AMENDMENT IN THE NATURE OF A SUBSTITUTE

TO H.R. ____

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Prescription Drug Sunshine, Transparency, Accountability and Reporting Act'' or the ''Prescription Drug STAR Act''.

SEC. 2. DRUG MANUFACTURER PRICE TRANSPARENCY.

(a) IN GENERAL.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128K the following new section:

''SEC. 1128L. DRUG MANUFACTURER PRICE TRANSPARENCY.

''(a) IN GENERAL.—With respect to each year, beginning with 2021, the Secretary shall, at least once during such year, determine if there is a triggered SPIKE increase (in accordance with subsection (b)) with respect to an applicable drug (as defined in subsection (f)(1)). If the Secretary determines, with respect to a year, there is such an increase with respect to an applicable drug, the manufacturer of the applicable drug shall submit to the Sec-

retary the justification described in subsection (c), subject to subsection (b)(4), for each such triggered SPIKE increase in accordance with the timing described in subsection (d)).

''(b) TRIGGERED SPIKE INCREASE.—

''(1) IN GENERAL.—A triggered SPIKE increase occurs, with respect an applicable drug and year (beginning with 2021 and referred to in this paragraph as the 'applicable year'), in any of the following cases:

''(A) If there is at least a 10 percent (or $10,000) cumulative increase with respect to the wholesale acquisition cost (or alternative cost measure specified by the Secretary under paragraph (3)) of such drug during a calendar-year period beginning and ending within the lookback period that is the 5-year period preceding such applicable year.

''(B) If there is at least a 25 percent (or $25,000) cumulative increase with respect to the wholesale acquisition cost (or such alternative cost measure) of such drug during any three-calendar-year period beginning and ending within such lookback period.

''(C) In the case of such a drug that is first covered under title XVIII with respect to such applicable year, if the estimated cost or spending under such title per individual or per user of such drug (as estimated by the Secretary) for such applicable year (or per course of treatment in such applicable year, as defined by the Secretary) is at least $26,000.

''(2) INDEXING DOLLAR AMOUNTS.—The dollar amounts applied under paragraph (1) for 2022 and each subsequent year shall be the dollar amounts specified in such paragraph for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year. If any amount established under paragraph (1), after application of this paragraph, for a year is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

''(3) ALTERNATIVE TO WAC.—The Secretary may, for purposes of making determinations under paragraph (1), in addition to using the wholesale acquisition cost for an applicable drug, use alternative cost measures of such drug, or use such alternative

cost measure if the wholesale acquisition cost is not available.

''(4) EXCEPTION.—A justification under subsection (c) shall not be required for a triggered SPIKE increase described in paragraph (1) of an applicable drug of a manufacturer if—

''(A) there is any portion of the lookback period described in the respective subparagraph of such paragraph for such increase that is included within the lookback period for another triggered SPIKE increase (or combination of such increases) for which a justification is made under this section for such drug by such manufacturer; or

''(B) such increase is less than the wholesale acquisition cost (or alternative cost measure specified by the Secretary under paragraph (3)) of such drug during the calendar-year period described in paragraph (1)(A) or the three-calendar-year period described in paragraph (1)(B), as applicable, for such increase, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending six months prior to the

calendar-year period so described and for the 36-month period ending six months prior to the three-calendar-year period so described, respectively.

''(5) UNIT DETERMINATION.—For purposes of determining the wholesale acquisition cost in carrying out this section, the Secretary shall determine a unit (such as a unit size) to apply.

''(6) PUBLIC POSTING.—Beginning with respect to 2021, the Secretary shall publicly post on the Internet website of the Department of Health and Human Services—

''(A) alternative percentages, dollar amounts, and lookback periods that, if applied under paragraph (1), would be projected to increase the number of applicable drugs for which a triggered SPIKE increase would occur for such year; and

''(B) the number of applicable drugs for which a triggered SPIKE increase would occur for such year if such an alternative percentage, dollar amount, or period were applied for such year.

''(c) JUSTIFICATION DESCRIBED.—

''(1) IN GENERAL.—The justification described in this subsection, with respect to a triggered SPIKE increase described in subsection (b)(1) of an applicable drug of a manufacturer, is—

''(A) all of the information described in paragraph (2);

''(B) all of the information and supporting documentation described in paragraph (3), as applicable to the increase and drug; and

''(C) a certification described in paragraph (4).

''(2) REQUIRED INFORMATION.—For purposes of paragraph (1), the information described in this paragraph is the following:

''(A) The individual factors that have contributed to the increase in the wholesale acquisition cost.

''(B) An explanation of the role of each factor in contributing to such increase.

''(3) INFORMATION AS APPLICABLE.—For purposes of paragraph (1), the information and supporting documentation described in this paragraph is the following, as applicable to the increase of the drug:

''(A) Total expenditures of the manufacturer on—

''(i) materials and manufacturing for such drug;

''(ii) acquiring patents and licensing for each drug of the manufacturer; and

''(iii) costs to purchase or acquire the drug from another company, if applicable.

''(B) The percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds.

''(C) The total expenditures of the manufacturer on research and development for such drug.

''(D) The total revenue and net profit generated from the applicable drug for each calendar year since drug approval.

''(E) The total costs associated with marketing and advertising for the applicable drug.

''(F) Additional information specific to the manufacturer of the applicable drug, such as—

''(i) the total revenue and net profit of the manufacturer for the period of such increase, as determined by the Secretary;

''(ii) metrics used to determine executive compensation;

''(iii) total expenditures on—

''(I) drug research and development; or

''(II) clinical trials on drugs that failed to receive approval by the Food and Drug Administration; and

''(iv) any additional information related to drug pricing decisions of the manufacturer.

''(G) Any other relevant information and supporting documentation necessary to justify the triggering SPIKE increase.

''(H) Any other relevant information and supporting documentation, as specified by the Secretary.

''(4) CERTIFICATION.—For purposes of paragraph (1), the certification described in this paragraph is a certification, that all such information and documentation is accurate and complete, by one of the following:

''(A) The chief executive officer of the manufacturer.

''(B) The chief financial officer of the manufacturer.

''(C) An individual who has delegated authority to sign for, and who reports directly to, such chief executive officer or chief financial officer.

''(d) TIMING.—

''(1) NOTIFICATION.—Not later than 60 days after the date on which the Secretary makes the determination that there is a triggering SPIKE increase with respect to an applicable drug, the Secretary shall notify the manufacturer of the applicable drug of such determination.

''(2) SUBMISSION OF JUSTIFICATION.—Not later than 90 days after the date on which a manufacturer receives a notification under paragraph (1), subject to subsection (b)(4), the manufacturer shall submit to the Secretary the justification required under subsection (a), including a summary of such justification, in a form and manner specified by the Secretary. In specifying such form, with respect to the summary required under the previous sentence, the Secretary shall provide that such summary shall be in an easily understandable format, as specified by the Secretary, and shall permit the manufacturer

to exclude proprietary information from such summary.

''(3) POSTING ON INTERNET WEBSITE.—Not later than 30 days after receiving the complete justification under paragraph (2), the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services the summary included for such justification.

''(e) PENALTIES.—

''(1) FAILURE TO SUBMIT TIMELY JUSTIFICATION.—If the Secretary determines that a manufacturer has failed to submit a justification as required under this section, including in accordance with the timing and form required, with respect to an applicable drug, the Secretary shall apply a civil monetary penalty in an amount of $10,000 for each day the manufacturer has failed to submit such justification as so required.

''(2) FALSE INFORMATION.—Any manufacturer that submits a justification under this section that knowingly provides false information in such justification is subject to a civil monetary penalty in an amount not to exceed $100,000 for each item of false information.

''(3) APPLICATION OF PROCEDURES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). Civil monetary penalties imposed under this subsection are in addition to other penalties as may be prescribed by law.

''(f) DEFINITIONS.—In this section:

''(1) APPLICABLE DRUG.—

''(A) IN GENERAL.—Subject to subparagraph (B), the term 'applicable drug' means, with respect to a lookback period described in subsection (b)(1), a covered outpatient drug (as defined in paragraph (2) of section 1927(k), without application of paragraph (3) of such section) that is covered under title XVIII and is not a low cost drug.

''(B) EXCLUSION OF LOW COST DRUGS.—For purposes of subparagraph (A), not later than January 1, 2021, the Secretary shall specify a threshold (such as a cost or spending threshold) for identifying (and shall identify) low cost drugs to be excluded from the definition of the term 'applicable drug', such as a

drug that has a wholesale acquisition cost of less than $10 per unit or less than $100 in average estimated expenditures under title XVIII per individual per year or per user of such drug per year. For purposes of this section, a drug shall not be considered specified as a low cost drug for a lookback period described in subsection (b)(1) with respect to a year unless such drug is identified as being below the specified threshold for the entirety of the lookback period.

''(2) MANUFACTURER.—The term 'manufacturer' has the meaning given that term in section 1847A(c)(6)(A).

''(3) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given that term in section 1847A(c)(6)(B).''.

(b) REPORTING TO THE SECRETARY OF THE TREASURY.—

(1) IN GENERAL.—Subpart A of part III of subchapter A of chapter 61 of the Internal Revenue Code of 1986 is amended by inserting after section 6039J the following new section:

"SEC. 6039K. DRUG PRICE SPIKE INCREASE REPORTING.

"Each manufacturer (within the meaning of section 1128L of the Social Security Act) shall file a return (at such time and in such form and manner as the Secretary may provide) showing for such year with respect to which such section applies all information and supporting documentation and the certification included within a justification reported by the manufacturer under subsection (c)(1) of such section.".

(2) CLERICAL AMENDMENT.—The table of sections for subpart A of part III of subchapter A of chapter 61 of such Code is amended by inserting after the item relating to section 6039J the following new item:

"Sec. 6039K. Drug price SPIKE increase reporting.".

SEC. 3. REQUIREMENT FOR MANUFACTURERS OF CERTAIN DRUGS, DEVICES, BIOLOGICALS, AND MEDICAL SUPPLIES TO REPORT ON PRODUCT SAMPLES PROVIDED TO CERTAIN HEALTH CARE PROVIDERS.

(a) IN GENERAL.—Section 1128G(a) of the Social Security Act (42 U.S.C. 1320a–7h(a)) is amended by adding at the end the following new paragraph:

"(3) CERTAIN PRODUCT SAMPLES.—

"(A) IN GENERAL.—In addition to the requirements under paragraphs (1)(A) and (2),

on the 90th day of each calendar year (beginning with 2023), any applicable manufacturer that provides a payment or other transfer of value that is a product sample described in subparagraph (B) to any covered recipient (or to an entity or individual at the request of, or designated on behalf of, such a covered recipient) shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information (aggregated per each drug, device, biological, or medical supply, as applicable) with respect to the preceding calendar year:

''(i) The total quantity of all such payments or other transfers of value provided to all covered recipients.

''(ii) The total value of all such payments or other transfers of value provided to all covered recipients.

''(iii) If applicable, information described in clauses (vii) and (viii) of paragraph (1)(A) with respect to such a payment or other transfer of value.

''(B) PRODUCT SAMPLE DESCRIBED.—For purposes of subparagraph (A), a product sample described in this subparagraph is a product

sample that is not intended to be sold and is intended for patient use.''.

(b) PUBLIC AVAILABILITY OF INFORMATION.—Section 1128G(c)(1)(C)(ii) of the Social Security Act (42 U.S.C. 1320a–7h(c)(1)(C)(ii)) is amended—

(1) by striking ''(ii) contains'' and inserting ''(ii)(I) with respect to information that is not information submitted under paragraph (3) of subsection (a), contains'';

(2) by striking '', as applicable;'' and inserting '', as applicable; and''; and

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

''(II) with respect to information submitted under paragraph (3) of subsection (a), contains information that is presented by the name of the applicable manufacturer, the total amount of all payments or other transfers of value described in such paragraph provided to all covered recipients, the total value of all such payments or other transfers of value provided to all covered recipients, and the name of the covered drug, device, biological, or medical supply, as applicable;''.

(c) CONFORMING AMENDMENT.—Section 1128G(e)(10)(B)(ii) of the Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)(ii)) is amended by striking ''Product samples'' and inserting ''Except for purposes of paragraph (3) of subsection (a), product samples''.

(d) REPORTING TO THE SECRETARY OF THE TREASURY.—

(1) IN GENERAL.—Subpart A of part III of subchapter A of chapter 61 of the Internal Revenue Code of 1986, as amended by section 2, is further amended by inserting after section 6039K the following new section:

''SEC. 6039L. PRODUCT SAMPLES OF APPLICABLE MANUFACTURERS.

''Each applicable manufacturer (within the meaning of section 1128G(a)(3) of the Social Security Act) shall file a return (at such time and in such form and manner as the Secretary may provide) showing for such year to which such section applies—

''(1) the amount described in section 1128G(a)(3)(A)(ii) of such Act with respect to such year, and

''(2) the portion of such amount for which a deduction was claimed under section 162.''.

(2) CLERICAL AMENDMENT.—The table of sections for subpart A of part III of subchapter A of chapter 61 of such Code, as amended by section 2, is further amended by inserting after the item relating to section 6039K the following new item:

"Sec. 6039L. Product samples of applicable manufacturers.".

SEC. 4. ANALYSIS AND REPORT ON INPATIENT HOSPITAL DRUG COSTS.

(a) ANALYSIS.—The Secretary of Health and Human Services shall conduct an analysis that, to the extent practicable—

(1) focuses on drugs that are furnished in the inpatient setting;

(2) includes data on inpatient hospital drug costs, Medicare spending, volume, and spending per admission;

(3) considers trends in inpatient hospital drug costs, such as trends by hospital size, classification of urban or rural, whether the hospital is a teaching hospital, or other categorization; and

(4) examines the impact of drug shortages on services that are furnished in an inpatient hospital setting.

In conducting such analysis, the Secretary may conduct hospital surveys, use data from hospital cost reports, or use other data as determined by the Secretary.

(b) REPORT.—Not later than January 1, 2021, the Secretary shall submit to the Committee on Ways and Means of the House of Representatives and the Finance Committee of the Senate a report on drug costs in the inpatient hospital setting, including the analyses described in paragraphs (1) through (4) of subsection (a).

(c) FUNDING.—For purposes of carrying out this section, there shall be transferred to the Secretary $3,000,000 from the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i).

SEC. 5. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.

Section 1150A of the Social Security Act (42 U.S.C. 1320b–23) is amended—

(1) in subsection (c), in the matter preceding paragraph (1), by inserting ''(other than as permitted under subsection (e))'' after ''disclosed by the Secretary''; and

(2) by adding at the end the following new subsection:

''(e) PUBLIC AVAILABILITY OF CERTAIN INFORMATION.—

''(1) IN GENERAL.—In order to allow the comparison of PBMs' ability to negotiate rebates, discounts, and price concessions and the amount of

such rebates, discounts, and price concessions that are passed through to plan sponsors, beginning January 1, 2020, the Secretary shall make available on the Internet website of the Department of Health and Human Services the information with respect to the second preceding calendar year provided to the Secretary on generic dispensing rates (as described in paragraph (1) of subsection (b) and information provided to the Secretary under paragraphs (2) and (3) of such subsection that, as determined by the Secretary, is with respect to each PBM.

''(2) AVAILABILITY OF DATA.—In carrying out paragraph (1), the Secretary shall ensure the following:

''(A) CONFIDENTIALITY.—The information described in such paragraph is displayed in a manner that prevents the disclosure of information on rebates, discounts, and price concessions, with respect to an individual drug or an individual plan.

''(B) CLASS OF DRUG.—The information described in such paragraph is made available by class of drug, using an existing classification system, but only if the class contains such number of drugs, as specified by the Secretary, to

ensure confidentiality of proprietary information or other information that is prevented to be disclosed under subparagraph (A).''.

SEC. 6. REQUIRING CERTAIN MANUFACTURERS TO REPORT DRUG PRICING INFORMATION WITH RESPECT TO DRUGS UNDER THE MEDICARE PROGRAM.

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

(1) in subsection (b)—

(A) in paragraph (2)(A), by inserting ''or subsection (f)(2), as applicable'' before the period at the end;

(B) in paragraph (3), in the matter preceding subparagraph (A), by inserting ''or subsection (f)(2), as applicable,'' before ''determined by''; and

(C) in paragraph (6)(A), in the matter preceding clause (i), by inserting ''or subsection (f)(2), as applicable,'' before ''determined by''; and

(2) in subsection (f)—

(A) by striking ''For requirements'' and inserting the following:

''(1) IN GENERAL.—For requirements''; and

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

''(2) MANUFACTURERS WITHOUT A REBATE AGREEMENT UNDER TITLE XIX.—

''(A) IN GENERAL.—In the case of a manufacturer of a drug or biological described in subparagraph (C), (E), or (G) of section 1842(o)(1) or in clause (ii) or (iii) of section 1881(b)(14)(B) that does not have a rebate agreement in effect under section 1927, for calendar quarters beginning on or after January 1, 2020, such manufacturer shall report to the Secretary the information described in subsection (b)(3)(A)(iii) of such section 1927 with respect to such drug or biological in a time and manner specified by the Secretary.

''(B) AUDIT.—Information reported under subparagraph (A) is subject to audit by the Inspector General of the Department of Health and Human Services.

''(C) VERIFICATION.—The Secretary may survey wholesalers and manufacturers that directly distribute drugs described in subparagraph (A), when necessary, to verify manufacturer prices and manufacturer's average sales

prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of such a drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(D) CONFIDENTIALITY.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph (other than the wholesale acquisition cost for purposes of carrying out this section) is confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or

wholesaler or prices charged for drugs by such manufacturer or wholesaler, except—

''(i) as the Secretary determines to be necessary to carry out this section (including the determination and implementation of the payment amount), or to carry out section 1847B;

''(ii) to permit the Comptroller General to review the information provided; and

''(iii) to permit the Director of the Congressional Budget Office to review the information provided.''.

(b) ENFORCEMENT.—Section 1847A such Act (42 U.S.C. 1395w–3a) is further amended—

(1) in subsection (d)(4)—

(A) in subparagraph (A), by striking ''IN GENERAL'' and inserting ''MISREPRESENTATION'';

(B) in subparagraph (B), by striking ''subparagraph (B)'' and inserting ''subparagraph (A), (B), or (C)'';

(C) by redesignating subparagraph (B) as subparagraph (D); and

(D) by inserting after subparagraph (A) the following new subparagraphs:

''(B) FAILURE TO PROVIDE TIMELY INFORMATION.—If the Secretary determines that a manufacturer described in subsection (f)(2) has failed to report on information described in section 1927(b)(3)(A)(iii) with respect to a drug or biological in accordance with such subsection, the Secretary shall apply a civil money penalty in an amount of $10,000 for each day the manufacturer has failed to report such information and such amount shall be paid to the Treasury.

''(C) FALSE INFORMATION.—Any manufacturer required to submit information under subsection (f)(2) that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law.''; and

(2) in subsection (c)(6)(A), by striking the period at the end and inserting '', except that, for purposes of subsection (f)(2), the Secretary may, if the Secretary determines appropriate, exclude repackagers of a drug or biological from such term.''.

(c) REPORT.—Not later than January 1, 2021, the Inspector General of the Department of Health and Human Services shall assess and submit to Congress a report on the accuracy of average sales price information submitted by manufacturers under section 1847A of the Social Security Act (42 U.S.C. 1395w–3a). Such report shall include any recommendations on how to improve the accuracy of such information.

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