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Medicaid Drug Rebate Agreements: Changes Require Immediate Action By Pharmaceutical Manufacturers

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For the first time since the enactment of the Medicaid Drug Rebate Program (MDRP), the Centers for Medicare and Medicaid Services (CMS) revised the National Medicaid Drug Rebate Agreement (NDRA) entered into between drug manufacturers and the U.S. Department of Health and Human Services (HHS).

Published in the Federal Register (83 Fed. Reg. 12770 (Mar. 23, 2018)), the final revised NDRA contains several noteworthy changes from the version currently in effect including:

- **Incorporating the statutory and/or regulatory definitions for defined terms in the NDRA.**This is intended to ensure that the NDRA remains consistent with the statutory and regulatory framework governing the MDRP.
- **Imposing new reporting obligations on drug manufacturers.** Among other things, the revised NDRA requires *manufacturers* to calculate and report the Unit Rebate Amount (URA) for their drug products, where previously CMS performed those calculations. In response to public comments, CMS explained that this added language is intended to "strengthen[]" CMS's existing position that drug manufacturers are responsible for making URA calculations.
- **Expanding the HHS Secretary's audit authority to encompass all pricing data submitted**. Pursuant to section 1927(b)(3)(A) of the Social Security Act; in the original version, the Secretary's audit authority is limited to Average Manufacturer Price and Best Price.
- **Revising penalties provisions.** In its penalties provisions, the revised NDRA now expressly provides that it does not limit the remedies available to the United States for a violation of the NDRA or any other law.

The MDRP is a complex system, involving the analysis and application of interrelated federal and state laws. The revisions listed above are not an exhaustive list of the changes found in the new NDRA. Manufacturers wishing to continue their participation in the MDRP now have six months to

assess these changes and how they impact their operations and policies and to submit a new NDRA.

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