

Office of Pharmacy Affairs Update
January 2017

A Final rule titled "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation" was published in the [Federal Register](#) on Thursday, January 5, 2017.

On June 17, 2015, HRSA issued a Notice of Proposed Rulemaking (NPRM) to implement Civil Monetary Penalties (CMPs) for manufacturers who knowingly and intentionally charge a covered entity more than the ceiling price for a covered outpatient drug; to provide clarity on the requirement that manufacturers calculate the 340B ceiling price on a quarterly basis; and to establish the requirement that a manufacturer charge a \$.01 (penny pricing policy) for drugs that calculation equals zero (80 FR 34583 (June 17, 2015)). The public comment period closed during August 2015, and HRSA received approximately 35 comments.

After review of the initial comments, HHS reopened the comment period (81 FR 22960 (April 19, 2016)) to invite additional comment on specific areas of the NPRM: 340B ceiling price calculations that result in a ceiling price that equals zero (penny pricing); the methodology that manufacturers utilize when estimating the ceiling price for a new covered outpatient drug; and the definition of the "knowing and intentional" standard to be applied when assessing a CMP on manufacturers who overcharge a covered entity. The comment period closed May 19, 2016, and HHS received approximately 70 additional comments. The rule was finalized and published on January 5, 2017.

The provisions of the final rule include:

- the requirement that a manufacturer calculate the 340B ceiling price on a quarterly basis;
- the requirement that a manufacturer charge \$0.01 per unit of measure if the 340B ceiling price calculation results in a ceiling price that equals zero (penny pricing);
- the methodology manufacturers must use when estimating the ceiling price for a new covered outpatient drug;
- an explanation of how a civil monetary penalty (CMP) would be imposed on a manufacturer that knowingly and intentionally overcharges a covered entity; and
- an explanation of what would constitute an instance of overcharging to trigger a CMP.

The final rule replaces all former guidance on Penny Pricing and New Drug Pricing, including the Penny Pricing Policy Release No. 2011-2 (November 21, 2011) and the Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 New Drug Pricing. The final rule will be effective March 6, 2017. However, HRSA recognizes that the effective date falls in the middle of a quarter. As such, HRSA plans to begin enforcing the requirements of this final rule at the start of the next quarter, which begins April 1, 2017.

HRSA plans to post FAQs and host a webinar to provide an overview of the final rule for all 340B stakeholders. Please stay tuned to our website for additional information.