

117TH CONGRESS
1ST SESSION

S. 2416

To amend title 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 21, 2021

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 title 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 2021” or the “NOVEL
6 Act of 2021”.

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

3 Section 1874 of the Social Security Act (42 U.S.C.
4 1395kk) is amended by adding at the end the following
5 new subsection:

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

8 “(1) IN GENERAL.—On and after the date that
9 is 180 calendar days after the date of enactment of
10 this subsection, in the case of a novel medical prod-
11 uct, the Secretary shall make modifications to the
12 HCPCS code set at least once every quarter.

13 “(2) REQUEST.—Upon the written confidential
14 request of a manufacturer of a novel medical prod-
15 uct, the Secretary shall make a determination
16 whether to assign a HCPCS code to such product.
17 Such request may occur on or after the date on
18 which the product receives a designation as a break-
19 through therapy under section 506(a) of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)),
21 a breakthrough device under section 515B of such
22 Act (21 U.S.C. 360e–3), or a regenerative advanced
23 therapy under section 506(g) of such Act (21 U.S.C.
24 356(g)).

25 “(3) DEADLINE FOR DETERMINATION AND NO-
26 TIFICATION.—

1 “(A) COMPLETE REQUEST.—If the Sec-
2 retary finds that a manufacturer has submitted
3 a complete request under paragraph (2), the
4 Secretary shall—

5 “(i) make a determination under such
6 paragraph with respect to the request by
7 not later than 180 calendar days after re-
8 ceiving the request; and

9 “(ii) notify the manufacturer of the
10 determination by not later than 30 cal-
11 endar days after making such determina-
12 tion.

13 “(B) INCOMPLETE REQUEST.—If the Sec-
14 retary finds that a manufacturer has submitted
15 an incomplete request under paragraph (2), the
16 Secretary shall notify the manufacturer of such
17 finding by not later than 10 calendar days after
18 receiving the request. Such notification shall
19 contain detailed instructions on how the manu-
20 facturer can rectify any issue with the request.

21 “(4) MONITORING UTILIZATION.—A HCPCS
22 code assigned under this subsection shall allow for
23 the reliable monitoring of utilization of the novel
24 medical product as described in paragraph (7).

1 “(5) EFFECTIVE DATE OF CODE ASSIGN-
2 MENT.—If the Secretary makes a determination to
3 assign a HCPCS code to a product under paragraph
4 (2), such code—

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

19 “(B) may not take effect before the date
20 the product is approved, cleared, or licensed by
21 the Food and Drug Administration.

22 “(6) TRADE SECRETS AND CONFIDENTIAL IN-
23 FORMATION.—No information submitted under
24 paragraph (2) shall be construed as authorizing the
25 Secretary to disclose any information that is a trade

1 secret or confidential information subject to section
2 552(b)(4) of title 5, United States Code.

3 “(7) INPATIENT PRODUCTS.—The Secretary
4 shall establish a code modifier within the hospital in-
5 patient prospective payment system under section
6 1886(d) to track the utilization and, to the extent
7 practicable, outcomes of novel medical products that
8 are assigned a HCPCS code pursuant to the expe-
9 dited coding process under this subsection and are
10 furnished by hospitals in inpatient settings.

11 “(8) AUTHORITY.—

12 “(A) INCORPORATION INTO AN EXISTING
13 PROCESS.—The Secretary may, as determined
14 appropriate, incorporate the request process
15 under this subsection into another HCPCS code
16 request process that the Secretary has in place.

17 “(B) WAIVER OF ELEMENTS OF EXISTING
18 PROCESSES.—In implementing this subsection,
19 the Secretary may waive such elements of other
20 HCPCS code request processes relating to ad-
21 vance planning as the Secretary determines ap-
22 propriate.

23 “(9) DEFINITIONS.—In this subsection:

24 “(A) NOVEL MEDICAL PRODUCT DE-
25 FINED.—The term ‘novel medical product’

means a drug, biological product, or medical device—

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

“(ii) that has been designated as—

“(I) a breakthrough therapy under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a));

“(II) a breakthrough device under section 515B of such Act (21 U.S.C. 360e–3); or

“(III) a regenerative advanced therapy under section 506(g) of such Act (21 U.S.C. 356(g)).

“(B) HCPCS DEFINED.—The term ‘HCPCS’ means the Healthcare Common Procedure Coding System.”.

SEC. 3. COVERAGE DETERMINATIONS FOR NOVEL MEDICAL PRODUCTS.

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

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

1 “(A) IN GENERAL.—The Secretary shall
2 facilitate an efficient coverage pathway to expedite
3 a national coverage decision for coverage
4 with evidence development process under this
5 title for novel medical products described in
6 subparagraph (D). The Secretary shall review
7 such novel medical products for the coverage
8 process on an expedited basis, beginning as
9 soon as the Secretary assigns a HCPCS code to
10 the product pursuant to the expedited coding
11 process under section 1874(h).

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
16 coverage with evidence development is appropriate,
17 issuance of a national coverage determination of
18 coverage with evidence development for a period up to,
19 but not to exceed, 4
20 years from the date of such determination.

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

1 manufacturer of the novel medical product a re-
2 port providing options for implementing alter-
3 native payment models under this title for the
4 class of products to which the novel medical
5 product belongs, which may include the utiliza-
6 tion of existing models in the commercial health
7 insurance market or any other payment model
8 deemed appropriate by the Secretary. Such re-
9 port shall include any recommendations for leg-
10 islation and administrative action as the Sec-
11 retary determines appropriate to facilitate such
12 payment arrangements.

13 “(D) NOVEL MEDICAL PRODUCTS DE-
14 SCRIBED.—For purposes of this paragraph, a
15 novel medical product described in this subpara-
16 graph is a novel medical product, as defined in
17 paragraph (9)(A) of section 1874(h), that is as-
18 signed a HCPCS code pursuant to the expe-
19 dited coding process under such section.

20 “(E) CLARIFICATION.—Nothing in this
21 paragraph shall prevent the Secretary from
22 issuing a noncoverage or a national coverage
23 determination for a novel medical product de-
24 scribed in subparagraph (D).”.

1 **SEC. 4. ENHANCING COORDINATION WITH THE FOOD AND**
2 **DRUG ADMINISTRATION.**

3 (a) PUBLIC MEETING.—

4 (1) IN GENERAL.—Not later than 12 months
5 after the date of enactment of this Act, the Sec-
6 retary of Health and Human Services (in this sec-
7 tion referred to as the “Secretary”) shall convene a
8 public meeting for the purposes of discussing and
9 providing input on improvements to coordination be-
10 tween the Food and Drug Administration and the
11 Centers for Medicare & Medicaid Services in pre-
12 paring for the availability of novel medical products
13 (as defined in section 1874(h)(9)(A) of the Social
14 Security Act, as added by section 2) on the market
15 in the United States.

16 (2) ATTENDEES.—The public meeting shall in-
17 clude—

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

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

4 (C) representatives of commercial health
5 insurance payers;

6 (D) stakeholders with expertise in the ad-
7 ministration and use of novel medical products,
8 including physicians; and

9 (E) stakeholders representing patients and
10 with expertise in the utilization of patient expe-
11 rience data in medical product development.

12 (3) TOPICS.—The public meeting shall include
13 a discussion of—

14 (A) the status of the drug and medical de-
15 vice development pipeline related to the avail-
16 ability of novel medical products;

17 (B) the anticipated expertise necessary to
18 review the safety and effectiveness of such prod-
19 ucts at the Food and Drug Administration and
20 current gaps in such expertise, if any;

21 (C) the expertise necessary to make cod-
22 ing, coverage, and payment decisions with re-
23 spect to such products within the Centers for
24 Medicare & Medicaid Services, and current gaps
25 in such expertise, if any;

1 (D) common differences in the data sets
2 necessary to determine the safety and effective-
3 ness of a novel medical product and the data
4 sets necessary to determine whether a novel
5 medical product meets the reasonable and nec-
6 essary requirements for coverage and payment
7 under title XVIII of the Social Security Act
8 pursuant to section 1862(a)(1)(A) of such Act
9 (42 U.S.C. 1395y(a)(1)(A));

10 (E) the availability of information for
11 sponsors of such novel medical products to meet
12 each of those requirements; and

13 (F) the coordination of information related
14 to significant clinical improvement over existing
15 therapies for patients between the Food and
16 Drug Administration and the Centers for Medi-
17 care & Medicaid Services with respect to novel
18 medical products.

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

1 (b) IMPROVING TRANSPARENCY OF CRITERIA FOR
 2 MEDICARE COVERAGE.—

3 (1) UPDATING GUIDANCE.—Not later than 18
 4 months after the public meeting under subsection
 5 (a), the Secretary shall update the final guidance en-
 6 titled “National Coverage Determinations with Data
 7 Collection as a Condition of Coverage: Coverage with
 8 Evidence Development” to improve the availability
 9 and coordination of information as described in sub-
 10 paragraphs (D) through (F) of subsection (a)(3),
 11 and clarify novel medical product clinical data re-
 12 quirements to meet the reasonable and necessary re-
 13 quirements for coverage and payment under title
 14 XVIII of the Social Security Act.

15 (2) FINALIZING UPDATED GUIDANCE.—Not
 16 later than 12 months after issuing draft guidance
 17 under paragraph (1), the Secretary shall finalize the
 18 updated guidance.

19 **SEC. 5. REPORT ON CODING, COVERAGE, AND PAYMENT**
 20 **PROCESSES UNDER MEDICARE FOR NEW**
 21 **MEDICAL PRODUCTS.**

22 (a) IN GENERAL.—Not later than 12 months after
 23 the date of enactment of this Act, the Secretary of Health
 24 and Human Services shall publish a report on the internet
 25 website of the Department of Health and Human Services

1 regarding processes under the Medicare program under
2 title XVIII of the Social Security Act (42 U.S.C. 1395
3 et seq.) with respect to the coding, coverage, and payment
4 of medical products described in subsection (b). Such re-
5 port shall include the following:

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

10 (2) Recommendations to—

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

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

23 (C) streamline the coverage process under
24 the Medicare program and incorporate input

1 from relevant stakeholders into such coverage
2 determinations; and

3 (D) identify potential mechanisms to incor-
4 porate novel payment designs similar to those
5 in development in commercial insurance plans
6 and State plans under title XIX of the Social
7 Security Act (42 U.S.C. 1396r et seq.) into the
8 Medicare program.

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

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