${\sim}116\mathrm{H}5281$ 

Sail I Bully Carta

(Original Signature of Member)

117TH CONGRESS 1ST SESSION



To amend title XIX of the Social Security Act to improve transparency and prevent the use of abusive spread pricing and related practices in the Medicaid program.

## IN THE HOUSE OF REPRESENTATIVES

Mr. CARTER of Georgia introduced the following bill; which was referred to the Committee on \_\_\_\_\_

## A BILL

- To amend title XIX of the Social Security Act to improve transparency and prevent the use of abusive spread pricing and related practices in the Medicaid program.
  - 1 Be it enacted by the Senate and House of Representa-
  - 2 tives of the United States of America in Congress assembled,

## **3** SECTION 1. SHORT TITLE.

4 This Act may be cited as the "Drug Price Trans-5 parency in Medicaid Act of 2021".

| 1  | SEC. 2. IMPROVING TRANSPARENCY AND PREVENTING THE       |
|----|---|
| 2  | USE OF ABUSIVE SPREAD PRICING AND RE-                   |
| 3  | LATED PRACTICES IN MEDICAID.                            |
| 4  | (a) PASS-THROUGH PRICING REQUIRED.—                     |
| 5  | (1) IN GENERAL.—Section 1927(e) of the So-              |
| 6  | cial Security Act (42 U.S.C. 1396r–8(e)) is amended     |
| 7  | by adding at the end the following:                     |
| 8  | "(6) Pass-through pricing required.—A                   |
| 9  | contract between the State and a pharmacy benefit       |
| 10 | manager (referred to in this paragraph as a 'PBM'),     |
| 11 | or a contract between the State and a managed care      |
| 12 | entity or other specified entity (as such terms are     |
| 13 | defined in section $1903(m)(9)(D)$ ) that includes pro- |
| 14 | visions making the entity responsible for coverage of   |
| 15 | covered outpatient drugs dispensed to individuals en-   |
| 16 | rolled with the entity, shall require that payment for  |
| 17 | such drugs and related administrative services (as      |
| 18 | applicable), including payments made by a PBM on        |
| 19 | behalf of the State or entity, is based on a pass-      |
| 20 | through pricing model under which—                      |
| 21 | "(A) any payment made by the entity or                  |
| 22 | the PBM (as applicable) for such a drug—                |
| 23 | "(i) is limited to—                                     |
| 24 | "(I) ingredient cost; and                               |
| 25 | "(II) a professional dispensing                         |
|    |   |

| 1  | sional dispensing fee that the State         |
|----|--|
| 2  | plan or waiver would pay if the plan         |
| 3  | or waiver was making the payment di-         |
| 4  | rectly;                                      |
| 5  | "(ii) is passed through in its entirety      |
| 6  | by the entity or PBM to the pharmacy or      |
| 7  | provider that dispenses the drug; and        |
| 8  | "(iii) is made in a manner that is con-      |
| 9  | sistent with section $1902(a)(30)(A)$ and    |
| 10 | sections 447.512, 447.514, and 447.518 of    |
| 11 | title 42, Code of Federal Regulations (or    |
| 12 | any successor regulation) as if such re-     |
| 13 | quirements applied directly to the entity or |
| 14 | the PBM, except that any payment by the      |
| 15 | entity or the PBM (as applicable) for the    |
| 16 | ingredient cost of a covered outpatient      |
| 17 | drug dispensed by providers and phar-        |
| 18 | macies referenced in clauses (i) or (ii) of  |
| 19 | section 447.518(a)(1) of title 42, Code of   |
| 20 | Federal Regulations (or any successor reg-   |
| 21 | ulation) shall be the same as the payment    |
| 22 | amount for the ingredient cost when dis-     |
| 23 | pensed by providers and pharmacies not       |
| 24 | referenced in such clauses, and in no case   |
| 25 | shall payment for the ingredient cost of a   |
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| 1  | covered outpatient drug be based on the           |
|----|---|
| 2  | actual acquisition cost of a drug dispensed       |
| 3  | by providers and pharmacies referenced in         |
| 4  | such clauses or take into account a drug's        |
| 5  | status as a drug purchased at a discounted        |
| 6  | price by a provider or pharmacy referenced        |
| 7  | in such clauses;                                  |
| 8  | "(B) payment to the entity or the PBM             |
| 9  | (as applicable) for administrative services per-  |
| 10 | formed by the entity or PBM is limited to a       |
| 11 | reasonable administrative fee that covers the     |
| 12 | reasonable cost of providing such services;       |
| 13 | "(C) the entity or the PBM (as applicable)        |
| 14 | shall make available to the State, and the Sec-   |
| 15 | retary upon request, all costs and payments re-   |
| 16 | lated to covered outpatient drugs and accom-      |
| 17 | panying administrative services incurred, re-     |
| 18 | ceived, or made by the entity or the PBM, in-     |
| 19 | cluding ingredient costs, professional dispensing |
| 20 | fees, administrative fees, post-sale and post-in- |
| 21 | voice fees, discounts, or related adjustments     |
| 22 | such as direct and indirect remuneration fees,    |
| 23 | and any and all other remuneration; and           |
| 24 | "(D) any form of spread pricing whereby           |
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any amount charged or claimed by the entity or

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| 1  | the PBM (as applicable) is in excess of the        |
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| 2  | amount paid to the pharmacies on behalf of the     |
| 3  | entity, including any post-sale or post-invoice    |
| 4  | fees, discounts, or related adjustments such as    |
| 5  | direct and indirect remuneration fees or assess-   |
| 6  | ments (after allowing for a reasonable adminis-    |
| 7  | trative fee as described in subparagraph (B)) is   |
| 8  | not allowable for purposes of claiming Federal     |
| 9  | matching payments under this title.                |
| 10 | "(7) PROTECTION AGAINST MANDATES RELAT-            |
| 11 | ING TO USE OF 340B DRUGS.—                         |
| 12 | "(A) IN GENERAL.—Notwithstanding any               |
| 13 | other provision of law, no State, Medicaid man-    |
| 14 | aged care organization (as defined in section      |
| 15 | 1903(m)(1)(A), or pharmacy benefit manager         |
| 16 | may prohibit a covered entity under section        |
| 17 | 340B of the Public Health Service Act, or a        |
| 18 | pharmacy under contract with a covered entity      |
| 19 | to dispense drugs on behalf of the covered enti-   |
| 20 | ty, from dispensing covered outpatient drugs       |
| 21 | purchased under such section to individuals re-    |
| 22 | ceiving benefits under this title and from receiv- |
| 23 | ing payment in accordance with this section, or    |
| 24 | require that such covered entity or pharmacy       |

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dispense covered outpatient drugs purchased under section 340B to such individuals.

3 "(B) NOTIFICATION.—The Secretary shall 4 notify States that States may not prohibit a 5 provider under this title that is a covered entity 6 under section 340B of the Public Health Serv-7 ices Act, or a pharmacy under contract with a 8 covered entity, from submitting claims for reim-9 bursement for drugs purchased under such sec-10 tion that are dispensed to individuals receiving 11 benefits under this title and may not require 12 such provider to dispense covered outpatient 13 drugs purchased under such section to such in-14 dividuals.".

15 (2) CONFORMING AMENDMENT.—Section
16 1903(m)(2)(A)(xiii) of such Act (42 U.S.C.
17 1396b(m)(2)(A)(xiii)) is amended—

18 (A) by striking "and (III)" and inserting
19 "(III)";

(B) by inserting before the period at the
end the following: ", and (IV) pharmacy benefit
management services provided by the entity, or
provided by a pharmacy benefit manager on behalf of the entity under a contract or other arrangement between the entity and the phar-

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| 1  | macy benefit manager, shall comply with the re-       |
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| 2  | quirements of section 1927(e)(6)"; and                |
| 3  | (C) by moving the left margin 2 ems to the            |
| 4  | left.   |
| 5  | (3) Effective date.—The amendments made               |
| 6  | by this subsection apply to contracts between States  |
| 7  | and managed care entities, other specified entities,  |
| 8  | or pharmacy benefits managers that are entered into   |
| 9  | or renewed on or after the date that is 18 months     |
| 10 | after the date of enactment of this Act.              |
| 11 | (b) Ensuring Accurate Payments to Phar-               |
| 12 | MACIES UNDER MEDICAID.—                               |
| 13 | (1) IN GENERAL.—Section 1927(f) of the Social         |
| 14 | Security Act (42 U.S.C. 1396r-8(f)) is amended-       |
| 15 | (A) by striking "and" after the semicolon             |
| 16 | at the end of paragraph (1)(A)(i) and all that        |
| 17 | precedes it through $((1))$ and inserting the fol-    |
| 18 | lowing:   |
| 19 | "(1) Determining pharmacy actual acqui-               |
| 20 | SITION COSTS.—The Secretary shall conduct a sur-      |
| 21 | vey of retail community pharmacy drug prices to de-   |
| 22 | termine the national average drug acquisition cost as |
| 23 | follows:  |
| 24 | "(A) USE OF VENDOR.—The Secretary                     |
| 25 | may contract services for—                            |

| 1  | "(i) with respect to retail community             |
|----|---|
| 2  | pharmacies, the determination of retail           |
| 3  | survey prices of the national average drug        |
| 4  | acquisition cost for covered outpatient           |
| 5  | drugs based on a monthly survey of such           |
| 6  | pharmacies, net of all discounts and re-          |
| 7  | bates (to the extent any information with         |
| 8  | respect to such discounts and rebates is          |
| 9  | available); and";                                 |
| 10 | (B) by adding at the end of paragraph (1)         |
| 11 | the following:                                    |
| 12 | "(F) SURVEY REPORTING.—In order to                |
| 13 | meet the requirement of section $1902(a)(54)$ , a |
| 14 | State shall require that any retail community     |
| 15 | pharmacy in the State that receives any pay-      |
| 16 | ment, reimbursement, administrative fee, dis-     |
| 17 | count, or rebate related to the dispensing of     |
| 18 | covered outpatient drugs to individuals receiv-   |
| 19 | ing benefits under this title, regardless of      |
| 20 | whether such payment, fee, discount, or rebate    |
| 21 | is received from the State or a managed care      |
| 22 | entity directly or from a pharmacy benefit man-   |
| 23 | ager or another entity that has a contract with   |
| 24 | the State or a managed care entity, shall re-     |
|    |   |

| 1  | spond to surveys of retail prices conducted       |
|----|---|
| 2  | under this subsection.                            |
| 3  | "(G) SURVEY INFORMATION.—Information              |
| 4  | on retail community actual acquisition prices     |
| 5  | obtained under this paragraph shall be made       |
| 6  | publicly available and shall include at least the |
| 7  | following:  |
| 8  | "(i) The monthly response rate of the             |
| 9  | survey including a list of pharmacies not in      |
| 10 | compliance with subparagraph (F).                 |
| 11 | "(ii) The sampling frame and number               |
| 12 | of pharmacies sampled monthly.                    |
| 13 | "(iii) Characteristics of reporting               |
| 14 | pharmacies, including type (such as inde-         |
| 15 | pendent or chain), geographic or regional         |
| 16 | location, and dispensing volume.                  |
| 17 | "(iv) Reporting of a separate national            |
| 18 | average drug acquisition cost for each drug       |
| 19 | for independent retail pharmacies and             |
| 20 | chain pharmacies.                                 |
| 21 | "(v) Information on price concessions             |
| 22 | including on and off invoice discounts, re-       |
| 23 | bates, and other price concessions to the         |
| 24 | extent that such information is available         |
| 25 | during the survey period.                         |

| 1  | "(vi) Information on average profes-          |
|----|---|
| 2  | sional dispensing fees paid.                  |
| 3  | "(H) REPORT ON SPECIALTY PHAR-                |
| 4  | MACIES.—                                      |
| 5  | "(i) IN GENERAL.—Not later than 1             |
| 6  | year after the effective date of this sub-    |
| 7  | paragraph, the Secretary shall submit a re-   |
| 8  | port to Congress examining specialty drug     |
| 9  | coverage and reimbursement under this         |
| 10 | title.  |
| 11 | "(ii) Content of Report.—Such re-             |
| 12 | port shall include a description of how       |
| 13 | State Medicaid programs define specialty      |
| 14 | drugs, how much State Medicaid programs       |
| 15 | pay for specialty drugs, how States and       |
| 16 | managed care plans determine payment for      |
| 17 | specialty drugs, the settings in which spe-   |
| 18 | cialty drugs are dispensed (such as retail    |
| 19 | community pharmacies or specialty phar-       |
| 20 | macies), whether acquisition costs for spe-   |
| 21 | cialty drugs are captured in the national     |
| 22 | average drug acquisition cost survey, and     |
| 23 | recommendations as to whether specialty       |
| 24 | pharmacies should be included in the sur-     |
| 25 | vey of retail prices to ensure national aver- |
|    |   |

| 1  | age drug acquisition costs capture drugs               |
|----|--|
| 2  | sold at specialty pharmacies and how such              |
| 3  | specialty pharmacies should be defined.";              |
| 4  | (C) in paragraph (2)—                                  |
| 5  | (i) in subparagraph (A), by inserting                  |
| 6  | ", including payments rates under Med-                 |
| 7  | icaid managed care plans," after "under                |
| 8  | this title"; and                                       |
| 9  | (ii) in subparagraph (B), by inserting                 |
| 10 | "and the basis for such dispensing fees"               |
| 11 | before the semicolon; and                              |
| 12 | (D) in paragraph (4), by inserting ", and              |
| 13 | \$5,000,000 for fiscal year 2023 and each fiscal       |
| 14 | year thereafter," after "2010".                        |
| 15 | (2) EFFECTIVE DATE.—The amendments made                |
| 16 | by this subsection take effect on the first day of the |
| 17 | first quarter that begins on or after the date that is |
| 18 | 18 months after the date of enactment of this Act.     |