AMENDMENT

OFFERED BY M__. _____

Strike section 201 and insert the following (and conform the table of contents accordingly):

SEC. 201. REDUCING MEDICARE PAYMENTS AND PATIENT COINSURANCE FOR SPECIFIED PART B DRUGS THROUGH MARKET-BASED ADJUSTMENTS.

(a) IN GENERAL.—Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a) is amended by adding at the end the following new subsection:

''(h) MANUFACTURER MARKET-BASED ADJUSTMENTS TO REDUCE MEDICARE PAYMENTS AND BENEFICIARY COINSURANCE PAYMENTS FOR COVERED PART B DRUGS.—

''(1) SECRETARIAL REQUIREMENTS.—

''(A) REDUCTION OF MEDICARE PAYMENT.—In the case that a covered part B drug is payable under this part and a claim for such drug is submitted under this title within the 1-year period after the date on which such drug was furnished, the Secretary shall, as the primary payer for such drug, make payment (as

appropriate) for such drug in an amount that is the product of—

''(i) the per-unit market-based adjustment of such drug; and

''(ii) the total number of billing units for such drug.

''(B) REDUCTION OF BENEFICIARY COINSURANCE.—For a beneficiary that is furnished a covered part B drug under this part, the Secretary shall adjust the amount of any applicable coinsurance for such drug to an amount that is equal to 20 percent of the per-unit market-based adjustment of such drug.

''(2) MANUFACTURER REQUIREMENTS.—

''(A) IN GENERAL.—For each calendar quarter, a manufacturer of a covered part B drug shall—

''(i) calculate the amount of the per-unit market-based adjustment for such drug; and

''(ii) report to the Secretary the amount described in clause (i) for each unit associated with each National Drug Code (including package size) in a manner similar to the manner in which manufac-

turers report average sales price information pursuant to section 1927(b)(3)(A)(iii).

''(B) GOOD FAITH EXEMPTION.—

''(i) IN GENERAL.—A manufacturer of a covered part B drug or covered individual may not be liable under subsection (b)(3)(B) or (c) of section 1927 or section 3729 through section 3733 of title 31, United States Code, if such manufacturer or covered individual—

''(I) carries out each requirement specified in subparagraph (A)(i) (including any faulty assumption or method) in good faith based on a reasonable assumption; and

''(II) documents any assumption in writing and submits such assumption to the Secretary in a manner similar to the manner in which manufacturers report average sales price information pursuant to section 1927(b)(3)(A)(iii).

''(ii) COVERED INDIVIDUAL DEFINED.—In this subparagraph, a 'covered individual' means an officer, employee, or

agent of a manufacturer of a covered part B drug.

''(3) PER-UNIT MARKET-BASED ADJUSTMENT.—In this subsection, the 'per-unit market-based adjustment' is—

''(A) for a calendar quarter, the average sales price (as defined in section 1847A(c)) of a covered part B drug for a manufacturer; minus

''(B) for such calendar quarter, the average net price of such drug for such manufacturer.

''(4) OTHER SECRETARIAL REQUIREMENTS.—The Secretary shall—

''(A) maintain data with respect to the current manufacturers of covered part B drugs;

''(B) maintain data with respect to the current manufacturer that owns the right to sell each covered part B drug (including each manufacturer that divested the right to sell such drug);

''(C) establish a dispute resolution process to resolve any issue relating to—

''(i) the number of units, with respect tor a covered part B drug, described in paragraph (1)(A)(ii); and

''(ii) the per-unit market-based adjustment, with respect to a covered part B drug;

''(D) in the case of a multiple source drug (as defined in subsection (c)(6)(C)) that is a covered part B drug, develop a billing and payment code system that attributes each unit of such drug to each manufacturer; and

''(E) not later than January 1, 2021, assign a claims modifier to each drug or biological that is subject to an agreement under section 340B(a) of the Public Health Service Act.

''(5) PAYMENT OF DIFFERENCE TO THE SMI TRUST FUND.—In the case that payment is made pursuant to paragraph (1)(A), the Secretary shall—

''(A) calculate the difference between the amount that is paid pursuant to such clause and the amount that would have been paid if the market-based adjustment was not applied; and

''(B) transfer the amount that is the difference calculated under subparagraph (A) to

the Federal Supplemental Medical Insurance Trust Fund under section 1841.

''(6) CONFIDENTIALITY OF INFORMATION.—

''(A) IN GENERAL.—Notwithstanding any other provision of law, information disclosed by a manufacturer under this subsection is confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or a price charged for an individual product or product family (or any related data that could be used to estimate such data), except as the Secretary determines to be necessary to carry out this subsection, the adjustment of the beneficiary coinsurance for a covered part B drug.

''(B) INDIVIDUAL PRODUCT OR PRODUCT FAMILY DEFINED.—In this paragraph, the term 'individual product or product family' means every drug or biological that is owned by the same manufacturer.

''(7) RULEMAKING.—Not later than 7 months after the date of the enactment of this subsection, the Secretary shall, through notice and comment rulemaking, issue regulations to carry out the requirements of this subsection.

''(8) DEFINITIONS.—In this subsection:

''(A) AVERAGE NET PRICE.—The term 'average net price' means the average sales price of a covered part B drug, excluding any net unit prices greater than the average sales price for such drug for the applicable calendar quarter.

''(B) COVERED PART B DRUGS.—

''(i) IN GENERAL.—The term 'covered part B drug' means a multiple source drug (as defined in subsection (c)(6)(C)), a single source drug or biological (as defined in subsection (c)(6)(D)), or a biosimilar biological product (as defined in subsection (c)(6)(H)) that—

''(I) is payable under this part;

''(II) was marketed for at least 1 quarter; and

''(III) the Secretary has published a payment rate for such drug.

''(ii) EXCEPTIONS.—Such term does not include—

''(I) a unit of a drug or biological that is not separately payable under this part (including a unit that is pay-

able as part of a grouping of items and services in an ambulatory payment classification under section 1833(t), a unit that is payable as part of a single payment under section 1833(i), or a unit that is payable under the payment system for renal dialysis services under section 1881(b)(14));

''(II) a unit of a drug or biological that is subject to a rebate under section 1927;

''(III) a unit of a drug or biological that is subject to an agreement under section 340B(a) of the Public Health Service Act;

''(IV) a unit of a drug or biological the Secretary elects to exclude in response to the Food and Drug Administration designating the drug as in shortage or in response to an emergency declared under section 319(a) of the Public Health Service Act, the Stafford Act, or the National Emergency Act;

''(V) a unit of a drug or biological that is designated by the Secretary for a rare disease or condition under section 526 of the Federal Food, Drug, and Cosmetic Act; and

''(VI) a unit of a drug or biological that is designated by the Secretary as a qualified infectious disease product under section 505E(d) of the Federal Food, Drug, and Cosmetic Act.''.

(b) EXCLUSIONS FROM CERTAIN PRICES.—

(1) AVERAGE SALES PRICE.—Section 1847A(c)(2) of the Social Security Act (42 U.S.C. 1395w–3a(c)(2)) is amended by adding at the end the following new subparagraph:

''(C) ADJUSTMENTS WITH MARKET-BASED ADJUSTMENTS.—Sales for a covered part B drug that exclude adjustments described in subsection (h)(1).''.

(2) BEST PRICE; AVERAGE MANUFACTURER PRICE.—Section 1927 (42 U.S.C. 1396r–8) is amended—

(A) in subsection (c)(1)(C)(i)—

(i) in subclause (V), by striking at the end ''and'';

(ii) in subclause (VI), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following new subclause:

''(VII) any adjustment described in section 1847A(h)(1) with respect to a covered part B drug.''; and

(B) in subsection (k)(1)(B)(i)—

(i) in subclause (IV), by striking at the end ''and'';

(ii) in subclause (V), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following new subclause:

''(VI) any adjustment described in section 1847A(h)(1) with respect to a covered part B drug.''.

(c) EFFECTIVE DATE.—The amendment made by subsections (a) and (b) shall apply for plans years beginning with plan year 2022.

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