



HHS Proposes Ban on Drug Rebates

HHS has proposed an ambitious overhaul of the drug purchasing system — banning manufacturer rebates that it says incentivize higher prices.

- ✓ HHS would end an exception (safe harbor) to a federal anti-kickback statute (AKS) that currently treats manufacturer **rebates** to insurers & pharmacy benefit managers (PBMs) as “**discounts**” eligible for “safe harbor” protection.*
- ✓ HHS would, however, create two new safe harbors that would allow those rebates to flow directly to patients and new flat fee arrangements to PBMs.
- ✓ The rule would only apply to federal programs
- ✓ Stakeholder feedback is due to HHS by April 8th.

Note: HHS has asked Congress for legislation extending the proposal to the commercial market.

* [Rebates](#) currently have safe harbor protection b/c they are characterized as “discounts” under the AKS. The discount safe harbor is not being eliminated; HHS would recharacterize manufacturer rebates as falling outside the discount safe harbor.

List Price vs Net Price

1 Pharmacies pay full price for drugs

Pharmacies purchase drugs from manufacturers at “**list price**” — the full price without any rebates applied.

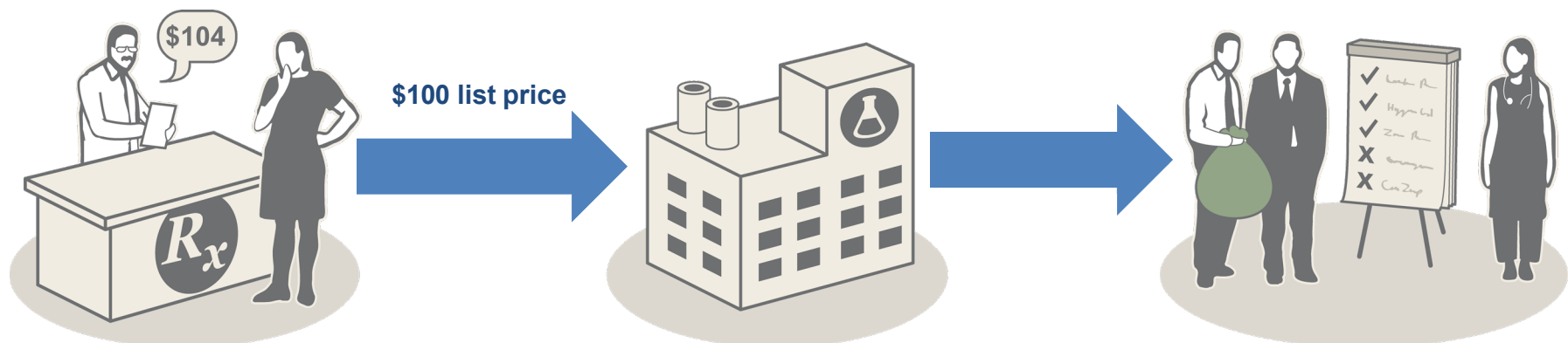
Pharmacies charge patients this full list price plus a pharmacy fee at the counter.

Patients pay part of this bill (copay) and the insurer picks up the rest.

2 Manufacturers pay rebates to PBMs based on sales

Rebates are paid if enrollees purchase a certain volume of the drug (usually, b/c the drug has preferential placement on formulary).

Rebates are usually a % of list price — so more expensive drugs usually have larger rebates — $\text{List price} - \text{Rebate} = \text{“net price.”}$



Typical Scenarios and Assumptions

3 PBMs take a cut of the rebate and set drug list prices

Insurers delegate setting up the Rx benefit to the PBM.

The PBM negotiates rebates and sets up the Rx formulary — the list of drugs that will be covered – and preferred -- by the insurer, and sets patient out-of-pocket cost.

PBMs keep a portion of the rebate -
- the more expensive the drug, the larger the rebate, so HHS proposal assumes PBMs give priority on the formulary to the more expensive drugs.

4 Savings are passed to enrollees via premiums

After PBM and insurer take a cut, Remainder of rebate goes to enrollees in the form of reduced premiums for the next plan year.

Any premium decreases are across-the-board, so all enrollees on the plan benefit, not the specific enrollee purchasing the drug.



Rebates as a share of Medicare Part D gross drug costs



Gross spending on Medicare Part D drugs, by type

Generic, no rebates*
\$35.7 billion

Brand, no rebates
\$27.3 billion

Brand, with rebates
\$78.3 billion

Note: Excludes direct discounts to pharmacies

Data seems to support HHS' assumption: Rebate expenditures are growing rapidly, as is the volume of sales of the most expensive drugs

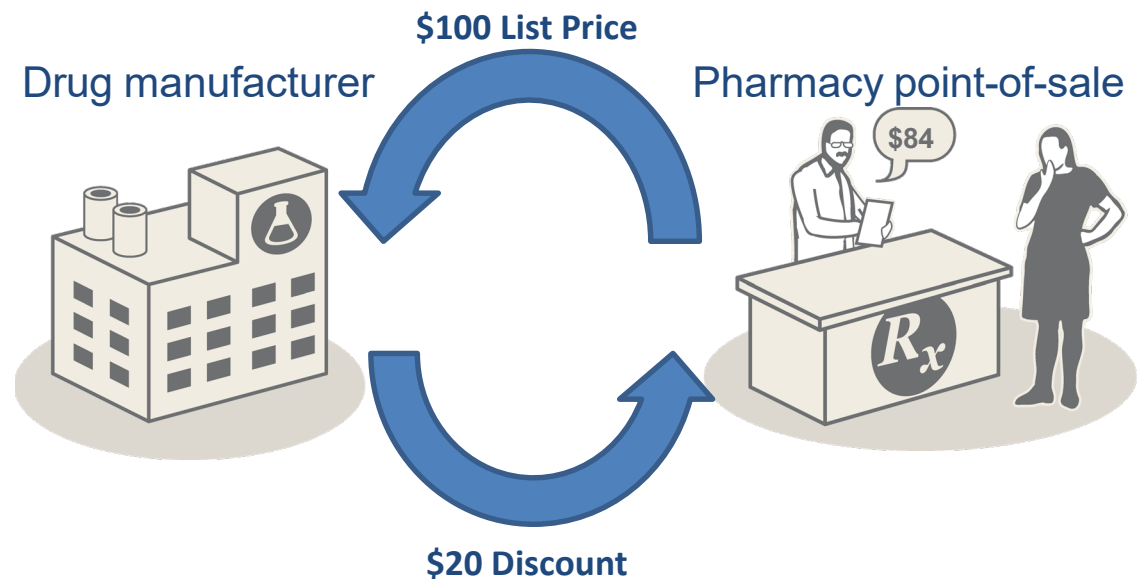
HHS proposal protects two new types of manufacturer payments

Even as HHS proposes elimination of existing rebate arrangements, it provides for two new types of payments manufacturers could make if they choose:

Manufacturers *could* offer rebates that go entirely to the customer

Manufacturers could still negotiate a rebate w/ a PBM or insurer – so long as the full value is given to the patient at the point-of-sale.

Manufacturers could pay pharmacies directly for the portion being discounted – to be reflected in any copays paid by the patient.



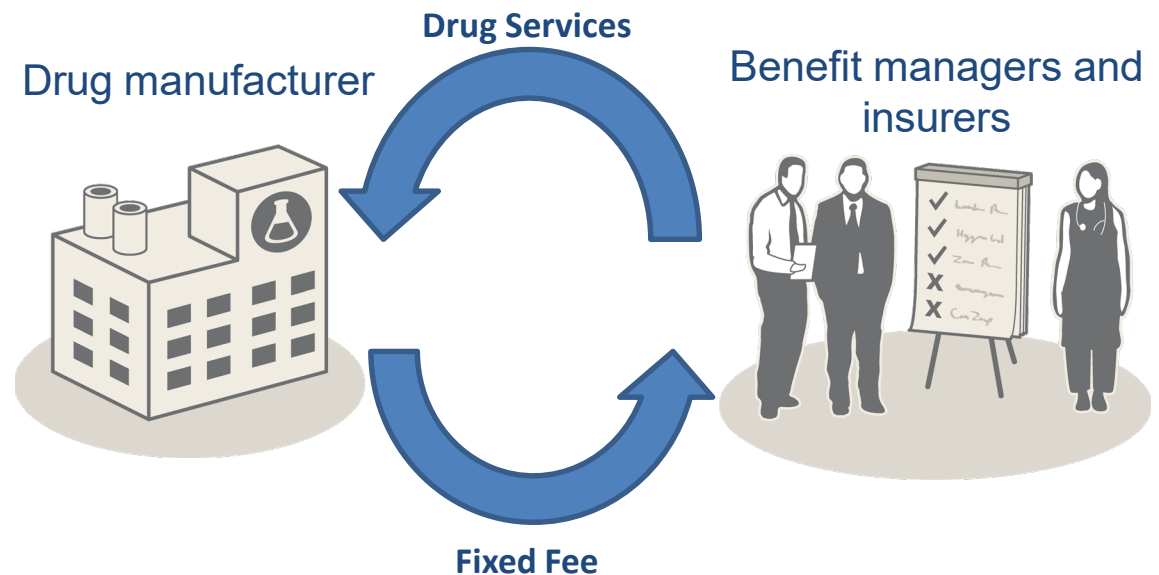
Since PBMs won't get a cut, will these rebates determine formulary placement? Will insurers increase copays or switch more drugs to coinsurance? Will premiums rise? Many outstanding questions...

Manufacturers *could* pay PBMs a fixed fee (not a %) for various services at fair market value

Manufacturers already pay PBMs extra rebate amounts in exchange for certain services.

i.e., A PBM might perform a review of how a drug is being used by an insurer's patients, which can help manufacturers tailor their business practices

But, what if PBMs give favorable formulary placement in exchange for these fees?



The proposed rule would continue to allow these or other arrangements – so long as payments to the PBM are not tied to a rebate or calculated as a % of the drug's price.



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