Small Entity Compliance Guide

Medicaid Program; Covered Outpatient Drugs Final Rule

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The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, Pub. L. 104-121, as amended by Pub. L. 110-28, May 25, 2007) contains requirements for issuance of "small entity compliance guides." Guides are to explain what actions affected entities must take to comply with agency rules. Such guides must be prepared when agencies issue final rules for which agencies were required to prepare a Final Regulatory Flexibility Analysis under the Regulatory Flexibility Act.

The complete text of this final rule with comment period can be found on the CMS website at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/covered-outpatient-drugs-policy.html

This final rule with comment period addresses key areas of Medicaid drug reimbursement and changes made to the Medicaid Drug Rebate Program by the Affordable Care Act. This final rule ensures federal and state savings on Medicaid drug costs, establishes the long term framework for the implementation of the Medicaid drug rebate program, and creates a more fair reimbursement system for Medicaid programs and pharmacies. It accomplishes these important goals by, among other things, creating a regulatory definition for Average Manufacturer Price (AMP); updating the Federal Upper Limit (FUL) formula for the payment of certain generic drugs; revising the definition of "states" to include U.S. territories (Puerto Rico, Virgin Islands, Guam, American Samoa and the Northern Mariana Islands) in the rebate program so that territories can also achieve savings in their drug expenditures; and ensuring that pharmacy reimbursement is aligned with the acquisition cost of drugs and that the states pay an appropriate professional dispensing fee. In this final rule with comment period we also solicited additional comments on the definition of line extension drugs and the treatment of new formulations that we may consider addressing in future rulemaking.

For purposes of the Regulatory Flexibility Act (RFA), three types of small businesses are potentially impacted by this final rule with comment period. These include small retail community pharmacies, small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, and small Medicaid managed care organizations (MCOs). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's (SBA) definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year).

For purposes of the RFA, most of the retail pharmacies are considered small businesses according to the SBA's size standards with total revenues of $27.5 million or less in any 1 year (https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf). The latest data

from National Community Pharmacist Association (NCPA) estimates that there are approximately 22,814 independent community pharmacies in 2013. With 73 percent of the independent pharmacies owned by single owner which are likely to meet the threshold of small entities, the possible small pharmacies would be about 16,654.

According to the SBA size standards, drug manufacturers are considered small businesses if they have fewer than 750 employees (Code 325412, (https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf). Approximately 610 drug manufacturers currently participate in the Medicaid Drug Rebate Program. We believe most manufacturers are small businesses and anticipate this final rule would have an impact on small drug manufacturers.

According to the SBA's size standards, an HMO, of which we have included MCOs, is considered a small business if it has revenues of $32.5 million or less in any 1 year (https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf). The Census of Bureau estimates that there are approximately 104 HMO/MCO Medical centers with an average revenue of $22 million annually. Because of limited data available, we are unable to quantify exactly how many MCOs fall within the HMO standard and meet the $32.5 million threshold, and contend that less than half of MCOs meet this standard.

This rule imposes Federal compliance requirements on these three types of small businesses (small retail community pharmacies, small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, and small Medicaid managed care organizations (MCOs)). In order to assist these small business entities in understanding and complying with the requirements of the Covered Outpatient Drug Final Rule with comment period, we have developed a web page that includes downloadable explanatory materials at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/covered-outpatient-drugs-policy.html. CMS plans to publish on an ongoing basis answers to frequently asked questions (FAQs) and will make these FAQs available through a link at the above web page.

CMS has issued a State Medicaid Director Letter (SMD #16-001) to provide guidance on the implementation of the Covered Outpatient Drug Final regulation provisions regarding reimbursement for covered outpatient drugs in the Medicaid Program (https://www.medicaid.gov/federal-policy-guidance/downloads/smd16001.pdf).

In addition, CMS has issued two manufacturer releases specific to the implementation of the final rule with comment. Manufacturer Release #96 provides guidance related to the transition period prior to enforcement of the 5i AMP provisions (https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-096.pdf). Manufacturer Release #98 provides guidance related to the drug category narrow exceptions process (https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-098.pdf).

Finally, since the final rule with comment established new reporting requirements for drug manufacturers, revisions to Drug Data Reporting for Medicaid (DDR) system were required. The DDR system is the mechanism used by manufacturers to report and certify pricing data to CMS on a monthly and quarterly basis. Therefore, CMS has communicated directly with each of the manufacturer's technical contacts (via email) in order to provide them with guidance and instructions regarding the system changes that are required in order for the manufacturers to make the necessary modifications to their file transfer programs in time for the next reporting cycle.