

.....
(Original Signature of Member)

118TH CONGRESS
2D SESSION

H. R. _____

To amend title XI of the Social Security Act to exclude from antikickback and other sanctions certain travel and lodging arrangements between manufacturers of drugs and individuals being administered such drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. GUTHRIE introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title XI of the Social Security Act to exclude from antikickback and other sanctions certain travel and lodging arrangements between manufacturers of drugs and individuals being administered such drugs, and for other purposes.

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 “Patient Access Act
5 of 2024”.

1 **SEC. 2. EXCLUDING FROM ANTIKICKBACK AND OTHER**
2 **SANCTIONS CERTAIN TRAVEL AND LODGING**
3 **ARRANGEMENTS BETWEEN MANUFACTUR-**
4 **ERS OF DRUGS AND INDIVIDUALS BEING AD-**
5 **MINISTERED SUCH DRUGS.**

6 (a) IN GENERAL.—Section 1128B of the Social Secu-
7 rity Act (42 U.S.C. 1320a–7b) is amended—

8 (1) in subsection (b)(3)—

9 (A) in subparagraph (K), by striking at
10 the end “and”;

11 (B) in subparagraph (L)(iii), by striking at
12 the end the period and inserting “; and”; and

13 (C) by adding at the end the following new
14 subparagraph:

15 “(M) an arrangement described in subsection
16 (i) between a manufacturer of a drug and an indi-
17 vidual who is prescribed such drug.”; and

18 (2) by adding at the end the following new sub-
19 section:

20 “(i) For purposes of subsection (b)(3)(M), an ar-
21 rangement described in this subsection between a manu-
22 facturer of a drug and an individual who is prescribed
23 such drug is an arrangement entered into on or after Jan-
24 uary 1, 2025, that satisfies each of the following:

25 “(1) The arrangement provides for payment or
26 reimbursement by the manufacturer for transpor-

1 tation, lodging, meals, or other incidental expenses
2 specified by the Secretary connected with the admin-
3 istration of such drug and relating to travel to and
4 from the facility at which such drug is to be admin-
5 istered, for the individual and up to two caregivers
6 of the individual (as determined appropriate by the
7 manufacturer, taking into account the individual's
8 age and medical needs) during any portion of the pe-
9 riod during which such individual is being adminis-
10 tered such drug (including initial visits to such facil-
11 ity before such administration, and followup visits to
12 such facility after such administration, relating to
13 the administration of such drug).

14 “(2) The arrangement does not provide for pay-
15 ment or reimbursement by the manufacturer for
16 transportation, lodging, meals, or other incidental
17 expenses described in paragraph (1) if the manufac-
18 turer knows that the individual is eligible to receive
19 at no cost, such transportation, lodging, meals, or
20 other out-of-pocket expenses, as applicable, from the
21 facility at which the drug is administered to the in-
22 dividual.

23 “(3) The manufacturer does not advertise the
24 arrangement and makes good-faith efforts to ensure
25 that the availability of such arrangement is not dis-

1 closed to such individual until after such drug is pre-
2 scribed to such individual, provided that such manu-
3 facturer does not interfere with a health care pro-
4 vider's ability to furnish such individual with any in-
5 formation determined appropriate by the provider.

6 “(4) If the arrangement provides for payment
7 or reimbursement by the manufacturer for transpor-
8 tation described in paragraph (1), such payment or
9 reimbursement is only for—

10 “(A) travel that is practical and conven-
11 ient, taking into account the individual's mobil-
12 ity or medical needs, which may include ground
13 transportation, air transportation, or transpor-
14 tation by train;

15 “(B) the costs directly associated with the
16 travel for the individual and caregivers as de-
17 scribed in paragraph (1), such as airfare, taxes,
18 tolls, gas, or other fees; and

19 “(C) travel between the individual's resi-
20 dence and the closest facility that is available to
21 administer such drug in a manner that is medi-
22 cally appropriate (as determined by the individ-
23 ual's health care provider) for the individual (or
24 between any lodging where such individual is

1 staying in relation to such administration and
2 such facility).

3 “(5) If the arrangement provides for payment
4 or reimbursement by the manufacturer for lodging
5 described in paragraph (1), such lodging is—

6 “(A) reasonable based on the individual’s
7 age and medical needs;

8 “(B) near the facility at which such indi-
9 vidual is to be administered such drug; and

10 “(C) only provided during the period de-
11 scribed in paragraph (1).

12 “(6) If the arrangement provides for payment
13 or reimbursement by the manufacturer for meals or
14 other incidental expenses described in paragraph (1),
15 the amount of such payment or reimbursement does
16 not exceed the per diem rate in effect for meals and
17 incidental expenses in the geographic area in which
18 such facility is located (as established by the General
19 Services Administration) for the individual and for
20 each caregiver allowed under the arrangement pur-
21 suant to paragraph (1).

22 “(7) The individual—

23 “(A) is determined to have income that
24 does not exceed the median income applicable to
25 a family of the size involved in the geographic

1 region (as specified by the Secretary) in which
2 such individual resides; and

3 “(B) lives more than 1 hour of driving dis-
4 tance (or 50 miles) from the nearest facility
5 that administers such drug and is accepting pa-
6 tients.

7 “(8) Such an arrangement is offered by the
8 manufacturer to individuals regardless of the facility
9 involved in the administration of the drug and re-
10 gardless of the insurance status of the individual.

11 “(9) The arrangement requires the individual to
12 agree to not request reimbursement from any Fed-
13 eral health care program for any costs for which
14 payment or reimbursement is made by the manufac-
15 turer under the arrangement.

16 “(10) The manufacturer certifies that the man-
17 ufacturer does not bill or shift the costs of the ar-
18 rangement to any of the Federal health care pro-
19 grams.”.

20 (b) GAO STUDY AND REPORT.—Not later than 3
21 years after the date of the enactment of this section, the
22 Comptroller General of the United States shall submit to
23 Congress a report on arrangements between a manufac-
24 turer of a drug and an individual who is prescribed such
25 drug described in subsection (i) of section 1128B of the

1 Social Security Act (42 U.S.C. 1320a–7b), as added by
2 subsection (a). Such report shall include—

3 (1) an analysis of the impact of such arrange-
4 ments on—

5 (A) access to transformative therapies, in-
6 cluding rare disease gene therapies;

7 (B) access to drugs that are the subject of
8 such arrangements, including socioeconomic dis-
9 parities with respect to such access; and

10 (C) the utilization by such individuals of—

11 (i) biosimilar biological products that
12 are the subject to such arrangements, as
13 compared to the utilization of the biological
14 products that are the reference products
15 for such biosimilar biological products; and

16 (ii) generic drugs that are the subject
17 to such arrangements, as compared to the
18 utilization of the drugs that are the ref-
19 erence drugs for such generic drugs;

20 (2) a description of any tax benefits obtained in
21 connection with such arrangements by manufactur-
22 ers offering such arrangements;

23 (3) a list of the drugs for which a manufacturer
24 of such drug offers such an arrangement; and

1 (4) with respect to each drug that is the subject
2 of such an agreement—

3 (A) the average cost directly associated
4 with the travel to and from the facility at which
5 such drug is to be administered, for the indi-
6 vidual administered such drug under such an
7 arrangement and caregivers of the individual,
8 as described in subsection (i)(1) of section
9 1128B of the Social Security Act (42 U.S.C.
10 1320a–7b), as added by subsection (a);

11 (B) the average distance so traveled by
12 such individuals and caregivers;

13 (C) the average family annual income of
14 such individuals;

15 (D) the average length of stay at the facil-
16 ity at which the drug is administered for such
17 individuals;

18 (E) the total number of such individuals
19 with whom such an arrangement has been
20 made; and

21 (F) the percentage of prescriptions for
22 such drug that are filled when such an arrange-
23 ment is available to the individual being admin-
24 istered such drug compared to the percentage

1 of prescriptions for such drug that are filled
2 when such an arrangement is not so available.