

**Amendment to the Amendment in the Nature of a Substitute to H.R. 3
Offered by Rep. Smith of Nebraska**

The amendment would improve incentives of the add-on payment and cap the add-on amount for Part B drugs.

AMENDMENT

OFFERED BY MR. SMITH OF NEBRASKA

Strike section 201.

Add at the end the following (and update the table of contents accordingly):

1 **TITLE _____ —MISCELLANEOUS**
2 **SEC. _____. PROVIDING FOR VARIATION IN PAYMENT FOR**
3 **CERTAIN DRUGS COVERED UNDER PART B**
4 **OF THE MEDICARE PROGRAM.**

5 (a) IN GENERAL.—Section 1847A(b) of the Social
6 Security Act (42 U.S.C. 1395w–3a(b)) is amended—

7 (1) in paragraph (1)—

8 (A) in subparagraph (A), by inserting after
9 “or 106 percent” the following: “(or, for a mul-
10 tiple source drug furnished on or after January
11 1, 2021, the applicable percent specified in
12 paragraph (9)(A) for the drug and quarter in-
13 volved)”; and

14 (B) in subparagraph (B) of paragraph (1),
15 by inserting after “106 percent” the following:
16 “(or, for a single source drug or biological fur-
17 nished on or after January 1, 2021, the appli-

1 cable percent specified in paragraph (9)(A) for
2 the drug or biological and quarter involved”);
3 and

4 (2) by adding at the end the following new
5 paragraph:

6 “(9) APPLICATION OF VARIABLE PERCENTAGES
7 BASED ON PERCENTILE RANKING OF PER BENE-
8 FICIARY ALLOWED CHARGES.—

9 “(A) APPLICABLE PERCENT TO BE AP-
10 PLIED.—

11 “(i) IN GENERAL.—Subject to clause
12 (ii), with respect to a drug or biological
13 furnished in a calendar quarter beginning
14 on or after January 1, 2021, if the Sec-
15 retary determines that the percentile rank
16 of a drug or biological under subparagraph
17 (B)(i)(III), with respect to per beneficiary
18 allowed charges for all such drugs or
19 biologicals, is—

20 “(I) at least equal to the 85th
21 percentile, the applicable percent for
22 the drug for such quarter under this
23 subparagraph is 104 percent;

24 “(II) at least equal to the 70th
25 percentile, but less than the 85th per-

1 centile, such applicable percent is 106
2 percent;

3 “(III) at least equal to the 50th
4 percentile, but less than the 70th per-
5 centile, such applicable percent is 108
6 percent; or

7 “(IV) less than the 50th per-
8 centile, such applicable percent is 110
9 percent.

10 “(ii) CASES WHERE DATA NOT SUFFI-
11 CIENTLY AVAILABLE TO COMPUTE PER
12 BENEFICIARY ALLOWED CHARGES.—In the
13 case of a drug or biological furnished for
14 which the amount of payment is deter-
15 mined under subparagraph (A) or (B) of
16 paragraph (1) and not under subsection
17 (c)(4), for calendar quarters during a pe-
18 riod in which data are not sufficiently
19 available to compute a per beneficiary al-
20 lowed charges for the drug or biological,
21 the applicable percent is 106 percent.

22 “(B) DETERMINATION OF PERCENTILE
23 RANK OF PER BENEFICIARY ALLOWED CHARGES
24 OF DRUGS.—

1 “(i) IN GENERAL.—With respect to a
2 calendar quarter beginning on or after
3 January 1, 2021, for drugs and biologicals
4 for which the amount of payment is deter-
5 mined under subparagraph (A) or (B) of
6 paragraph (1), except for drugs or
7 biologicals for which data are not suffi-
8 ciently available, the Secretary shall—

9 “(I) compute the per beneficiary
10 allowed charges (as defined in sub-
11 paragraph (C)) for each such drug or
12 biological;

13 “(II) adjust such per beneficiary
14 allowed charges for the quarter, to the
15 extent provided under subparagraph
16 (D); and

17 “(III) array such adjusted per
18 beneficiary allowed charges for all
19 such drugs or biologicals from high to
20 low and rank such drugs or biologicals
21 by percentile of such arrayed per ben-
22 eficiary allowed charges.

23 “(ii) FREQUENCY.—The Secretary
24 shall make the computations under clause
25 (i)(I) every 6 months (or, if necessary, as

1 determined by the Secretary, every 9 or 12
2 months) and such computations shall apply
3 to succeeding calendar quarters until a
4 new computation has been made.

5 “(iii) APPLICABLE DATA PERIOD.—
6 For purposes of this paragraph, the term
7 ‘applicable data period’ means the most re-
8 cent period for which the data necessary
9 for making the computations under clause
10 (i) are available, as determined by the Sec-
11 retary.

12 “(C) PER BENEFICIARY ALLOWED
13 CHARGES DEFINED.—In this paragraph, the
14 term ‘per beneficiary allowed charges’ means,
15 with respect to a drug or biological for which
16 the amount of payment is determined under
17 subparagraph (A) or (B) of paragraph (1)—

18 “(i) the allowed charges for the drug
19 or biological for which payment is so made
20 for the applicable data period, as estimated
21 by the Secretary; divided by

22 “(ii) the number of individuals for
23 whom any payment for the drug or biologi-
24 cal was made under paragraph (1) for the

1 applicable data period, as estimated by the
2 Secretary.

3 “(D) ADJUSTMENT TO REFLECT CHANGES
4 IN AVERAGE SALES PRICE.—In applying this
5 paragraph for a particular calendar quarter, the
6 Secretary shall adjust the per beneficiary al-
7 lowed charges for a drug or biological by multi-
8 plying such per beneficiary allowed charges
9 under subparagraph (C) for the applicable data
10 period by the ratio of—

11 “(i) the average sales price for the
12 drug or biological for the most recent cal-
13 endar quarter used under subsection
14 (c)(5)(B); to

15 “(ii) the average sales price for the
16 drug or biological for the calendar quarter
17 (or the weighted average for the quarters
18 involved) included in the applicable data
19 period.”.

20 (b) APPLICATION OF JUDICIAL REVIEW PROVI-
21 SIONS.—Section 1847A(g) of the Social Security Act is
22 amended—

23 (1) by striking “and” at the end of paragraph
24 (4);

1 (2) by striking the period at the end of para-
2 graph (5) and inserting “; and”; and

3 (3) by adding at the end the following new
4 paragraph:

5 “(6) the determination of per beneficiary al-
6 lowed charges of drugs or biologicals and ranking of
7 such charges under subsection (b)(9).”.

8 **SEC. _____. ESTABLISHMENT OF MAXIMUM ADD-ON PAY-**
9 **MENT FOR DRUGS AND BIOLOGICALS.**

10 (a) IN GENERAL.—Section 1847A of the Social Secu-
11 rity Act (42 U.S.C. 1395w–3a), as previously amended,
12 is further amended—

13 (1) in subsection (b)—

14 (A) in paragraph (1), in the matter pre-
15 ceding subparagraph (A), by striking “para-
16 graph (7)” and inserting “paragraphs (7) and
17 (10)”; and

18 (B) by adding at the end the following new
19 paragraph:

20 “(10) MAXIMUM ADD-ON PAYMENT AMOUNT.—

21 “(A) IN GENERAL.—In determining the
22 payment amount under the provisions of sub-
23 paragraph (A), (B), or (C) of paragraph (1) of
24 this subsection, subsection (c)(4), or subsection
25 (d)(3)(C) for a drug or biological furnished on

1 or after January 1, 2021, if the applicable add-
2 on payment (as defined in subparagraph (B))
3 for each drug or biological on a claim for a date
4 of service exceeds the maximum add-on pay-
5 ment amount specified under subparagraph (C)
6 for the drug or biological, then the payment
7 amount otherwise determined for the drug or
8 biological under those provisions, as applicable,
9 shall be reduced by the amount of such excess.

10 “(B) APPLICABLE ADD-ON PAYMENT DE-
11 FINED.—In this paragraph, the term ‘applicable
12 add-on payment’ means the following amounts,
13 determined without regard to the application of
14 subparagraph (A):

15 “(i) In the case of a multiple source
16 drug, an amount equal to the difference
17 between—

18 “(I) the amount that would oth-
19 erwise be applied under paragraph
20 (1)(A); and

21 “(II) the amount that would be
22 applied under such paragraph if ‘100
23 percent’ were substituted for ‘106 per-
24 cent’.

1 “(ii) In the case of a single source
2 drug or biological, an amount equal to the
3 difference between—

4 “(I) the amount that would oth-
5 erwise be applied under paragraph
6 (1)(B); and

7 “(II) the amount that would be
8 applied under such paragraph if ‘100
9 percent’ were substituted for ‘106 per-
10 cent’.

11 “(iii) In the case of a biosimilar bio-
12 logical product, the amount otherwise de-
13 termined under paragraph (8)(B).

14 “(iv) In the case of a drug or biologi-
15 cal during the initial period described in
16 subsection (c)(4), an amount equal to the
17 difference between—

18 “(I) the amount that would oth-
19 erwise be applied under such sub-
20 section; and

21 “(II) the amount that would be
22 applied under such subsection if ‘100
23 percent’ were substituted, as applica-
24 ble, for—

1 “(aa) ‘103 percent’ in sub-
2 paragraph (B)(i) of such sub-
3 section; or

4 “(bb) any percent in excess
5 of 100 percent applied under
6 subparagraph (B)(ii) of such sub-
7 section.

8 “(v) In the case of a drug or biologi-
9 cal to which subsection (d)(3)(C) applies,
10 an amount equal to the difference be-
11 tween—

12 “(I) the amount that would oth-
13 erwise be applied under such sub-
14 section; and

15 “(II) the amount that would be
16 applied under such subsection if ‘100
17 percent’ were substituted, as applica-
18 ble, for—

19 “(aa) any percent in excess
20 of 100 percent applied under
21 clause (i) of such subsection; or

22 “(bb) ‘103 percent’ in clause
23 (ii) of such subsection.

24 “(C) MAXIMUM ADD-ON PAYMENT AMOUNT
25 SPECIFIED.—For purposes of subparagraph

1 (A), the maximum add-on payment amount
2 specified in this subparagraph is—

3 “(i) for each of 2021 through 2028,
4 \$1,000; and

5 “(ii) for a subsequent year, the
6 amount specified in this subparagraph for
7 the preceding year increased by the per-
8 centage increase in the consumer price
9 index for all urban consumers (all items;
10 United States city average) for the 12-
11 month period ending with June of the pre-
12 vious year.

13 Any amount determined under this subpara-
14 graph that is not a multiple of \$10 shall be
15 rounded to the nearest multiple of \$10.”;

16 (2) in subsection (c)(4)(A)(ii), by striking “in
17 the case” and inserting “subject to subsection
18 (b)(10), in the case”.

19 (b) CONFORMING AMENDMENTS RELATING TO SEPA-
20 RATELY PAYABLE DRUGS.—

21 (1) OPPTS.—Section 1833(t)(14) of the Social
22 Security Act (42 U.S.C. 1395l(t)(14)) is amended—

23 (A) in subparagraph (A)(iii)(II), by insert-
24 ing “, subject to subparagraph (I)” after “are
25 not available”; and

1 (B) by adding at the end the following new
2 subparagraph:

3 “(I) APPLICATION OF MAXIMUM ADD-ON
4 PAYMENT FOR SEPARATELY PAYABLE DRUGS
5 AND BIOLOGICALS.—In establishing the amount
6 of payment under subparagraph (A) for a speci-
7 fied covered outpatient drug that is furnished
8 as part of a covered OPD service (or group of
9 services) on or after January 1, 2021, if such
10 payment is determined based on the average
11 price for the year established under section
12 1847A pursuant to clause (iii)(II) of such sub-
13 paragraph, the provisions of subsection (b)(10)
14 of section 1847A shall apply to the amount of
15 payment so established in the same manner as
16 such provisions apply to the amount of payment
17 under section 1847A.”.

18 (2) ASC.—Section 1833(i)(2)(D) of the Social
19 Security Act (42 U.S.C. 1395l(i)(2)(D)) is amend-
20 ed—

21 (A) by moving clause (v) 6 ems to the left;

22 (B) by redesignating clause (vi) as clause
23 (vii); and

24 (C) by inserting after clause (v) the fol-
25 lowing new clause:

1 “(vi) If there is a separate payment
2 under the system described in clause (i) for
3 a drug or biological furnished on or after
4 January 1, 2021, the provisions of sub-
5 section (t)(14)(I) shall apply to the estab-
6 lishment of the amount of payment for the
7 drug or biological under such system in the
8 same manner in which such provisions
9 apply to the establishment of the amount
10 of payment under subsection (t)(14)(A).”.

