

116TH CONGRESS
2D SESSION

H. R. 8624

To amend title XVIII of the Social Security Act to authorize the extension of pass-through status under the Medicare program for certain drugs and devices impacted by COVID–19.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 16, 2020

Mr. WENSTRUP (for himself and Mr. BISHOP of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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

A BILL

To amend title XVIII of the Social Security Act to authorize the extension of pass-through status under the Medicare program for certain drugs and devices impacted by COVID–19.

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 “Protecting Access to
5 Innovation During COVID–19 Act”.

1 **SEC. 2. AUTHORIZING THE EXTENSION OF PASS-THROUGH**
2 **STATUS UNDER THE MEDICARE PROGRAM**
3 **FOR CERTAIN DRUGS AND DEVICES IM-**
4 **PACTED BY COVID-19.**

5 Section 1833(t)(6) of the Social Security Act (42
6 U.S.C. 1395l(t)(6)) is amended by adding at the end the
7 following new subparagraph:

8 “(K) AUTHORITY TO EXTEND PASS-
9 THROUGH STATUS FOR CERTAIN DRUGS AND
10 DEVICES IMPACTED BY COVID-19.—

11 “(i) IN GENERAL.—Notwithstanding
12 the preceding provisions of this paragraph,
13 in the case of an eligible drug or device (as
14 defined in clause (iv)), if the Secretary de-
15 termines, prior to or on the date of the ex-
16 piration of pass-through status for such
17 drug or device (or, in the case of such a
18 drug or device whose pass-through status
19 expired before the date of the enactment of
20 this subparagraph, not later than 30 days
21 after such date), that the cost of such drug
22 or device is unable to be accurately cal-
23 culated due to the effects of COVID-19,
24 the Secretary may extend the pass-through
25 status of such eligible drug or device in ac-
26 cordance with clause (ii).

1 “(ii) EXTENSION.—The Secretary
2 may extend the pass-through status of an
3 eligible drug or device described in clause
4 (i) with respect to which a determination
5 has been made under such clause—

6 “(I) in the case of a drug or de-
7 vice whose period of pass-through sta-
8 tus expired during the emergency pe-
9 riod described in section
10 1135(g)(1)(B) before the date of the
11 enactment of this subparagraph, for a
12 period beginning on the first day after
13 such period of up to the number of
14 days occurring during such period
15 during which such drug or device had
16 pass-through status;

17 “(II) in the case of a drug or de-
18 vice whose period of pass-through sta-
19 tus would otherwise expire during
20 such emergency period on or after
21 such date of enactment—

22 “(aa) for the remainder of
23 such period; and

24 “(bb) for a period beginning
25 on the first day after such period

1 of up to the number of days oc-
2 ccurring during such period dur-
3 ing which such drug or device
4 had pass-through status (not tak-
5 ing into account any extension of
6 such status pursuant to this sub-
7 clause); and

8 “(III) in the case of a drug or
9 device not described in subclause (I)
10 or (II), by the number of days occur-
11 ring during such emergency period
12 during which such drug or device had
13 pass-through status.

14 “(iii) SPECIAL RULES FOR ALREADY-
15 EXPIRED DRUGS AND DEVICES.—In the
16 case of an eligible drug or device described
17 in clause (ii)(I) for which payment under
18 this subsection was packaged into a pay-
19 ment for a covered OPD service (or group
20 of services) and whose period of pass-
21 through status is extended in accordance
22 with such clause, the Secretary—

23 “(I) shall, for the period during
24 which such extension is in effect for
25 such drug or device—

1 “(aa) remove, during such
2 period, the packaged costs of
3 such drug or device (as deter-
4 mined by the Secretary) from the
5 payment amount under this sub-
6 section for the covered OPD serv-
7 ice (or group of services) with
8 which it is packaged; and

9 “(bb) not make any adjust-
10 ments to payment amounts under
11 this subsection for a covered
12 OPD service (or group of serv-
13 ices) for which no costs were re-
14 moved under subclause (I); and

15 “(II) may not, when calculating
16 the cost of such drug or device at the
17 end of such extension, take into ac-
18 count claims for such drug or device
19 made while such drug or device was
20 so packaged.

21 “(iv) ELIGIBLE DRUG OR DEVICE DE-
22 FINED.—For purposes of this subpara-
23 graph, the term ‘eligible drug or device’
24 means a drug or device with pass-through
25 status in effect during any portion of the

1 emergency period described in section
2 1135(g)(1)(B).”.

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