

116TH CONGRESS
1ST SESSION

S. 2326

To amend titles XI and XVIII of the Social Security Act to provide for expedited coding and coverage of novel medical products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 30, 2019

Mr. BURR (for himself, Mr. BENNET, Mr. SCOTT of South Carolina, and Mr. CARPER) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend titles XI and XVIII of the Social Security Act to provide for expedited coding and coverage of novel medical products, and for other purposes.

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 “New Opportunities for
5 Value that Extend Lives Act of 2019” or the “NOVEL
6 Act of 2019”.

1 **SEC. 2. EXPEDITED CODING OF NOVEL MEDICAL PROD-**
2 **UCTS.**

3 Section 1174(b)(2)(B) of the Social Security Act (42
4 U.S.C. 1320d–3(b)(2)(B)) is amended by adding at the
5 end the following new clauses:

6 “(iii) EXPEDITED CODING OF NOVEL
7 MEDICAL PRODUCTS.—

8 “(I) IN GENERAL.—Notwith-
9 standing paragraph (1), in the case of
10 a novel medical product (as defined in
11 clause (iv)), the Secretary shall make
12 modifications to the HCPCS code set
13 at least once every quarter.

14 “(II) REQUEST.—Upon the writ-
15 ten confidential request of a manufac-
16 turer of a novel medical product, the
17 Secretary shall make a determination
18 whether to assign a HCPCS code to
19 such product. Such request may occur
20 on or after the date on which the
21 product receives a designation as a
22 breakthrough therapy under section
23 506(a) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 356(a)),
25 a breakthrough device under section
26 515B of such Act (21 U.S.C. 360e–

1 3), or a regenerative advanced therapy
2 under section 506(g) of such Act (21
3 U.S.C. 356(g)).

4 “(III) DEADLINE FOR DETER-
5 MINATION; NOTIFICATION.—The Sec-
6 retary shall—

7 “(aa) not later than 180 cal-
8 endar days after receiving the re-
9 quest of a manufacturer under
10 subclause (II), make a deter-
11 mination under such subclause
12 with respect to the request; and

13 “(bb) not later than 30 cal-
14 endar days after making such de-
15 termination, notify the manufac-
16 turer of the determination.

17 “(IV) MONITORING UTILIZATION
18 AND OUTCOMES.—A HCPCS code as-
19 signed under this clause shall allow
20 for the reliable monitoring of utiliza-
21 tion and outcomes of the novel med-
22 ical product as described in clause
23 (vi).

24 “(V) EFFECTIVE DATE OF CODE
25 ASSIGNMENT.—If the Secretary makes

1 a determination to assign a HCPCS
2 code to a product under subclause
3 (II), such code—

4 “(aa) may be assigned with-
5 in the first quarter after the
6 manufacturer files, with respect
7 to such product, a new drug ap-
8 plication under section 505(b) of
9 the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 355(b)),
11 a biological product license appli-
12 cation under section 351(a) of
13 the Public Health Service Act
14 (42 U.S.C. 262(a)), a premarket
15 application under section 515(c)
16 of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C.
18 360e(c)), a report under section
19 510(k) of such Act (21 U.S.C.
20 360k), or a request for classifica-
21 tion under section 513(f)(2) of
22 such Act (21 U.S.C. 360e(f)(2));
23 and

24 “(bb) may not take effect
25 before the date the product is ap-

proved, cleared, or licensed by
the Food and Drug Administra-
tion.

“(VI) TRADE SECRETS AND CON-
FIDENTIAL INFORMATION.—No infor-
mation submitted under subclause (II)
shall be construed as authorizing the
Secretary to disclose any information
that is a trade secret or confidential
information subject to section
552(b)(4) of title 5, United States
Code.

“(iv) NOVEL MEDICAL PRODUCT DE-
FINED.—For purposes of this subpara-
graph, the term ‘novel medical product’
means a drug, biological product, or med-
ical device—

“(I) that has not been assigned a
HCPCS code; and

“(II) that has been designated as
a breakthrough therapy under section
506(a) of the Federal Food, Drug,
and Cosmetic Act (21 U.S.C. 356(a)),
a breakthrough device under section
515B of such Act (21 U.S.C. 360e—

1 3), or a regenerative advanced therapy
 2 under section 506(g) of such Act (21
 3 U.S.C. 356(g)).

4 “(v) HCPCS DEFINED.—For pur-
 5 poses of this subparagraph, the term
 6 ‘HCPCS’ means the Healthcare Common
 7 Procedure Coding System.

8 “(vi) INPATIENT PRODUCTS.—The
 9 Secretary shall establish a code modifier
 10 within the hospital inpatient prospective
 11 payment system under section 1886(d) to
 12 track the utilization and outcomes of novel
 13 medical products that are assigned a
 14 HCPCS code pursuant to the expedited
 15 coding process under clause (iii) and are
 16 furnished by hospitals in inpatient set-
 17 tings.”.

18 **SEC. 3. COVERAGE DETERMINATIONS FOR NOVEL MEDICAL**
 19 **PRODUCTS.**

20 Section 1862(l) of the Social Security Act (42 U.S.C.
 21 1395y(l)) is amended by adding at the end the following
 22 new paragraph:

23 “(7) COVERAGE PATHWAY FOR NOVEL MEDICAL
 24 PRODUCTS.—

1 “(A) IN GENERAL.—The Secretary shall
2 facilitate an efficient coverage pathway to expedite a national coverage decision for coverage
3 with evidence development process under this
4 title for novel medical products described in
5 subparagraph (D). The Secretary shall review
6 such novel medical products for the coverage
7 process on an expedited basis, beginning as
8 soon as the Secretary assigns a HCPCS code to
9 the product under clause (iii)(V)(aa) of section
10 1174(b)(2)(B).
11

12 “(B) DETERMINATION OF COVERAGE WITH
13 EVIDENCE DEVELOPMENT.—Such coverage
14 pathway shall include, with respect to such
15 novel medical products, if the Secretary determines coverage with evidence development is
16 appropriate, issuance of a national coverage determination of coverage with evidence development
17 for a period up to, but not to exceed, 4
18 years from the date of such determination.
19
20

21 “(C) MODERNIZING PAYMENT OPTIONS
22 FOR NOVEL MEDICAL PRODUCTS.—Not later
23 than 4 years after issuing such national coverage determination, the Secretary shall submit
24 to Congress and to the manufacturer of the
25

novel medical product a report providing options for alternative payment models under this title for the novel medical product or class of such products, which may include the utilization of existing models in the commercial health insurance market. Such report shall include any recommendations for legislation and administrative action as the Secretary determines appropriate to facilitate such payment arrangements.

“(D) NOVEL MEDICAL PRODUCTS DESCRIBED.—For purposes of this paragraph, a novel medical product described in this subparagraph is a novel medical product, as defined in clause (iv) of section 1174(b)(2)(B), that is assigned a HCPCS code pursuant to the expedited coding process under clause (iii) of such section.

“(E) CLARIFICATION.—Nothing in this paragraph shall prevent the Secretary from issuing a noncoverage or a national coverage determination for a novel medical product.”.

SEC. 4. ENHANCING COORDINATION WITH THE FOOD AND DRUG ADMINISTRATION.

(a) PUBLIC MEETING.—

1 (1) IN GENERAL.—Not later than 12 months
2 after the date of the enactment of this Act, the Sec-
3 retary shall convene a public meeting for the pur-
4 poses of discussing and providing input on improve-
5 ments to coordination between the Food and Drug
6 Administration and the Centers for Medicare & Med-
7 icaid Services in preparing for the availability of
8 novel medical products (as defined in section
9 1174(b)(2)(B)(iv) of the Social Security Act, as
10 added by section 2) on the market in the United
11 States.

12 (2) ATTENDEES.—The public meeting shall in-
13 clude—

14 (A) representatives of relevant Federal
15 agencies, including representatives from each of
16 the medical product centers within the Food
17 and Drug Administration and representatives
18 from the coding, coverage, and payment offices
19 within the Centers for Medicare & Medicaid
20 Services;

21 (B) stakeholders with expertise in the re-
22 search and development of novel medical prod-
23 ucts, including manufacturers of such products;

24 (C) representatives of commercial health
25 insurance payers;

1 (D) stakeholders with expertise in the ad-
2 ministration and use of novel medical products,
3 including physicians; and

4 (E) stakeholders representing patients and
5 with expertise in the utilization of patient expe-
6 rience data in medical product development.

7 (3) TOPICS.—The public meeting shall include
8 a discussion of—

9 (A) the status of the drug and medical de-
10 vice development pipeline related to the avail-
11 ability of novel medical products;

12 (B) the anticipated expertise necessary to
13 review the safety and effectiveness of such prod-
14 ucts at the Food and Drug Administration and
15 current gaps in such expertise, if any;

16 (C) the expertise necessary to make cod-
17 ing, coverage, and payment decisions with re-
18 spect to such products within the Centers for
19 Medicare & Medicaid Services, and current gaps
20 in such expertise, if any;

21 (D) trends in the differences in the data
22 necessary to determine the safety and effective-
23 ness of a novel medical product and the data
24 necessary to determine whether a novel medical
25 product meets the reasonable and necessary re-

1 quirements for coverage and payment under
2 title XVIII of the Social Security Act pursuant
3 to section 1862(a)(1)(A) of such Act (42 U.S.C.
4 1395y(a)(1)(A));

5 (E) the availability of information for
6 sponsors of such novel medical products to meet
7 each of those requirements; and

8 (F) the coordination of information related
9 to significant clinical improvement over existing
10 therapies for patients between the Food and
11 Drug Administration and the Centers for Medi-
12 care & Medicaid Services with respect to novel
13 medical products.

14 (4) TRADE SECRETS AND CONFIDENTIAL IN-
15 FORMATION.—No information discussed as a part of
16 the public meeting under this section shall be con-
17 strued as authorizing the Secretary to disclose any
18 information that is a trade secret or confidential in-
19 formation subject to section 552(b)(4) of title 5,
20 United States Code.

21 (b) IMPROVING TRANSPARENCY OF CRITERIA FOR
22 MEDICARE COVERAGE.—

23 (1) UPDATING GUIDANCE.—Not later than 18
24 months after the public meeting under subsection
25 (a), the Secretary of Health and Human Services

1 shall update the final guidance entitled “National
2 Coverage Determinations with Data Collection as a
3 Condition of Coverage: Coverage with Evidence De-
4 velopment” to improve the availability and coordina-
5 tion of information as described in subparagraphs
6 (D) through (F) subsection (a)(3), and clarify novel
7 medical product clinical data requirements to meet
8 reasonable and necessary requirements for coverage
9 and payment under title XVIII of the Social Secu-
10 rity Act.

11 (2) FINALIZING UPDATED GUIDANCE.—Not
12 later than 12 months after issuing draft guidance
13 under paragraph (1), the Secretary shall finalize the
14 updated guidance.

15 **SEC. 5. REPORT ON CODING, COVERAGE, AND PAYMENT**
16 **PROCESSES UNDER MEDICARE FOR NEW**
17 **MEDICAL PRODUCTS.**

18 (a) IN GENERAL.—Not later than 12 months after
19 the date of enactment of this Act, the Secretary of Health
20 and Human Services shall publish a report on the internet
21 website of the Department of Health and Human Services
22 regarding processes under the Medicare program under
23 title XVIII of the Social Security Act (42 U.S.C. 1395
24 et seq.) with respect to the coding, coverage, and payment

1 of medical products described in subsection (b). Such re-
2 port shall include the following:

3 (1) A description of challenges in the coding,
4 coverage, and payment processes under the Medicare
5 program for medical products described in such sub-
6 section.

7 (2) Recommendations to—

8 (A) incorporate patient experience data
9 (such as the impact of a disease or condition on
10 the lives of patients and patient treatment pref-
11 erences) into the coverage and payment proc-
12 esses within the Centers for Medicare & Med-
13 icaid Services;

14 (B) decrease the length of time to make
15 national and local coverage determinations
16 under the Medicare program (as those terms
17 are defined in subparagraph (A) and (B), re-
18 spectively, of section 1862(l)(6) of the Social
19 Security Act (42 U.S.C. 1395y(l)(6)));

20 (C) streamline the coverage process under
21 the Medicare program and incorporate input
22 from relevant stakeholders into such coverage
23 determinations; and

24 (D) identify potential mechanisms to incor-
25 porate novel payment designs similar to those

1 in development in commercial insurance plans
2 and State plans under title XIX of the Social
3 Security Act (42 U.S.C. 1396r et seq.) into the
4 Medicare program.

5 (b) MEDICAL PRODUCTS DESCRIBED.—For purposes
6 of subsection (a), a medical product described in this sub-
7 section is a medical product, including a drug, biological
8 (including gene and cell therapy and gene editing), or
9 medical device, that has been designated as a break-
10 through therapy under section 506(a) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)), a
12 breakthrough device under section 515B of such Act (21
13 U.S.C. 360e–3), or a regenerative advanced therapy under
14 section 506(g) of such Act (21 U.S.C. 356(g)).

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