

118TH CONGRESS
2D SESSION

S. 5275

To amend title XVIII of the Social Security Act to facilitate patient access to certain pediatric technologies.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 25, 2024

Mrs. BLACKBURN 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 facilitate patient access to certain pediatric technologies.

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 “Access to Pediatric
5 Technologies Act of 2024”.

6 **SEC. 2. FACILITATING ACCESS TO PEDIATRIC TECH-**
7 **NOLOGIES.**

8 (a) IN GENERAL.—Section 1848 of the Social Secu-
9 rity Act (42 U.S.C. 1395w–4) is amended by adding at
10 the end the following new subsection:

1 “(u) FACILITATING ACCESS TO PEDIATRIC TECH-
2 NOLOGIES.—

3 “(1) IN GENERAL.—For each qualifying pedi-
4 atric technology (as defined in paragraph (4)) fur-
5 nished on or after January 1, 2026, the Secretary
6 shall, upon receipt of a manufacturer request under
7 paragraph (3), establish national relative value units
8 under the physician fee schedule established under
9 this section, to the extent no such national relative
10 value units have been established for such qualifying
11 pediatric technology under such fee schedule.

12 “(2) PAYMENT METHODOLOGY.—The Secretary
13 shall establish national relative value units for a
14 qualifying pediatric technology under this sub-
15 section—

16 “(A) in accordance with the payment
17 methodology established under this section and
18 applicable regulations; and

19 “(B) using available data related to the
20 qualifying pediatric technology, which may in-
21 clude applicable contractor pricing information,
22 claims data, time and motion studies, invoice
23 information, or other information used by the
24 Secretary in establishing payment rates.

25 “(3) IMPLEMENTATION.—

1 “(A) IN GENERAL.—Upon written request
2 to the Secretary from the manufacturer of a
3 qualifying pediatric technology, the Secretary
4 shall establish national relative value units
5 under paragraph (1) through the annual rule-
6 making process for the physician fee schedule
7 established under this section, in accordance
8 with the timeline described in subparagraph
9 (B).

10 “(B) TIMELINE.—

11 “(i) In the case where the Secretary
12 receives a request under this paragraph on
13 or before May 1 of a given year from a
14 manufacturer with respect to a qualifying
15 pediatric technology of the manufacturer,
16 the Secretary shall establish national rel-
17 ative value units for the qualifying pedi-
18 atric technology in the rulemaking process
19 during that year for the physician fee
20 schedule established under this section.

21 “(ii) In the case where the Secretary
22 receives a request under this paragraph
23 after May 1 of a given year from a manu-
24 facturer with respect to a qualifying pedi-
25 atric technology of the manufacturer, the

1 Secretary shall establish national relative
2 value units for the qualifying pediatric
3 technology in the rulemaking process dur-
4 ing the following year for the physician fee
5 schedule established under this section.

6 “(C) CONTENT OF MANUFACTURER RE-
7 QUESTS.—A manufacturer submitting a request
8 under paragraph with respect to a qualifying
9 pediatric technology of the manufacturer shall
10 include in such request information to verify
11 that the technology is a qualifying pediatric
12 technology and to allow the Secretary to estab-
13 lish national relative value units for such tech-
14 nology, including (to the extent available) con-
15 tractor pricing information, claims data, time
16 and motion studies, invoice information, or
17 other relevant information.

18 “(4) QUALIFYING PEDIATRIC TECHNOLOGY DE-
19 FINED.—In this subsection, the term ‘qualifying pe-
20 diatric technology’ means a medical device that is—

21 “(A) covered under this title;

22 “(B) approved, cleared, or authorized
23 under section 510(k), 513(f)(2), or 515 of the
24 Federal Food, Drug, and Cosmetic Act (21
25 U.S.C. 360(k), 360c(f)(2), 360e);

1 “(C) described by a temporary Level I
2 HCPCS Code intended for emerging tech-
3 nologies, services, or procedures; and

4 “(D)(i) used as part of a procedure pre-
5 dominantly performed on pediatric patients; or

6 “(ii) has otherwise been specifically de-
7 signed for safe and effective use in pediatric
8 populations.

9 “(5) RULE OF CONSTRUCTION.—Nothing in
10 this subsection shall be construed to require cov-
11 erage of a qualifying pediatric technology under this
12 title or alter the requirements of section
13 1862(a)(1)(A).”.

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