6 “(G) SEPARATE PAYMENT FOR CERTAIN
7 DIAGNOSTIC RADIOPHARMACEUTICALS.—

8 “(i) IN GENERAL.—Notwithstanding
9 any other provision of this subsection, with
10 respect to services furnished on or after
11 January 1, 2022, the Secretary shall not
12 package, and shall make a separate pay-
13 ment as specified in clause (ii) for a diag-
14 nostic radiopharmaceutical (as defined in
15 clause (v)) with an estimated mean per day
16 product cost equal to or exceeding the
17 threshold specified in clause (iii).

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

23 “(I) the average sales price for
24 the drug established under section
25 1847A, to the extent the average sales
26 price is available, as calculated and

1 adjusted by the Secretary to the ex-
2 tent such adjustment is adopted for
3 other specified covered outpatient
4 drugs under paragraph (14)(A); or

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

19 Nothing in this subparagraph shall be con-
20 strued as affecting eligibility of diagnostic
21 radiopharmaceuticals for pass-through pay-
22 ments under paragraph (6).

23 “(iii) THRESHOLD.—For purposes of
24 this subparagraph, the threshold specified
25 in this clause—

1 “(I) for 2022, is \$500; and

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

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

17 “(v) DEFINITION OF DIAGNOSTIC
18 RADIOPHARMACEUTICAL.—For purposes of
19 this subparagraph, the term ‘diagnostic
20 radiopharmaceutical’ means a drug or bio-
21 logical that is described in section 315.2(a)
22 of title 21, Code of Federal Regulations, or
23 any successor regulation, and is approved
24 by the Food and Drug Administration on
25 or after January 1, 2008.”.

1 (b) NO IMPACT ON COPAYMENT.—Section
2 1833(t)(8)(E) of the Social Security Act (42 U.S.C.
3 1395l(t)(8)(E)) is amended—

4 (1) in the heading, by inserting “AND SEPA-
5 RATE PAYMENTS FOR CERTAIN DIAGNOSTIC RADIO-
6 PHARMACEUTICALS” after “PASS-THROUGH ADJUST-
7 MENTS”; and

8 (2) by inserting “and paragraph (16)(G)” after
9 “such adjustments”).

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