Massachusetts, and Rhode Island are control strategy SIPs, and they contain 2008 motor vehicle budgets for VOCs and NO_X by nonattainment area. Table 4 contains these VOC and NO_X transportation conformity budgets in units of tons per summer day:

TABLE 4.—CONFORMITY BUDGETS IN THE CONNECTICUT, MASSACHUSETTS, AND RHODE ISLAND RFP PLANS

Area name	2008 Transportation conformity budgets (tons/day)	
	VOC	NO_X
NY–NJ–CT area (CT portion)	29.7	60.5
Greater Connecticut	28.5	54.3
Bos-Law-Wor (E. MA) area	68.30	191.30
Springfield (W. MA) area	11.80	31.30
Providence	24.64	28.26

EPA issued letters on June 2, 2008 to Connecticut, March 7, 2008 to Massachusetts, and June 16, 2008 to Rhode Island in which we stated these budgets were adequate for use in transportation conformity determinations. Additionally, EPA published announcements of these adequacy findings in the **Federal Register** on June 12, 2008 for Connecticut (73 FR 33428), March 18, 2008 for Massachusetts (73 FR 14466), and June 30, 2008 for Rhode Island (36862). In today's action, we are proposing approval of the 2008 conformity budgets for VOC and NO_X for the areas shown in Table 4 above.

Connecticut and Rhode Island increased their projected 2008 motor vehicle emission estimates slightly to provide a buffer to their transportation conformity budgets. Connecticut increased its 2008 motor vehicle emission estimates by 2 percent, and Rhode Island by 0.5 tons/day. Doing so made meeting the 2008 RFP emission target slightly more difficult to achieve. However, both of these states were able to meet their respective RFP targets even after increasing their projected 2008 motor vehicle emission estimates. These increases are reflected in the budgets shown above in Table 4, and were also used in the projected, controlled 2008 emission estimates shown in step 7 of Tables 3 a, b, and e. The Connecticut and Rhode Island 2008 motor vehicle conformity budgets are approvable because these states were able to show that they can meet their 2008 RFP emission target levels even after providing these buffers to their budgets.

IV. Proposed Action

EPA's review indicates that the 2002 base year emission inventories, RFP plans, transportation conformity budgets, and contingency plans submitted by Connecticut on February 1, 2008, Massachusetts on January 31, 2008, and Rhode Island on April 30, 2008 to meet, in part, their obligations under EPA's 1997 8-hour ozone standard meet the requirements for these programs. Therefore, EPA is proposing to approve these listed components of the state's submittals as revisions to each state's SIP. Additionally, EPA is proposing approval of three rules adopted by Connecticut that will reduce VOC emissions in the state. It should be noted that each states' submittal also included other SIP elements, most notably attainment demonstrations for EPA's 1997 8-hour ozone standard, but EPA is not acting on those other components at this time. Additional details regarding the state's submittals and EPA's review of these submittals is contained in the technical support document (TSD) prepared for this action. The TSD is available in the docket for this action. EPA is soliciting public comments on the issues discussed in this proposal or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to the EPA New England Regional Office listed in the **ADDRESSES** section of this **Federal Register.**

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L.104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

Dated: September 9, 2010.

Ira W. Leighton,

Acting Regional Administrator, EPA New England.

[FR Doc. 2010–23402 Filed 9–17–10; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Chapter I

340B Drug Pricing Program Manufacturer Civil Monetary Penalties

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Advance notice of proposed rulemaking and request for comments.

SUMMARY: Section 602 of Public Law 102–585, the "Veterans Health Care Act

of 1992" enacted Section 340B of the Public Health Service Act (PHSA). Section 340B implements a drug pricing program by which manufacturers enter into an agreement to sell covered outpatient drugs to particular covered entities at a price not exceeding the amount determined under a statutory formula. Manufacturers are required by section 1927(a) of the Social Security Act to enter in agreements with the Secretary that comply with section 340B if they participate in the Medicaid Drug Rebate Program. Section 7102(a) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148) requires the Secretary of HHS to develop and issue regulations for the 340B Drug Pricing Program (340B Program) establishing standards for the imposition of sanctions in the form of civil monetary penalties for manufacturers that knowingly and intentionally overcharge a covered entity for a 340B drug. As HHS never has had civil monetary penalty authority that addresses manufacturing overcharging of the 340B Program, these regulations present a number of issues that have the potential to impact stakeholders. Accordingly, the Health Resources and Services Administration (HRSA) is issuing this advance notice of proposed rulemaking (ANPRM) to solicit public comment on multiple issues regarding the implementation of this requirement. These comments will be used to help draft a proposed rule that will be published in the **Federal Register** for public comments.

DATES: Submit electronic or written comments by November 19, 2010.

ADDRESSES: Comments in response to this ANPRM should be marked "Comments on the Civil Monetary Penalties" and sent to Mr. Bradford R. Lang, Public Health Analyst, Office of Pharmacy Affairs (OPA), Health Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857. Comments may also be e-mailed to: *opacmp@hrsa.gov*.

FOR FURTHER INFORMATION CONTACT: CDR Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Healthcare Services Bureau (HSB), Health Resources Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

The Affordable Care Act introduces a number of changes to the 340B Program. The Affordable Care Act creates several new categories of eligibility for program participation and provides a number of tools for improving program compliance by manufacturers and covered entities. As one of the many changes created by the Affordable Care Act, section 7102(a) amends section 340B(d) of the PHSA to require the Secretary of HHS to provide for the imposition of civil monetary penalties against manufacturers. As amended by the Affordable Care Act, section 340B(d)(1)(B)(vi) of the PHSA provides for:

(vi) The imposition of sanctions in the form of civil monetary penalties, which—

(I) Shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act;

(II) Shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) Shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

Section 7102(a) of the Affordable Care Act requires the Secretary of HHS to use funds appropriated under section 340B(d)(4) of the PHSA to provide for improvements in compliance by manufacturers and covered entities. The Affordable Care Act also includes provisions to improve covered entity compliance and the imposition of sanctions. These provisions addressing sanctions for covered entities will be addressed separately.

The 340B Program creates complex relationships, not only between drug manufacturers and covered entities, but also involves, among others, wholesalers, group purchasing organizations, pharmacies, and state Medicaid agencies. Changes to the 340B Program have the potential to alter these complex relationships. Prior to enactment of the Affordable Care Act, HRSA did not have civil monetary penalty authority for the 340B Program. This ANPRM is being issued to gather comments to consider in the development of these regulations.

II. Request for Comments

The purpose of this document is to obtain information and public comment on how to efficiently and effectively implement the civil monetary penalties authorized Section 7102(a) of the Affordable Care Act. Although HRSA has identified several issues and areas where HRSA believes comment would be particularly helpful, comments may be submitted on any issues directly relevant to the implementation of the specified requirements.

Areas for which HRSA is expressly seeking comment include: (1) Existing Models; (2) Threshold Determination; (3) Administrative Process Elements; (4) Hearing; (5) Appeals Process; (6) Definitions; (7) Penalty Computation; (8) Payment of Penalty; and (9) Integration of Civil Monetary Penalties with Other Provisions in the Affordable Care Act.

Commenters are requested to specify as clearly as possible which statutory provision they are commenting on and provide a rationale for their proposals.

1. Existing Models

HRSA is seeking comments regarding any aspects of other existing models for civil monetary penalties that can be adapted to the 340B Program. While the 340B Program has not had civil monetary penalty authority in the past, HHS has experience with creating and implementing civil monetary penalties in a number of other contexts. Certain portions of these other civil monetary penalty authorities can provide useful insight as HRSA implements the 340B Program civil monetary penalty authority.

HRSA is currently reviewing the civil monetary penalty authority exercised by the OIG, Federal Aviation Administration, Treasury, Food and Drug Administration, United States Department of Agriculture, Federal Deposit Insurance Corporation, and CMS to determine what portions of these authorities may be adapted for the 340B Program. Specifically, HRSA is reviewing the October 2005 DHHS Office of Inspector General report "Deficiencies in Oversight of the 340B Drug Pricing Program" (OEI–05–02–00072) which recommended that HRSA consider as a model the Centers for Medicare and Medicaid Services' (CMS) statutory authority to enforce the Medicaid rebate program, pursuant to section 1927(b)(3)(C)(i) of the Social Security Act, and seek similar authorities with respect to enforcement of the 340B Program. HRSA is also contemplating the use and adaptation of the procedures codified at 42 CFR part 1003, which includes procedures for the imposition of civil monetary penalties by the OIG. As such, please comment on the extent to which provisions similar to 42 CFR part 1003 should be applied in civil monetary penalty regulations applicable to manufacturers. HRSA is seeking information on other existing regulations or procedures on civil monetary penalties that may provide additional guidance specifically relating

to manufacturers and civil monetary penalties.

2. Threshold Determination

HRSA welcomes comments on when the civil monetary penalty provision should be applied. HRSA is contemplating an oversight process incorporating a variety of elements to gather and consider grounds for applying the penalty provision. These include, but are not limited to, the amount of the overcharge, the frequency of the overcharge, the compliance history of the manufacturer in question, and the number of covered entities affected. The Affordable Care Act provides HRSA with a range of new compliance tools. HRSA may use this information to determine when it is most appropriate to utilize its civil monetary penalty authority and when it is more appropriate to utilize its other available compliance mechanisms.

3. Administrative Process Elements

HRSA is seeking comments on the administrative processes that would best administer civil monetary penalties tailored to meet the unique context of the 340B Program. Systems must be created to address how civil monetary penalty claims will be processed, what type of notice should be required for proposed determinations, what involvement should be available to overcharged covered entities, and what type of notice should be given to third parties and the public, etc. HRSA invites comments on the applicability of the particular administrative procedures in 42 CFR part 1003 and the appropriateness of additional procedural elements.

4. Hearing

Civil monetary penalty systems typically offer the opportunity for a hearing. HRSA is inviting comments on the manner in which such a hearing would be structured. HRSA is considering a large number of issues involved in creating a fair and efficient hearing process, including, but not limited to: Decision-making individual or make-up of the decision making body; ex parte contacts; prehearing conferences; discovery; subpoenas; fees; form, filing, and service of papers; motions; sanctions; burden of proof; evidence; and post-hearing briefs.

5. Appeals Process

HRSA is considering under what circumstances (if any) exist with respect to establishing an appeal review process and who should hear such an appeal. HRSA is also considering which types of matters may be appealed. HRSA also invites comments on how the civil monetary process should interact with the administrative dispute resolution process required by section 340B(d)(3).

6. Definitions

There are a number of key terms needing a clearly established definition in administering this provision in a fair and efficient manner:

a. "Instance"—HRSA believes that "instance" in this context could potentially be defined either as a per unit of drug and/or per commercial transaction. If an entity purchases 100 units of a particular drug in a single transaction, should this constitute 100 instances or a single instance? HRSA also contemplates including instances of refusing to sell a covered outpatient drug in violation of the pharmaceutical pricing agreement to be subject to a penalty where a covered entity has purchased the drug outside the 340B Program at a price greater than the ceiling price.

b. "Knowing and intentional"—HRSA contemplates a standard whereby knowing and intentional can be inferred from the circumstances. For example, the knowledge and intent of employees or agents of a manufacturer may be attributed to the company as a whole. In cases where the ceiling price is known by the manufacturer, the manufacturer knows that a purchaser is a covered entity, and the covered entity is knowingly charged a price in excess of the ceiling price, a finder of fact would be able to infer intentionality of the violation even in cases where no single individual had knowledge of all of these elements. HRSA anticipates there may be circumstances where repeated violations could be considered to be knowingly and intentional if, for example, a manufacturer repeatedly miscalculates a ceiling price or otherwise establishes a system where overcharges are a highly probable consequence.

7. Penalty Computation

In cases where there is a finding that a manufacturer has knowingly and intentionally charged a covered entity an amount in excess of the ceiling price, HRSA contemplates application of variable penalties under the statute. HRSA proposes the following criteria for consideration: (i) Previous record of overcharging; (ii) timeliness of response; (iii) cooperation and good faith; (iv) number of covered entities impacted by the overcharges; (v) impact on patient access; (vi) economic loss to covered entities; (vi) economic gain to the manufacturer; and (vii) relative economic impact on manufacturer as to sufficiency to deter. In determining the penalty, discretion would be given to the deciding official or body. Furthermore, HRSA contemplates that there may be circumstances under which a penalty may be waived for reasons of equity or other good cause.

8. Payment of Penalty

Once a penalty is assessed there are a number of methods for transferring the penalty to the government. HRSA expects to have the application of interest from the date of the overcharge. HRSA also contemplates the ability to adjust the amount of the penalty. To the extent that a penalty payment or an assessment is not paid in a timely manner, a civil action could be pursued by the government.

9. Integration of Civil Monetary Penalties With Other Provisions in Affordable Care Act

In addition to the compliance tools already available to HRSA, such as audits and alternative dispute resolution, the Affordable Care Act provides HRSA with many additional tools to monitor compliance. These additional tools include establishing procedures to verify the accuracy of ceiling prices, creating processes for manufacturers to refund overcharges, selective auditing of manufacturers, and providing access to ceiling price information. To ensure its most effective use, the new civil monetary penalty authority must be used in conjunction with these other compliance tools. HRSA anticipates that information gathered from these other compliance tools will be useful in civil monetary penalty actions and also that information gathered in civil monetary penalty actions will be useful in implementing these other compliance tools. HRSA invites comments concerning the relationship between civil monetary penalties and other oversight mechanisms, such as dispute resolution, spot audits, and others.

While these nine areas were identified for comment, we welcome comments on any other issues that stakeholders believe are relevant to implementing an effective process for civil money penalties.

Dated: September 14, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–23461 Filed 9–17–10; 8:45 am]

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