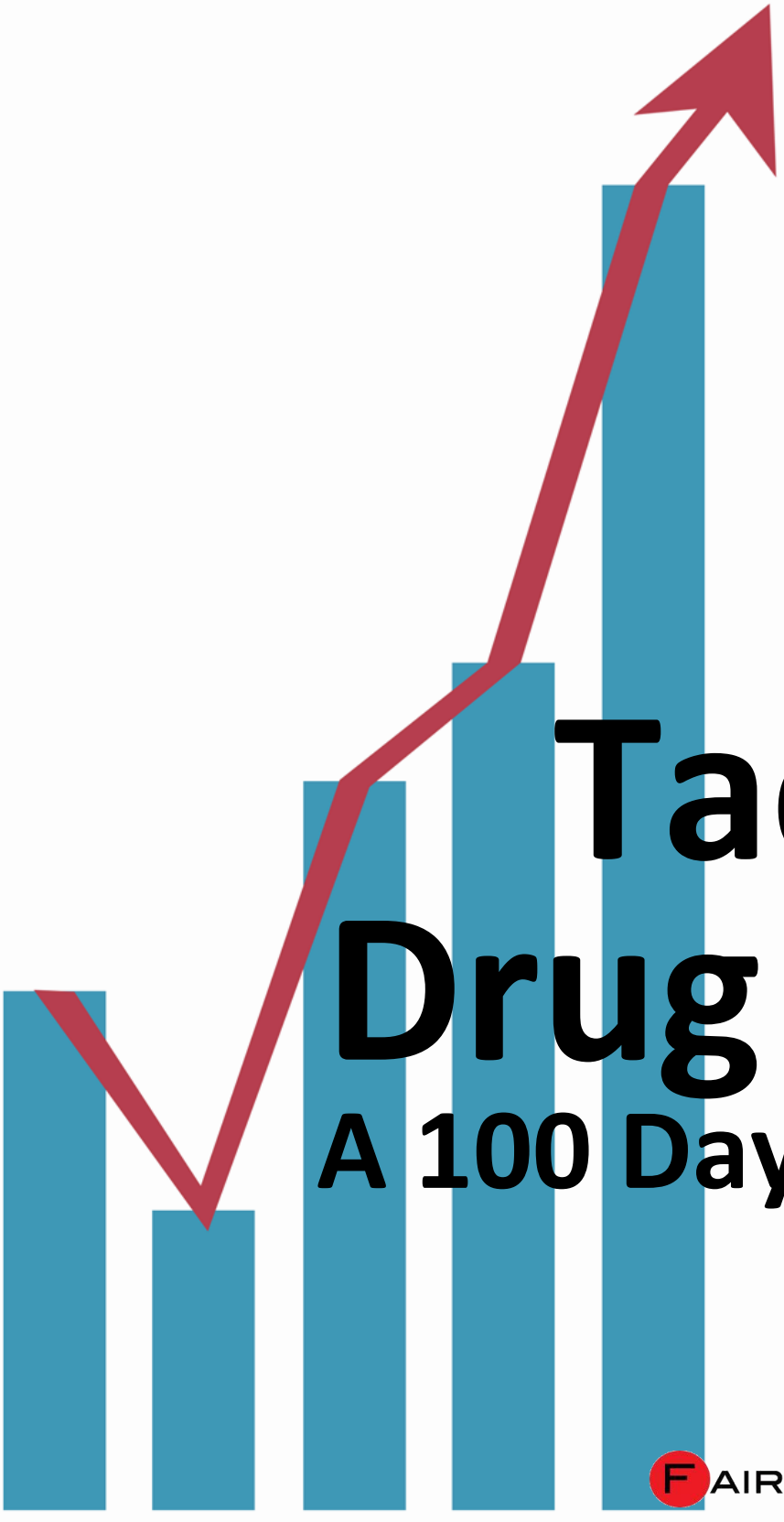

Tackling Drug Costs

A 100 Day Roadmap

Sean Dickson
NASTAD
with Tim Horn
Treatment Action Group
on behalf of the
FAIR PRICING COALITION

About the Fair Pricing Coalition

The Fair Pricing Coalition, founded by the late Martin Delaney of Project Inform, is a national coalition of activists and policy leaders who work on HIV and viral hepatitis drug pricing issues, and to help control drug costs for patients who are privately insured, underinsured and uninsured. The Fair Pricing Coalition also works to ensure access for individuals covered by state AIDS Drug Assistance Programs (ADAPs), Medicare, and Medicaid. For more information about the Fair Pricing Coalition and its history, visit: www.fairpricingcoalition.org.

This report is authored by:

Sean Dickson, sdickson@nastad.org (primary contact), Senior Manager, Health Systems Integration, at NASTAD (National Alliance of State & Territorial AIDS Directors) in Washington, DC. www.nastad.org, with

Tim Horn, tim.horn@treatmentactiongroup.org, Deputy Executive Director, HIV & HCV Programs, at Treatment Action Group (TAG) in New York, NY. Tim is also Co-Chair of the Fair Pricing Coalition. www.treatmentactiongroup.org

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Model Legislation

The Prescription Reduction In Cost and Expenditures (PRICE) Act of 2017

Statutory text as amended

Revisions to Average Manufacturer Price - 42 U.S.C. §1396r-8

42 U.S.C. §1396r-8(k)

(k) Definitions.—In the section—

(1) Average manufacturer price.—

(A) In general.—Subject to subparagraph (B), the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by—.

(i) wholesalers for drugs distributed to retail community pharmacies; and

(ii) retail community pharmacies that purchase drugs directly from the manufacturer.

(B) Exclusion of customary prompt pay discounts and other payments.—

(i) In general.—The average manufacturer price for a covered outpatient drug shall exclude—

(I) customary prompt pay discounts extended to wholesalers;

(II) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);

(III) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;

(IV) payments, rebates, and discounts related to the sale or transfer of an authorized generic drug as that term is defined under section 505(t) of the Food, Drug, and Cosmetic Act;

~~(IV) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy; and~~

(V) discounts provided by manufacturers under section 1860D–14A; and

(VI) discounts provided to prisons, jails, or correctional facilities.

(ii) Inclusion of other discounts and payments.—~~Notwithstanding~~ Except as specified in clause (i), the following shall be included in the average manufacturer price for a covered outpatient drug—

(I) any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies**;**

(II) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order

pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy ~~shall be included in the average manufacturer price for a covered outpatient drug~~.

…

(10) Retail community pharmacy

The term "retail community pharmacy" means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term includes pharmacies that dispense prescription medications to patients primarily through the mail and pharmacy benefit managers. Such term does not include ~~a pharmacy that dispenses prescription medications to patients primarily through the mail,~~ nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, or government pharmacies~~, or pharmacy benefit managers~~.

42 U.S.C. §1396r-8(c)(1)

(C) “Best price” defined

For purposes of this section—

(i) In general The term “best price” means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355 (c)]), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, pharmacy benefit manager, managed care organization, insurer, hospital, clinic, mail order pharmacy, long term care provider, manufacturer, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section (including inpatient prices charged to hospitals described in section 256b (a)(4)(L) of this title);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1395w–141 of this title; ~~and~~

(VI) any prices charged which are negotiated by a prescription drug plan under part D of subchapter XVIII of this chapter, by an MA–PD plan under part C of such subchapter with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1395w–132 (a)(2) of this title) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such subchapter, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1395w–114a of this title; and

(VII) any prices charged to a prison, jail, or correctional facility.

(ii) Special rules The term “best price”—

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount; and

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355 (c)], shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, pharmacy benefit manager, managed care organization, insurer, hospital, clinic, mail order pharmacy, long term care provider, manufacturer, or governmental entity within the United States, excluding those prices described in subclauses (I) through (~~IV~~VII) of clause (i).

(iii) Application of auditing and recordkeeping requirements-- With respect to a covered entity described in section 256b (a)(4)(L) of this title, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 256b (a)(5)(C) of this title.

42 U.S.C. §1396r-8(c)

(2) Additional rebate for single source and innovator multiple source drugs.—

…

(D) No m~~M~~aximum rebate amount.—Manufacturers are required to rebate the full sum ~~In no case shall the sum~~ of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period beginning after ~~December 31, 2009~~January 1, 2018, even if such sum shall exceed 100 percent of the average manufacturer price of the drug.

(E) Additional rebate multiplier – The amount of the additional rebate specified in subparagraph (A) shall be –

(i) Doubled, if the average manufacturer price for the dosage form and strength of the drug for the period exceeds 1.05 multiplied by the amount calculated under clause (ii)(II) of subparagraph (A); and

(ii) Tripled, if the average manufacturer price for the dosage form and strength of the drug for the period exceeds 1.25 multiplied by the amount calculated under clause (ii)(II) of subparagraph (A).

(F) Consideration of baseline average manufacturer price

In the case of a covered outpatient drug approved by the Food and Drug Administration after January 1, 2018, if the baseline average manufacturer price is less than the average manufacturer price for the first full calendar quarter after the day on which the drug was first marketed, clause (ii)(II) of subparagraph (A) shall be applied by substituting “baseline average manufacturer price” for “average manufacturer price.”

(3) Rebate for other drugs

…

(C) Additional rebate

(i) In general

The amount of the rebate specified in this paragraph for a rebate period, with respect to each dosage form and strength of a covered outpatient drug other than a single source drug or an innovator multiple source drug of a manufacturer, shall be increased in the manner that the rebate for a dosage form and strength of a single source drug or an innovator multiple source drug is increased under subparagraphs (A), (D), (E), and (F) ~~and (D)~~ of paragraph (2), except as provided in clause (ii).

(ii) Special rules for application of provision

In applying subparagraphs (A) and (D) of paragraph (2) under clause (i)-

(I) the reference in subparagraph (A)(i) of such paragraph to "1990" shall be deemed a reference to "2014";

(II) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to "the calendar quarter beginning July 1, 1990" shall be deemed a reference to "the calendar quarter beginning July 1, 2014"; and

(III) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to "September 1990" shall be deemed a reference to "September 2014";

(IV) the references in subparagraph (D) of such paragraph to "paragraph (1)(A)(ii)"~~,~~ and "this paragraph"~~,~~ ~~and "December 31, 2009" s~~hall be deemed references to "subparagraph (A)"~~,~~ and "this subparagraph"~~,~~ ~~and "December 31, 2014"~~, respectively; and

(V) any reference in such paragraph to a "single source drug or an innovator multiple source drug" shall be deemed to be a reference to a drug to which clause (i) applies.

…

(4) Baseline average manufacturer price

(A) For a single source drug or innovator multiple source drug approved by the Food and Drug Administration after January 1, 2018, the Secretary shall calculate a “baseline average manufacturer price” for each drug. The baseline average manufacturer price shall equal—

(i) the average of--

(I) the average manufacturer prices for the first full quarter after the day on which each of the drugs were first marketed, each increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the newly approved drug was approved exceeds such index for the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed, for

(II) each of the single source drugs or innovator multiple source drugs in the top third of single source drugs or innovator multiple source drugs by sales volume in the quarter prior to approval in the same drug category or to treat the same condition as the newly approved drug.

(ii) multiplied by—

(I) 200 percent, if the average number of years since approval by the Food and Drug Administration of the drugs considered in clause (i)(II) of subparagraph (A) exceeds ten years;

(II) 150 percent, if the average number of years since approval by the Food and Drug Administration of the drugs considered in clause (i)(II) of subparagraph (A) exceeds five years but does not exceed ten years; or

(III) 125 percent, if the average number of years since approval by the Food and Drug Administration of the drugs considered in clause (i)(II) of subparagraph (A) does not exceed five years.

(B) Notwithstanding subparagraph (A), if a drug is determined by the Secretary to be so exceptionally novel that it cannot be compared to existing drugs in the same drug category or to treat the same condition, the Secretary shall calculate a baseline average manufacturer price that considers the improvement in treatment value over the drugs considered in clause (i)(II) of subparagraph (A). The Secretary shall issue regulations to determine "exceptionally novel" drugs and their baseline average manufacturer price.

(C) For a noninnovator multiple source drug approved by the Food and Drug Administration after January 1, 2018 which is therapeutically equivalent to a single source or innovator multiple source drug approved after January 1, 2018, as determined by the Food and Drug Administration, the baseline average manufacturer price shall be the baseline average manufacturer price of the innovator multiple source drug to which the noninnovator multiple source drug is therapeutically equivalent, reduced by 25 percent.

(D) For a noninnovator multiple source drug approved by the Food and Drug Administration after January 1, 2018 which is therapeutically equivalent to a single source or innovator multiple source drug approved before January 1, 2018, as determined by the Food and Drug Administration, the baseline average manufacturer price shall be the baseline average manufacturer price as calculated under subparagraph (A), reduced by 25 percent.

(E) The Secretary shall issue regulations implementing this provision within 180 days.

42 U.S.C. §1396r-8

(l) Disclosures for excessive price increases

(A) If a covered outpatient drug is subject to the additional rebate calculated under the methodology in 42 U.S.C. §1396r-8(c)(2)(E)(ii), including such an additional rebate under 42 U.S.C. §1396r-8(c)(3), the manufacturer of the covered outpatient drug shall submit a report to the Secretary within 90 days detailing research and development costs for the drug, production costs, marketing expenditures (including provider detailing, direct-to-consumer marketing, and any activities or funding associated with supporting, communicating, or researching off-label uses of the drug), Federal and non-profit funding that supported the drug's development (including prior to the manufacturer's acquisition of the drug), detailed breakdowns of the patient population receiving the drug, detailed breakdowns of the number of prescriptions paid for by various private and public payers and the total amount expended for the drug by each payer and any discounts or rebates provided to that payer, detailed executive compensation, and other such information as the Secretary shall determine. The Secretary shall release such reports to the public on a quarterly basis.

(B) The Secretary shall have authority to levy civil monetary penalties for failure to submit a complete and accurate report under this section, as determined by the Secretary through regulation.

Revisions to Average Sales Price - 42 U.S.C. §1395w-3a

42 U.S.C. §1395w-3a(d)

(3) Limitation on average sales price

(A) In general

The Secretary ~~may~~ shall disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).

(B) Applicable threshold percentage defined

In this paragraph, the term "applicable threshold percentage" means—

(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; ~~and~~

(ii) in 2006 through 2017~~and subsequent years~~, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both; and

(iii) in 2018 and subsequent years, 5 percent.

(C) Authority to adjust average sales price

The Inspector General shall, on a quarterly basis, review all reported average sales prices to determine if the reported average sales price for a drug or biological ~~If the Inspector General finds that the average sales price for a drug or biological~~ exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage. Should the reported average sales price for a drug or biological exceed the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary ~~(at such times as the Secretary may specify to carry out this subparagraph)~~ and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—

(i) the widely available market price for the drug or biological (if any); or

(ii) 103 percent of the average manufacturer price (as determined under section 1396r–8 (k)(1) of this title) for the drug or biological.

Revisions to Non-Federal Average Manufacturer Price - 38 U.S.C. §8126

38 U.S.C. §8126

(c) With respect to any covered drug the price of which is determined in accordance with a pharmaceutical pricing agreement entered into pursuant to subsection (a)(2), beginning on or after January 1, 1993, the manufacturer shall provide a discount in an amount equal to—

(A) the amount by which the change in non-Federal price exceeds the amount equal to—

(1) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the last day of the month preceding the month during which the contract for the covered drug goes into effect (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period as the Secretary considers appropriate); multiplied by

(2) the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) between the last month of the period described in paragraph (1) and the last month preceding the month during which the contract goes into effect for which Consumer Price Index data is available.

(B) multiplied by—

(1) Two, if the amount by which the change in non-Federal price exceeds 1.05 multiplied by the amount calculated under clauses (1) and (2) of subparagraph (A);

(2) Three, if the amount by which the change in non-Federal price exceeds 1.25 multiplied by the amount calculated under clauses (1) and (2) of subparagraph (A); or

(3) One, if the amount by which the change in non-Federal price does not exceed 1.05 multiplied by the amount calculated under clauses (1) and (2) of subparagraph (A).

38 U.S.C. §8126(h)

(5) The term "non-Federal average manufacturer price" means, with respect to a covered drug and a period of time (as determined by the Secretary), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers, retail community pharmacies, and other direct purchasers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, including rebates or discounts provided to pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy but not taking into account—

(A) any prices paid by the Federal Government; ~~or~~

(B) any prices paid by or rebates or discounts to entities to whom sales are exempt from inclusion in the determination of "best price" under section 42 U.S.C. 1396r–8 (c)(1)(C)(i); or

(C~~B~~) any prices found by the Secretary to be merely nominal in amount.