II

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

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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.

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 ''New Opportunities for Value that Extend Lives Act of 2021'' or the ''NOVEL Act of 2021''.

SEC. 2. EXPEDITED CODING OF NOVEL MEDICAL PRODUCTS.

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

''(h) EXPEDITED CODING OF NOVEL MEDICAL PRODUCTS.—

''(1) IN GENERAL.—On and after the date that is 180 calendar days after the date of enactment of this subsection, in the case of a novel medical product, the Secretary shall make modifications to the HCPCS code set at least once every quarter.

''(2) REQUEST.—Upon the written confidential request of a manufacturer of a novel medical product, the Secretary shall make a determination whether to assign a HCPCS code to such product. Such request may occur on or after the date on which the product receives a designation 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–3), or a regenerative advanced therapy under section 506(g) of such Act (21 U.S.C. 356(g)).

''(3) DEADLINE FOR DETERMINATION AND NOTIFICATION.—

"(A) COMPLETE REQUEST.—If the Secretary finds that a manufacturer has submitted a complete request under paragraph (2), the Secretary shall—

"(i) make a determination under such paragraph with respect to the request by not later than 180 calendar days after receiving the request; and

"(ii) notify the manufacturer of the determination by not later than 30 calendar days after making such determination.

"(B) INCOMPLETE REQUEST.—If the Secretary finds that a manufacturer has submitted an incomplete request under paragraph (2), the Secretary shall notify the manufacturer of such finding by not later than 10 calendar days after receiving the request. Such notification shall contain detailed instructions on how the manufacturer can rectify any issue with the request.

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

"(5) EFFECTIVE DATE OF CODE ASSIGNMENT.—If the Secretary makes a determination to assign a HCPCS code to a product under paragraph (2), such code—

"(A) may be assigned within the first quarter after the manufacturer files, with respect to such product, a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)), a biological product license application under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), a premarket application under section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)), a report under section 510(k) of such Act (21 U.S.C. 360k), or a request for classification under section 513(f)(2) of such Act (21 U.S.C. 360c(f)(2)); and

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

"(6) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—No information submitted under paragraph (2) 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.

''(7) INPATIENT PRODUCTS.—The Secretary shall establish a code modifier within the hospital inpatient prospective payment system under section 1886(d) to track the utilization and, to the extent practicable, outcomes of novel medical products that are assigned a HCPCS code pursuant to the expedited coding process under this subsection and are furnished by hospitals in inpatient settings.

''(8) AUTHORITY.—

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

''(B) WAIVER OF ELEMENTS OF EXISTING PROCESSES.—In implementing this subsection, the Secretary may waive such elements of other HCPCS code request processes relating to advance planning as the Secretary determines appropriate.

''(9) DEFINITIONS.—In this subsection:

''(A) NOVEL MEDICAL PRODUCT DEFINED.—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.—

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

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

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

manufacturer of the novel medical product a report providing options for implementing alternative payment models under this title for the class of products to which the novel medical product belongs, which may include the utilization of existing models in the commercial health insurance market or any other payment model deemed appropriate by the Secretary. 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 paragraph (9)(A) of section 1874(h), that is assigned a HCPCS code pursuant to the expedited coding process under 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 described in subparagraph (D).''.

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

(a) PUBLIC MEETING.—

(1) IN GENERAL.—Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall convene a public meeting for the purposes of discussing and providing input on improvements to coordination between the Food and Drug Administration and the Centers for Medicare & Medicaid Services in preparing for the availability of novel medical products (as defined in section 1874(h)(9)(A) of the Social Security Act, as added by section 2) on the market in the United States.

(2) ATTENDEES.—The public meeting shall include—

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

(B) stakeholders with expertise in the research and development of novel medical products, including manufacturers of such products;

(C) representatives of commercial health insurance payers;

(D) stakeholders with expertise in the administration and use of novel medical products, including physicians; and

(E) stakeholders representing patients and with expertise in the utilization of patient experience data in medical product development.

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

(A) the status of the drug and medical device development pipeline related to the availability of novel medical products;

(B) the anticipated expertise necessary to review the safety and effectiveness of such products at the Food and Drug Administration and current gaps in such expertise, if any;

(C) the expertise necessary to make coding, coverage, and payment decisions with respect to such products within the Centers for Medicare & Medicaid Services, and current gaps in such expertise, if any;

(D) common differences in the data sets necessary to determine the safety and effectiveness of a novel medical product and the data sets necessary to determine whether a novel medical product meets the reasonable and necessary requirements for coverage and payment under title XVIII of the Social Security Act pursuant to section 1862(a)(1)(A) of such Act (42 U.S.C. 1395y(a)(1)(A));

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

(F) the coordination of information related to significant clinical improvement over existing therapies for patients between the Food and Drug Administration and the Centers for Medicare & Medicaid Services with respect to novel medical products.

(4) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—No information discussed as a part of the public meeting under this section 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.

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

(1) UPDATING GUIDANCE.—Not later than 18 months after the public meeting under subsection (a), the Secretary shall update the final guidance entitled ''National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development'' to improve the availability and coordination of information as described in subparagraphs (D) through (F) of subsection (a)(3), and clarify novel medical product clinical data requirements to meet the reasonable and necessary requirements for coverage and payment under title XVIII of the Social Security Act.

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

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

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

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

(1) A description of challenges in the coding, coverage, and payment processes under the Medicare program for medical products described in such subsection.

(2) Recommendations to—

(A) incorporate patient experience data (such as the impact of a disease or condition on the lives of patients and patient treatment preferences) into the coverage and payment processes within the Centers for Medicare & Medicaid Services;

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

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

from relevant stakeholders into such coverage determinations; and

(D) identify potential mechanisms to incorporate novel payment designs similar to those in development in commercial insurance plans and State plans under title XIX of the Social Security Act (42 U.S.C. 1396r et seq.) into the Medicare program.

(b) MEDICAL PRODUCTS DESCRIBED.—For purposes of subsection (a), a medical product described in this subsection is a medical product, including a drug, biological (including gene and cell therapy and gene editing), or medical device, 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–3), or a regenerative advanced therapy under section 506(g) of such Act (21 U.S.C. 356(g)).

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