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118TH CONGRESS
2D SESSION

H. R. 8749

To amend title XVIII of the Social Security Act to promote preparedness and Medicare beneficiary access to safer, more accurate sterile intravenous drug preparations through automated hospital infrastructure.

IN THE HOUSE OF REPRESENTATIVES

JUNE 14, 2024

Mr. KELLY of Pennsylvania introduced the following bill; which was referred to the Committee on Ways and Means

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A BILL

To amend title XVIII of the Social Security Act to promote preparedness and Medicare beneficiary access to safer, more accurate sterile intravenous drug preparations through automated hospital infrastructure.

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 ''Safer Compounding in Hospitals Act of 2024''.

SEC. 2. PROMOTING PREPAREDNESS AND MEDICARE BENEFICIARY ACCESS TO SAFER, MORE ACCURATE STERILE INTRAVENOUS DRUG PREPARATIONS THROUGH AUTOMATED HOSPITAL INFRASTRUCTURE.

Section 1886(d)(5) of the Social Security Act (42 U.S.C. 1395ww(d)(5)) is amended by adding at the end the following new subparagraph:

''(N)(i) Subject to clause (iv), in the case of a subsection (d) hospital and with respect to a discharge of an individual occurring on or after October 1, 2025, and before October 1, 2031, who was furnished a sterile intravenous treatment prepared with closed system automation device technology (as defined in clause (v)) by such hospital in compliance with all applicable requirements and regulations of the Food and Drug Administration, the Secretary shall provide an additional payment to such hospital of $40 for each such treatment so furnished.

''(ii) The Secretary shall establish a method to identify sterile intravenous treatments prepared with closed system automation device technology through the use of ICD 10 PCS codes, diagnosis codes, condition codes, or such other means as determined appropriate by the Secretary.

''(iii) The Secretary shall make such adjustments to payments under this subsection as the Secretary deter-

mines necessary to ensure that aggregate expenditures under this subsection with respect to a fiscal year with application of this subparagraph are estimated to be equal to such expenditures under this subsection with respect to such year without application of this subparagraph.

''(iv) Aggregate payments made under this subparagraph with respect to discharges occurring during a fiscal year may not exceed $40,000,000.

''(v) For purposes of this subparagraph, the term 'closed system automation device technology' means equipment that is cleared or approved by the Food and Drug Administration and that—

''(I) aseptically compounds ready-to-administer compounded sterile preparations without direct human manipulation;

''(II) creates, monitors, and assures an uncompromised ISO 5 environment, with continuous isolation of its interior from the external environment;

''(III) demonstrates unidirectional air within the compounding chamber and loading area or areas;

''(IV) incorporates barcode verification of all drug ingredients, which are comprised solely of fin-

ished sterile drug products approved by the Food and Drug Administration;

''(V) assures drug dose accuracy and control using gravimetric (or comparable) analysis;

''(VI) provides photographic evidence of all supply containers;

''(VII) applies labels to compounded sterile preparations within ISO 5 environment;

''(VIII) maintains detailed compounding, cleaning, and other operational records; and

''(IX) is developed, manufactured, and serviced as a pharmacy compounding device or system per guidance promulgated by the Food and Drug Administration.''.

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