

116TH CONGRESS
2D SESSION

H. R. 7518

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

JULY 9, 2020

Mr. MICHAEL F. DOYLE of Pennsylvania (for himself and Mr. KELLY of Pennsylvania) introduced the following bill; which was referred to the Committee on Ways and Means

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.

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 “Safer Compounding
5 in Hospitals Act of 2020”.

1 **SEC. 2. PROMOTING PREPAREDNESS AND MEDICARE BENE-**
2 **FICIARY ACCESS TO SAFER, MORE ACCURATE**
3 **STERILE INTRAVENOUS DRUG PREPARA-**
4 **TIONS THROUGH AUTOMATED HOSPITAL IN-**
5 **FRASTRUCTURE.**

6 (a) IN GENERAL.—Section 1886(d)(5) is amended by
7 adding at the end the following new subparagraph:

8 “(N)(i) Subject to clause (iv), in the case of a sub-
9 section (d) hospital and with respect to a discharge of an
10 individual occurring on or after October 1, 2020, and be-
11 fore October 1, 2026, who was furnished a sterile intra-
12 venous treatment prepared with closed system automation
13 device technology (as defined in clause (v)) by such hos-
14 pital in compliance with all applicable requirements and
15 regulations of the Food and Drug Administration, the Sec-
16 retary shall provide an additional payment to such hospital
17 of \$25 for each such treatment so furnished.

18 “(ii) The Secretary shall establish a method to iden-
19 tify sterile intravenous treatments prepared with closed
20 system automation device technology through the use of
21 ICD 10 PCS codes, diagnosis codes, condition codes, or
22 such other means as determined appropriate by the Sec-
23 retary.

24 “(iii) The Secretary shall make such adjustments to
25 payments under this subsection as the Secretary deter-
26 mines necessary to ensure that aggregate expenditures

1 under this subsection with respect to a fiscal year with
2 application of this subparagraph are estimated to be equal
3 to such expenditures under this subsection with respect
4 to such year without application of this subparagraph.

5 “(iv) Aggregate payments made under this subpara-
6 graph with respect to discharges occurring during a fiscal
7 year may not exceed \$40,000,000.

8 “(v) For purposes of this subparagraph, the term
9 ‘closed system automation device technology’ means equip-
10 ment that is cleared or approved by the Food and Drug
11 Administration and that—

12 “(I) aseptically compounds ready-to-administer
13 compounded sterile preparations without direct
14 human manipulation;

15 “(II) creates, monitors, and assures an
16 uncompromised ISO 5 environment, with continuous
17 isolation of its interior from the external environ-
18 ment;

19 “(III) demonstrates unidirectional air within
20 the compounding chamber and loading area or
21 areas;

22 “(IV) incorporates barcode verification of all
23 drug ingredients, which are comprised solely of fin-
24 ished sterile drug products approved by the Food
25 and Drug Administration;

1 “(V) assures drug dose accuracy and control
2 using gravimetric (or comparable) analysis;

3 “(VI) provides photographic evidence of all sup-
4 ply containers;

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

7 “(VIII) maintains detailed compounding, clean-
8 ing, and other operational records; and

9 “(IX) is developed, manufactured, and serviced
10 as a pharmacy compounding device or system per
11 guidance promulgated by the Food and Drug Ad-
12 ministration.”.

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