I

118TH CONGRESS
1ST SESSION

H. R. 4882

To amend title XVIII of the Social Security Act to promote laboratory price transparency under the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

JULY 25, 2023

Mrs. MILLER of West Virginia introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to promote laboratory price transparency under the Medicare program.

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 "Clinical Laboratory Price Transparency Act of 2023".

SEC. 2. PROMOTING LABORATORY PRICE TRANSPARENCY UNDER THE MEDICARE PROGRAM.

Part E of title XVIII of the Social Security Act (42 U.S.C. 1395x et seq.) is amended by adding at the end the following new section:

"SEC. 1899C. LABORATORY PRICE TRANSPARENCY REQUIREMENT.

"(a) IN GENERAL.—Beginning January 1, 2025, each applicable laboratory that receives payment under this title for furnishing a specified clinical diagnostic laboratory test shall—

"(1) make publicly available (in a manner and form specified by the Secretary) on an Internet website the information described in subsection (b) with respect to each such specified clinical diagnostic laboratory test that such laboratory is so available to furnish; and

"(2) ensure that such information is updated not less frequently than annually.

"(b) INFORMATION DESCRIBED.—For purposes of subsection (a), the information described in this subsection is, with respect to an applicable laboratory and a specified clinical diagnostic laboratory test, the following:

"(1) The discounted cash price for such test (or, if no such price exists, the gross charge for such test).

''(2) If required by the Secretary, the deidentified minimum negotiated rate in effect between such laboratory and any group health plan or group or individual health insurance coverage for such test and the deidentified maximum negotiated rate in effect between such laboratory and any such plan or coverage for such test.

''(c) METHOD AND FORMAT.—Not later than January 1, 2028, the Secretary shall establish one or more methods and formats for each provider of services and supplier to use in compiling and making public standard charges and prices (as applicable) pursuant to subsection (a). Any such method and format—

''(1) may be similar to any template made available by the Centers for Medicare & Medicaid Services as of the date of the enactment of this subsection;

''(2) shall meet such standards as determined appropriate by the Secretary in order to ensure the accessibility and usability of such charges and prices; and

''(3) shall be updated as determined appropriate by the Secretary, in consultation with stakeholders.

"(d) MONITORING COMPLIANCE.—The Secretary shall, through notice and comment rulemaking and in consultation with the Inspector General of the Department of Health and Human Services, establish a process to monitor compliance with this section.

"(e) ENFORCEMENT.—

"(1) IN GENERAL.—In the case that the Secretary determines that an applicable laboratory is not in compliance with subsection (a)—

"(A) not later than 30 days after such determination, the Secretary shall notify such laboratory of such determination;

"(B) upon request of the Secretary, such laboratory shall submit to the Secretary, not later than 45 days after such request is sent, a corrective action plan to comply with such subsection; and

"(C) if such laboratory continues to fail to comply with such paragraph after the date that is 90 days after such notification is sent (or, in the case of such a laboratory that has submitted a corrective action plan described in subparagraph (B) in response to a request so described, after the date that is 90 days after such submission), the Secretary may impose a

civil monetary penalty in an amount not to exceed $300 for each subsequent day during which such failure to comply is ongoing.

''(2) INCREASE AUTHORITY.—In applying this paragraph with respect to violations occurring in 2027 or a subsequent year, the Secretary may through notice and comment rulemaking increase the amount of the civil monetary penalty under paragraph (1)(C).

''(3) APPLICATION OF CERTAIN PROVISIONS.—The provisions of section 1128A (other than subsections (a) and (b) of such section) shall apply to a civil monetary penalty imposed under this subsection in the same manner as such provisions apply to a civil monetary penalty imposed under subsection (a) of such section.

''(4) AUTHORITY TO WAIVE OR REDUCE PENALTY.—The Secretary may waive or reduce any penalty otherwise applicable with respect to an applicable laboratory under this paragraph if the Secretary determines that imposition of such penalty would result in a significant hardship for such laboratory (such as in the case of an applicable laboratory located in a rural or underserved area where imposi-

tion of such penalty may result in, or contribute to, a lack of access to care for individuals in such area).

''(5) CLARIFICATION OF NONAPPLICABILITY OF OTHER ENFORCEMENT PROVISIONS.—Notwithstanding any other provision of this title, this subsection shall be the sole means of enforcing the provisions of this section.

''(f) DEFINITIONS.—In this section:

''(1) APPLICABLE LABORATORY.—The term 'applicable laboratory' has the meaning given such term in section 414.502, of title 42, Code of Federal Regulations (or any successor regulation).

''(2) GROUP HEALTH PLAN; GROUP HEALTH INSURANCE COVERAGE; INDIVIDUAL HEALTH INSURANCE COVERAGE.—The terms 'group health plan', 'group health insurance coverage', and 'individual health insurance coverage' have the meaning given such terms in section 2791 of the Public Health Service Act.

''(3) SPECIFIED CLINICAL DIAGNOSTIC LABORATORY TEST.—The term 'specified clinical diagnostic laboratory test' means a clinical diagnostic laboratory test that is included on the list of shoppable services specified by the Centers for Medicare & Medicaid Services pursuant to section 180.60 of title

45, Code of Federal Regulations (or a successor regulation), other than such a test that is an advanced diagnostic laboratory test (as defined in section 1834A(d)(5)).".

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