[DISCUSSION DRAFT]

118TH CONGRESS 1ST SESSION  
H. R. _____  

To establish patient protections with respect to highly rebated drugs.

IN THE HOUSE OF REPRESENTATIVES

M. _______ introduced the following bill; which was referred to the Committee on ____________________

A BILL

To establish patient protections with respect to highly rebated drugs.

Be it enacted by the Senate and House of Representa-
tives of the United States of America in Congress assembled,

SECTION 1. REQUIREMENTS WITH RESPECT TO COST-
SHARING FOR HIGHLY REBATED DRUGS.

Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.) is amended by adding at the end the following:
“SEC. 2729A. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR HIGHLY REBATED DRUGS.

“(a) IN GENERAL.—Beginning on April 1, 2024, and annually thereafter, the Secretary shall certify (or recertify, if applicable) as a ‘highly rebated drug’ any drug identified in reports submitted under section 2799A–10 for which total rebates, reductions in price, and other forms of remuneration in the previous year exceeded 50 percent of total annual spending on such drug in such year.

“(b) DEDUCTIBLE AND COST-SHARING LIMITATIONS FOR CERTIFIED DRUGS.—Beginning on January 1, 2025, a group health plan or a health insurance issuer offering group or individual health insurance coverage (or entity that provides pharmacy benefits management services on behalf of such a plan or issuer) that provides coverage of any highly rebated drug shall not impose cost-sharing in excess of, per 30-day supply, the quotient of the annual net price paid by such group health plan or health insurance issuer (or entity that provides pharmacy benefits management services on behalf of such a plan or issuer), in the previous calendar year, per 30-day supply of such specific highly rebated drug, divided by 12.

“(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT TO FORMULARY EXCLUSION.—Beginning on January 1, 2025, in the case of a specific highly rebated drug covered...
by a group health plan or health insurance issuer offering
group or individual health insurance coverage (or entity
that provides pharmacy benefits management services on
behalf of such plan or issuer) that provides coverage of
a specific highly rebated drug that was not covered in the
previous year, such group health plan or health insurance
issuer shall not receive from a drug manufacturer a reduc-
tion in price or other remuneration with respect to such
specific highly rebated drug received by an enrollee in the
plan or coverage and covered by the plan or coverage, un-
less—

“(1) any such reduction in price is reflected at
the point of sale to the enrollee; and

“(2) any such other remuneration is a flat fee-
based service fee not contingent on total volume of
sales that a manufacturer of prescription drugs pays
to an entity that provides pharmacy benefits man-
agement services.

“(d) REPORTS TO CONGRESS.—Not later than January 1, 2026, and annually thereafter, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall submit a joint report to the appropriate congressional committees, which shall include—

“(1) the wholesale acquisition costs of each spe-
cific highly rebated drug per 30-day supply;
“(2) the net price of each specific highly rebated drug per 30-day supply;

“(3) trends in wholesale acquisition costs of each specific highly rebated drug; and

“(4) trends in net price of each specific highly rebated drug.

“(e) DEFINITIONS.—In this section:

“(1) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term ‘appropriate Congressional Committees’ means—

“(A) the Committee on Health, Education, Labor, and Pensions of the Senate;

“(B) the Committee on Finance of the Senate;

“(C) the Committee on Energy and Commerce of the House of Representatives;

“(D) the Committee on Ways and Means of the House of Representatives; and

“(E) the Committee on Education and the Workforce of the House of Representatives.

“(2) ENTITY THAT PROVIDES PHARMACY BENEFITS MANAGEMENT SERVICES.—The term ‘entity that provides pharmacy benefits management services’ means—
“(A) any entity that, pursuant to a written
agreement with a group health plan or a health
insurance issuer offering group or individual
health insurance coverage, directly or through
an intermediary—

“(i) acts as a price negotiator on be-
half of the plan or coverage; or

“(ii) manages the prescription drug
benefits provided by the plan or coverage,
which may include the processing and pay-
ment of claims for prescription drugs, the
performance of drug utilization review, the
processing of drug prior authorization re-
quests, the adjudication of appeals or
grievances related to the prescription drug
benefit, contracting with network phar-
macies, controlling the cost of covered pre-
scription drugs, or the provision of related
services; or

“(B) any entity that is owned, affiliated, or
related under a common ownership structure
with an entity described in subparagraph (A).

“(3) Net Price.—The term ‘net price’, with
respect to a prescription drug, means the final price
paid by a group health plan or health insurance
issuer offering group or individual health insurance
coverage after applying any rebates or product-spe-
cific remuneration.”.