

1 biological furnished on or after January 1,
2 2021, the applicable percent specified in
3 paragraph (9)(A) for the drug or biological
4 and quarter involved”); and
5 (B) by adding at the end the following new
6 paragraph:

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

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

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

21 “(I) at least equal to the 85th
22 percentile, the applicable percent for
23 the drug for such quarter under this
24 subparagraph is 102 percent;

1 “(II) at least equal to the 70th
2 percentile, but less than the 85th per-
3 centile, such applicable percent is 104
4 percent;

5 “(III) at least equal to the 50th
6 percentile, but less than the 70th per-
7 centile, such applicable percent is 106
8 percent; or

9 “(IV) less than the 50th per-
10 centile, such applicable percent is 108
11 percent.

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

1 “(B) DETERMINATION OF PERCENTILE
2 RANK OF PER BENEFICIARY ALLOWED CHARGES
3 OF DRUGS.—

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

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

16 “(II) adjust such per beneficiary
17 allowed charges for the quarter, to the
18 extent provided under subparagraph
19 (D); and

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

1 “(ii) FREQUENCY.—The Secretary
2 shall make the computations under clause
3 (i)(I) every 6 months (or, if necessary, as
4 determined by the Secretary, every 9 or 12
5 months) and such computations shall apply
6 to succeeding calendar quarters until a
7 new computation has been made.

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

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

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

1 “(ii) the number of individuals for
2 whom any payment for the drug or biologi-
3 cal was made under paragraph (1) for the
4 applicable data period, as estimated by the
5 Secretary.

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

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

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

23 (2) APPLICATION OF JUDICIAL REVIEW PROVI-
24 SIONS.—Section 1847A(g) of the Social Security Act
25 is amended—

1 (A) by striking “and” at the end of para-
2 graph (4);

3 (B) by striking the period at the end of
4 paragraph (5) and inserting “; and”; and

5 (C) by adding at the end the following new
6 paragraph:

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

10 (b) REQUIRING REGULATIONS ON ALLOCATION OF
11 BUNDLED DISCOUNTS AMONG DRUG PRODUCTS.—

12 (1) IN GENERAL.—The Secretary of Health and
13 Human Services shall promulgate final regulations,
14 to be effective no later than July 1, 2021, that re-
15 quire manufacturers, in implementing section 1847A
16 of the Social Security Act (42 U.S.C. 1395w–3a)
17 and in order that the average sales price for each
18 drug accurately reflects the average transaction
19 price for that drug, to allocate the total value of all
20 bundled discounts proportionately according to the
21 dollar value of the units of each drug sold under a
22 bundled arrangement.

23 (2) ALTERNATIVE APPROACHES.—After pro-
24 mulgating such regulations, the Secretary may revise
25 such regulations to incorporate alternative ap-

1 proaches, such as allocating discounts to reflect con-
2 tingencies in the contracts between manufacturers
3 and purchasers of drugs, in a way that more accu-
4 rately represents the average transaction prices for
5 drugs with bundled discounts.

