Navigating the proposed changes to the Medicaid Drug Rebate Program

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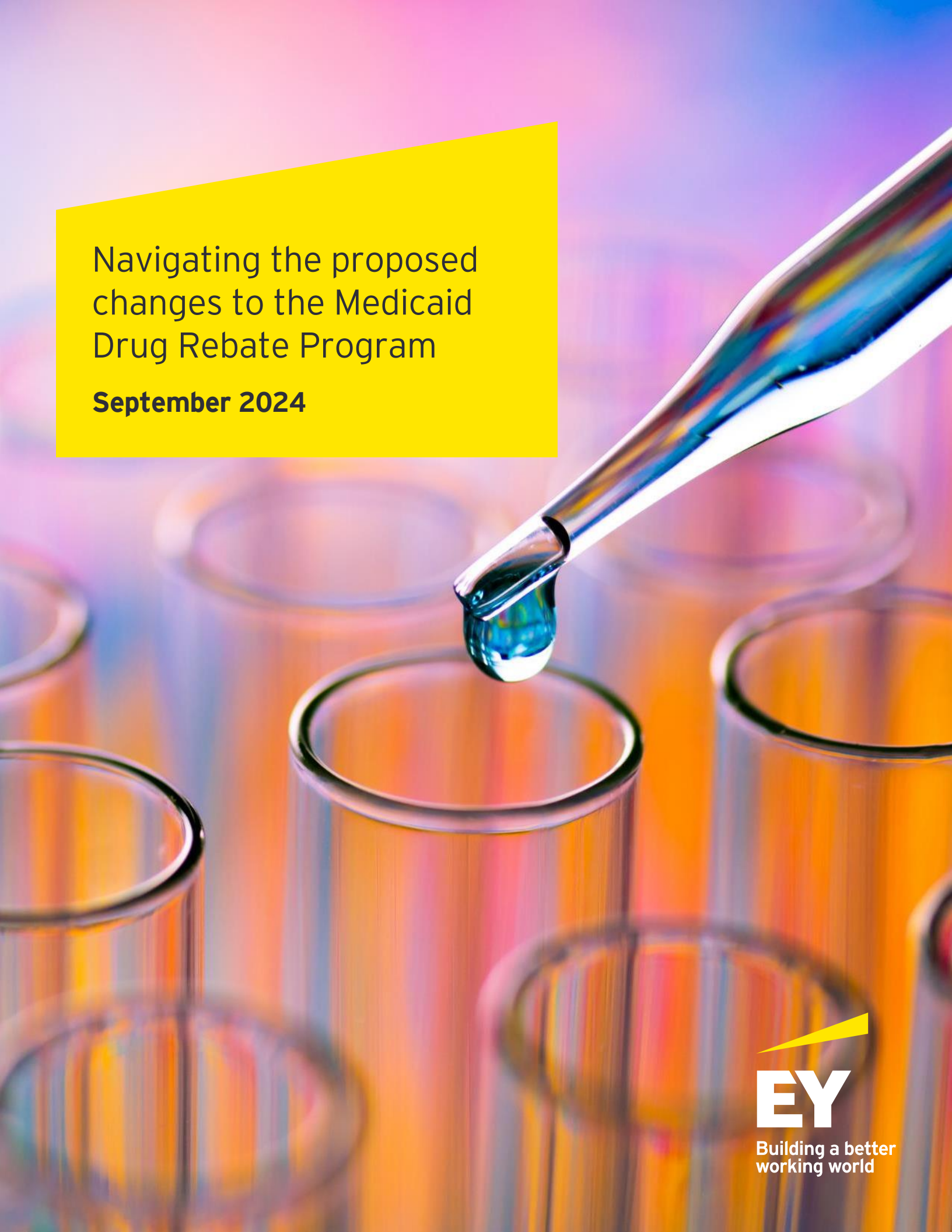

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The Centers for Medicare & Medicaid Services (CMS) published a proposed rule on May 26, 2023, called "Medicaid Program; Misclassification of Drugs, Program Administration, and Program Integrity Updates Under the Medicaid Drug Rebate Program."[1]

The proposed rule aims to modify the Medicaid Drug Rebate Program (MDRP) requirements and includes several regulatory changes. If implemented, this may require many drug manufacturers to redesign their operations, evaluate their commercial contracting strategies and update financial forecasting. Two of the impactful changes proposed by CMS that drug manufacturers should evaluate are the definition of "internal investigation" for purposes of manufacturer's Medicaid pricing revisions and the drug price verification survey.

Key proposed changes:

	Proposed change	Expected impact
1 Definition of "internal investigation"	Requires manufacturers to make a finding indicating a violation of statute or regulation before being granted an exception to the 12-quarter time frame for reporting changes to Average Manufacturer Price (AMP) and BP data.	Increase the timing and frequency of compliance assessments and increase the risk of penalties and sanctions for noncompliance or misreporting.
2 Drug price verification survey	Requires manufacturers to provide to CMS detailed information about pricing, charges, distribution, utilization, costs, etc. to verify drug prices submitted to MDRP.	Increased compliance costs and failure to comply can result in civil monetary penalties.

[1] U.S. Federal Register, 88 FR 34238.

Definition of an 'internal investigation' for purposes of revising reported prices

- CMS is proposing to define "internal investigation" regarding drug manufacturer requests an exception to the 12-quarter time frame for reporting changes to previously certified AMP and BP, customary prompt pay discounts, or nominal prices, that is due to an "internal investigation," the manufacturer must make a finding that indicates a violation of statute or regulation in the original report and provide supporting data, before CMS will consider such a request.

Under the current MDRP rules and regulations, manufacturers must report any revisions to AMP, BP, customary prompt pay discounts, and nominal prices within 12 quarters from the quarter when the data were due unless certain exceptions apply. One such exception is reporting under an "internal investigation," subject to different interpretations due to lack of definition.

This proposed regulation change will impact the timing of periodic MDRP compliance assessments and AMP and BP restatements for manufacturers. Within the proposed rule, CMS mentions that this change would discourage manufacturers from leveraging this exception to recoup overpaid rebates from the states resulting from errors of previously reported prices, unrelated to fraud,.

Manufacturers will need to evaluate and consult with legal to determine the best timing to modify submitted pricing that may favor them by applying an updated methodology or reasonable assumptions. This change may increase a manufacturers' risk of monetary penalties, sanctions or temporary suspension of their drugs from the Medicaid program due to noncompliance with the proposed requirements or misclassification/misreporting of their drug pricing. In addition, the proposed change, if enacted, should be considered during business or asset mergers and acquisitions because it can impact the value of the investment.

Operationally, manufacturers may need to invest in resources, schedule time to conduct periodic program assessments, and make timely corrections within the 12-quarter time frame of the original submission to ensure compliance with MDRP rules and regulations without requesting an "internal investigation" exception.

Manufacturers should consider the following factors when evaluating the implications of this proposed change:

Area	Factors to evaluate
Operations	▸ What updates do you need to make to the written policy, procedures and reasonable assumption documents? ▸ Is additional training necessary for departments other than government pricing, which provide information, data, and processes relied upon for MDRP reporting to avoid corrections beyond the 12-quarter time frame?
Compliance assessments	▸ How much due diligence and analytics should be performed in each period to minimize potential corrections? ▸ How frequently should MDRP assessments be conducted to monitor compliance to allow for corrections within the 12-quarter time frame? ▸ What due diligence do you need to perform relative to MDRP pricing if considering a merger or acquisition?

Drug price verification survey

- CMS is proposing an annual process to identify a list of 10 drugs for drug price verification based on a three-step approach.

Under the MDRP statute, CMS has the authority to survey manufacturers and obtain information about their reported drug prices. CMS is proposing to specify the circumstances in which surveys are necessary to verify prices, and to outline the information that would be requested to ensure accurate payments can be made.

According to CMS, these surveys aim to verify prices reported under the MDRP and ensure that Medicaid payments and applicable drug rebates are economically efficient and sufficient to provide access to care. Failure to comply with the drug price verification survey reporting requirements would result in civil monetary penalties. Additionally, CMS is proposing to post non-proprietary information provided by manufacturers and wholesalers on its website, allowing interested parties to comment on the public information as part of the verification process.

CMS is proposing an annual process to identify a list of 10 drugs for price verification based on a three-step approach. CMS defines the proposed terms in Medicaid Program, Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program.2

Similar to the information required under the Inflation Reduction Act-Medicare negotiation program, CMS proposes to collect various information on the identified drugs, including pricing, charges, distribution, utilization, product and clinical details, costs of production, research and marketing, and any other information determined by the Secretary as relevant for verifying drug prices.

Consult with your legal department to ensure on to address confidentiality on information provide to CMS.

Medicaid spending	▸ Highest drug spending per claim ▸ Highest total Medicaid drug spending ▸ Highest one year price increase (among single source drugs) ▸ Highest launch price
Additional criteria	▸ A manufacturer's willingness to negotiate further rebates either through a CMS-authorized supplemental rebate ▸ A manufacturer's participation in a CMS drug pricing program or initiative under which participating manufacturers negotiate directly with CMS
Consideration	If more than 10 drugs remain on the list after the exclusions, CMS will consider factors such as a manufacturer's efforts to lower drug prices through alternative arrangements, such as subscription models, values-based purchasing arrangements or other special arrangements.

Manufacturers should take into account the following considerations when evaluating the implications of this proposed change:

- Have you assessed your product portfolio and Medicaid spend to determine if any product(s) may be selected for a drug price verification survey?
- Do you have readily available data regarding production, research and marketing costs?
- How will you align and quantify historical research costs associated with the development of successful and unsuccessful drugs?
- What methods will you use to quantify production costs across all stages?

[2] U.S. Federal Register, 88 FR 34271-34272.

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