

NCPA's Minimum Requirements on the Proposed Rule Regarding the Rebate Safe Harbor

HHS' OIG has published a proposed rule that seeks to prohibit rebates paid by manufacturers to plans under Medicare Part D and Medicaid MCOs from the discount safe harbor. This means that kickbacks given to PBM's would be prohibited under the law. The proposed rule, instead, creates a new safe harbor that allows for point-of-sale price reductions from manufacturers to plans. By moving manufacturer rebates to the point of sale, this proposal intends to reduce list prices and lower patients' out-of-pocket drug costs.

NCPA has spent a great deal of time and effort analyzing and speaking to stakeholders on the implications of this proposed rule for community pharmacies, including but not limited to potential legal, commercial, financial, and regulatory impacts. Based on our analysis, NCPA has prepared the following "Minimum Requirements" for NCPA to provide support for finalization of the proposed rule. NCPA encourages your organization to utilize these Minimum Requirements in your own comments to the proposed rule.

Public comments are due on April 8, 2019.

Minimum Requirements:

Contingent on NCPA's support for the proposed rule, listed below are the following Minimum Requirements for independent community pharmacies:

1. Fix Pharmacy DIR:

- A system contemplated by this rule shall not go into effect without, at a minimum, finalization of the CMS proposed rule on pharmacy price concessions, 83 Fed. Reg. 62,152 (Nov. 30, 2018).

2. Timeliness of payments:

- Independent community pharmacies shall, at a minimum, be paid in full for the total and final reimbursement, including any chargeback amounts, for a drug product consistent with protections provided under the Medicare Part D prompt pay rules, 42 C.F.R. § 423.520.

3. Transparency:

- Independent community pharmacies shall have at the point of sale full visibility, in the approved claim, to the total and final reimbursement due the pharmacy.
- Independent community pharmacies shall have at the point of sale full visibility to the existence and total and final amount of any chargeback amounts due.

- Independent community pharmacies shall receive claim-level detail in electronic remittance advices that substantiate the total and final reimbursement of payor amounts and chargeback amounts.

4. Financial viability:

- Independent community pharmacies shall assume no monetary liability for implementation of a system contemplated by the proposed rule. For example, should fees transpire from the operation of such system, such fees shall not be paid by pharmacies.
- Independent community pharmacies' total and final reimbursement shall not be affected by the negotiated rate between the plan/PBM and manufacturer under a system contemplated by the proposed rule. Instead, pharmacies shall be made whole under such system based on a pharmacy's drug acquisition cost, the pharmacy's contracted rate between the pharmacy and plan/PBM, and a patient's out-of-pocket payment.

5. Agency oversight:

- A system contemplated by this rule shall not go into effect without relevant regulatory action from relevant agencies to ensure appropriate oversight and alignment of such system in applicable government programs.

6. Small business protections:

- A system contemplated by this rule shall not go into effect without implementation of small business community pharmacy protections, including but not limited to: right to appeal, inquire about missing payments, utilize audit processes, and engage in dispute resolution.
- Independent community pharmacies shall be held harmless from activity of other parties in violation of the Anti-Kickback Statute.

7. Opportunity to choose business partners:

- Independent community pharmacies shall have the opportunity to do business with any trading partner in the supply, billing, or reconciliation chain in a new system contemplated by this rule.