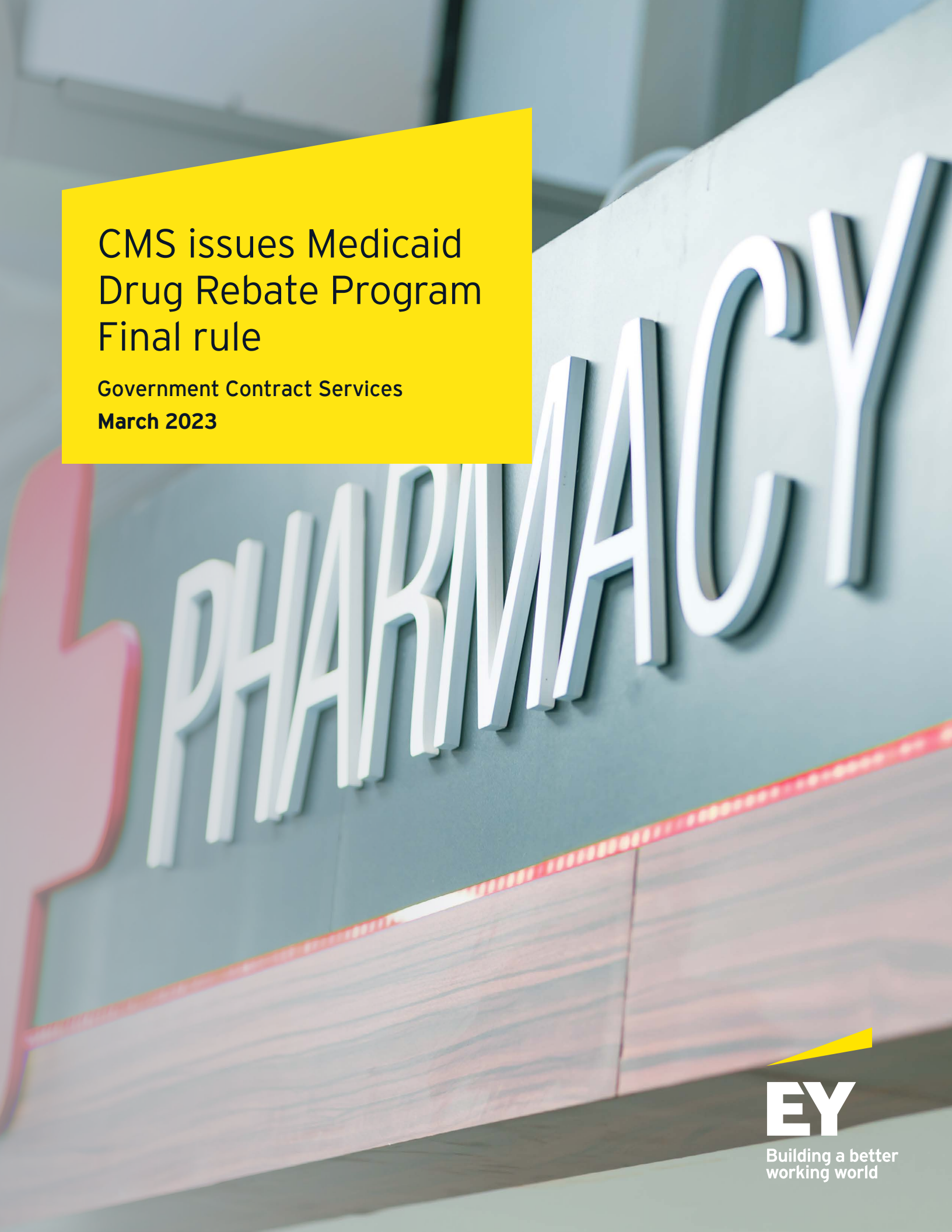

CMS issues Medicaid Drug Rebate Program Final rule

Government Contract Services

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EY

Building a better working world

Based on **revised regulations** from the Centers for Medicare & Medicaid Services (CMS) issued in November 2021, drug manufacturers are taking steps to assess the:

Narrow exception and drug category updates

The CMS final rule aligned the regulation (42 CFR 447.502) to the amended statute in section 1927(k)(7)(A)(ii) of the Social Security Act relative to the narrow exception. In limited circumstances, drugs with new drug application (NDA) approval might be more appropriately treated and classified as non-innovator multiple-source drugs rather than single-source or innovator multiple-source drugs after the CMS grants the narrow exception.

Drug manufacturers should consider the following when determining the correct product classification in response to the CMS final rule:

1. Will this CMS final rule change how you interpret and apply narrow exceptions when computing Medicaid rebates?
2. Do you agree with the CMS interpretation that the narrow 2 exception is retroactively effective April 1, 2016?
3. Is your product data reported to CMS consistent across all product attributes?
4. What operational and procedural challenges are you facing to implement this CMS final rule requirement?
5. If you submitted a narrow exception to CMS but have not received an approval, what is your interpretation and application of this CMS final rule?

Authorized generics – effective March 1, 2021

The Continuing Appropriations Act of 2020 and Health Extenders Act of 2019 (Health Extenders Act) that were effective in October 2019 made changes to section 1927(k) of the Social Security Act, revising how drug manufacturers calculate the average manufacturer price (AMP) for a branded drug for which the drug manufacturer permits an authorized generic to be sold. As a result of the Health Extenders Act, drug manufacturers are no longer permitted to include (blend) the sales of an authorized generic in the calculation of AMP for the branded product. The CMS final rule aligned the regulation (42 CFR 447.502, 447.504, and 447.506) to the amended statute in the sections 1927(k)(1)(C) and (k)(11) of the Social Security Act.

Drug manufacturers should consider the following when calculating AMP for brand and generic products:

1. Have you established proper non-blending/blending relationships for all your products and all your government pricing calculations?
2. How are you interpreting and implementing the CMS final rule among the different business and corporate relationships?
3. Are there any situations where blending is appropriate and in accordance with Medicaid Drug Rebate Program (MDRP) rules and regulations?

Key highlights from the CMS rule

Extent and timing of updates to internal policies, procedures and practices

Operational implications on resources, data and systems

Impact of the changes on commercial contracting, government pricing calculations and gross-to-net estimates

Value-based purchasing (VBP) agreements – effective July 1, 2022

The CMS final rule advances CMS' efforts to support VBP arrangements by providing drug manufacturers with regulatory support, provide sufficient regulatory framework to support such arrangements and promote transparency, flexibility and innovation in drug pricing. The CMS final rule defines a VBP agreement as an arrangement that "substantially" links pricing or payment to the effectiveness or performance outcome in a patient population.

The CMS final rule allows manufacturers to report multiple best prices (BPs) when engaged in a VBP agreement. CMS expects reporting multiple BPs will avoid unnecessary impact resulting from a single BP in circumstances when a VBP arrangement provides a significant discount on a drug that does not satisfy a performance metric. However, a single BP must still be reported for the drug not affiliated with a VBP arrangement. CMS will calculate a unit rebate amount (URA) and invoice manufacturers based on the distinct BPs related to a specific outcome and a BP not affiliated with a VBP arrangement. Manufacturers can also elect not to report multiple BPs and only follow existing rules or treat a VBP arrangement as a "bundled sale" and report a single BP. The change in the CMS final rule promotes VBP agreements and allows increased flexibility in the MDRP process, ultimately allowing drug manufacturers to determine how best to implement reporting procedures.

Due to new VBP provisions, CMS has indicated it will permit BP restatements resulting from a VBP arrangement outside of the current 12-quarter rule.

Drug manufacturers should consider and analyze operational and financial implications to determine which approach makes the most sense for them.

- ✓ To what extent are you going to adopt and implement the new VBP provisions?
- ✓ How are you interpreting "substantially" and applying it in your policies, procedures and possibly in reasonable assumption documentation, since CMS did not explicitly define "substantially" in the final rule?
- ✓ Do you have sufficient data transparency and standardization allowing for linking the outcomes data to transactional data to compute multiple BPs?
- ✓ Is your current government pricing system able to handle the new source data to compute multiple BPs?
- ✓ What updates do you need to make to written policy, procedures and reasonable assumption documents?
- ✓ What updates do you need to make to Medicaid rebate forecasting tools and estimates for affected products if you pay rebates based on multiple URAs?
- ✓ How will you adapt your processes based upon how CMS changes their processes to restate BP after the 12-quarter window closes?
- ✓ What data validation procedures are you going to perform on Medicaid rebate invoices, specifically monitoring of state utilization at each price point?

Line extension definition – effective January 1, 2022

After several years of experience with drug manufacturers self-reporting their line extensions and numerous inquiries from drug manufacturers regarding the identification of drugs as line extensions and inconsistency among drug manufacturers in their identification of drugs as line extensions, the CMS final rule provides specific guidance on how to identify a line extension drug by defining "line extension" and "new formulation."

Line extension: For a drug, a new formulation of the drug, but does not include an abuse deterrent formulation of the drug.

New formulation: For a drug, a change to the drug, including, but not limited to, an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration or ingredients.

Drug manufacturer considerations

- ✓ Have you identified all your line extension products, and are you reporting the appropriate product attributes to CMS?
- ✓ Do you need to reevaluate the URA calculation in your system and update Medicaid rebate forecasting tools and estimates in light of the CMS final rule?
- ✓ How does the CMS final rule impact your line extension identification process prior to the effective date of January 1, 2022?

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