II

119TH CONGRESS
1ST SESSION

S. 249

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

IN THE SENATE OF THE UNITED STATES

JANUARY 24, 2025

Mrs. BLACKBURN (for herself and Mr. LANKFORD) 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 facilitate patient access to certain pediatric technologies.

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 ''Access to Pediatric Technologies Act of 2025''.

SEC. 2. FACILITATING ACCESS TO PEDIATRIC TECHNOLOGIES.

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

''(u) FACILITATING ACCESS TO PEDIATRIC TECHNOLOGIES.—

''(1) IN GENERAL.—For each qualifying pediatric technology (as defined in paragraph (4)) furnished on or after January 1, 2026, the Secretary shall, upon receipt of a manufacturer request under paragraph (3), establish national relative value units under the physician fee schedule established under this section, to the extent no such national relative value units have been established for such qualifying pediatric technology under such fee schedule.

''(2) PAYMENT METHODOLOGY.—The Secretary shall establish national relative value units for a qualifying pediatric technology under this subsection—

''(A) in accordance with the payment methodology established under this section and applicable regulations; and

''(B) using available data related to the qualifying pediatric technology, which may include applicable contractor pricing information, claims data, time and motion studies, invoice information, or other information used by the Secretary in establishing payment rates.

''(3) IMPLEMENTATION.—

"(A) IN GENERAL.—Upon written request to the Secretary from the manufacturer of a qualifying pediatric technology, the Secretary shall establish national relative value units under paragraph (1) through the annual rulemaking process for the physician fee schedule established under this section, in accordance with the timeline described in subparagraph (B).

"(B) TIMELINE.—

"(i) In the case where the Secretary receives a request under this paragraph on or before May 1 of a given year from a manufacturer with respect to a qualifying pediatric technology of the manufacturer, the Secretary shall establish national relative value units for the qualifying pediatric technology in the rulemaking process during that year for the physician fee schedule established under this section.

"(ii) In the case where the Secretary receives a request under this paragraph after May 1 of a given year from a manufacturer with respect to a qualifying pediatric technology of the manufacturer, the

Secretary shall establish national relative value units for the qualifying pediatric technology in the rulemaking process during the following year for the physician fee schedule established under this section.

''(C) CONTENT OF MANUFACTURER REQUESTS.—A manufacturer submitting a request under this paragraph with respect to a qualifying pediatric technology of the manufacturer shall include in such request information to verify that the technology is a qualifying pediatric technology and to allow the Secretary to establish national relative value units for such technology, including (to the extent available) contractor pricing information, claims data, time and motion studies, invoice information, or other relevant information.

''(4) QUALIFYING PEDIATRIC TECHNOLOGY DEFINED.—In this subsection, the term 'qualifying pediatric technology' means a medical device that is—

''(A) covered under this title;

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

"(C) described by a temporary Level I HCPCS Code intended for emerging technologies, services, or procedures; and

"(D)(i) used as part of a procedure predominantly performed on pediatric patients; or

"(ii) has otherwise been specifically designed for safe and effective use in pediatric populations.

"(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require coverage of a qualifying pediatric technology under this title or alter the requirements of section 1862(a)(1)(A).".

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