1005'' the term ''procedures'' may be read to not encompass definitions and standards for CMPs. Therefore, they suggested modifying the sentence to state, ''Pursuant to a delegation of authority, the HHS Office of Inspector General (OIG) will have the authority to bring CMP actions utilizing the definitions, standards, and procedures applied to civil monetary penalties under 42 CFR parts 1003 and 1005.'' It was also suggested to add a definition of ''knowingly and intentionally'' to section 1003.101 of the OIG regulations.

Response: HHS does not believe it necessary to add the delegation of authority to OIG in the regulatory text. HHS believes that pursuant to a separate delegation of authority, OIG has the authority to handle CMP actions utilizing the definitions, standards, and procedures applied to civil monetary penalties under 42 CFR parts 1003 and 1005, as applicable. Consistent with the proposed rule, we have finalized the regulatory text indicating that CMPs will be imposed pursuant to the procedures contained at 42 CFR part 1003. No further rulemaking is required to apply the procedures at 42 CFR part 1003 to the imposition of CMPs. HHS will monitor activities relating to the evaluation and pursuit of CMPs and, if necessary, will consider issuing additional guidance about procedures applicable to such actions.

Comment: A few commenters were concerned about the decision to delegate CMP actions to OIG. They stated that HHS has not identified a specific delegation, and that 42 CFR parts 1003 and 1005 only provide for the imposition of CMPs under specific statutory authorities, which do not include the 340B statute's CMP provisions. They argued that unless OIG amends their regulations to apply them to a 340B proceeding, HHS will need to develop, take comments on, and ultimately finalize a new proposal setting out procedures for seeking and imposing CMPs against manufacturers. A few commenters noted that some portions of 42 CFR parts 1003 and 1005 are inapplicable in a 340B context.

Response: As noted above, a delegation of authority to OIG for a CMP from the Secretary of HHS is sufficient. HHS does not perceive there to be any conflict between the procedural aspects of 42 CFR part 1003 and the imposition of CMPs. HHS notes that 42 CFR part 1005 applies to appeals of exclusions and civil monetary penalties and assessments and would not be directly relevant to the initial imposition of a CMP. Accordingly, HHS finalized the regulatory text indicating that CMPs will be imposed pursuant to the applicable procedures contained at 42 CFR part 1003. No further rulemaking is required to apply the procedures at 42 CFR part 1003 to the imposition of CMPs. HHS will monitor activities relating to the evaluation and pursuit of CMPs and, if necessary, will consider issuing additional guidance about procedures applicable to such actions.

III. Regulatory Impact Analysis

HHS has examined the effects of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 8, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB).

This final rule will not have economic impacts of $100 million or more in any 1 year, and, therefore, has not been designated an ''economically significant'' rule under section 3(f)(1) of Executive Order 12866. The 340B Program as a whole creates significant savings for entities purchasing drugs through the program, with total savings estimated to be $6 billion in CY 2015.[1] However, this final rule would not significantly impact the Program. This final rule codifies current policies, some of which have been modified, regarding calculation of the 340B ceiling price and manufacturer civil monetary penalties. HHS does not anticipate that the imposition of civil monetary penalties would result in significant economic impact.

The 340B Program uses information that already must be reported under Medicaid to calculate the statutorily defined 340B ceiling price as required by this final rule. Because the components of the 340B ceiling price are already calculated by the manufacturers under the MDRP and reported to CMS, HHS does not believe this portion of the final rule would have an impact on manufacturers. The impact on manufacturers would also be limited with respect to calculation of the 340B ceiling price as defined in this final rule due to the fact that manufacturers regularly calculate the 340B ceiling price and have been doing so since the program's inception.

Separate from calculation of the 340B ceiling price, manufacturers are required to ensure they do not overcharge covered entities, and a civil monetary penalty could result from overcharging if it met the standards in this final rule. HHS envisions using these penalties in rare situations. Since the Program's inception, issues related to overcharges have been resolved between a manufacturer and a covered entity and any issues have generally been due to technical errors in the calculation. For the penalties to be used as defined in the statute and in this rule, the manufacturer overcharge would have to be the result of a knowing and intentional act. Based on anecdotal

[1] In CY 2015, 340B covered entities spent approximately $12 billion on the total purchases of 340B drugs under the 340B Program. This data was obtained from the 340B Prime Vendor Program. This amount represents 2.6 percent of the overall prescription drug market. Assuming covered entities pay 25 to 50 percent less than non-340B prices, HHS calculated the estimated total savings in CY 2015 to be approximately $6 billion.