a final disapproval. The available sanctions include a prohibition on the approval by the Secretary of Transportation of certain highway projects or the awarding of certain federal highway funding, and a requirement that new or modified stationary sources or emissions units for which a permit is required under Part D of Title I of the CAA achieve an emissions reductions-to-increases ratio of at least 2-to-1. In addition, EPA is required by section 502(d)(2)(B) of the CAA to apply one of the sanctions in section 179(b), as selected by the Administrator, on the date 18 months after the effective date of a final disapproval, unless prior to that date Virginia has submitted a revised operating permits program and EPA has determined that it corrects the deficiencies that prompted the final disapproval. Moreover, if the Administrator finds a lack of good faith on the part of Virginia, both sanctions shall apply after the expiration of the 18-month period until the Administrator determines that Virginia has come into compliance. In all cases, if, six months after EPA applies the first sanction, Virginia has not submitted a revised program that EPA has determined corrects the disapproved program's deficiencies, a second sanction is required. Finally, if EPA has not granted full approval to Virginia's program by November 15, 1995, and Virginia's program at that point does not have interim approval status, EPA must promulgate, administer and enforce a Federal permits program for Virginia on that date.

EPA first disapproved Virginia's operating permits program in a Federal Register notice published on December 5, 1994, which became effective on January 5, 1995. As a result, EPA's authority to apply discretionary sanctions to Virginia arose on January 5, 1995, and the 18-month period before which EPA is required to apply sanctions also began on that date.

Consequently, following today's proposed disapproval EPA continues to have the authority to apply discretionary sanctions to Virginia and will be required to apply sanctions on July 5, 1996, unless by that date EPA determines Virginia has corrected each of the deficiencies that prompted EPA's original disapproval. Moreover, if today's proposed disapproval is finalized, EPA would be required to apply sanctions 18 months after the effective date of such action, unless by that date EPA determines Virginia has corrected each of the deficiencies that prompted EPA's disapproval and that were not the subject of the original final disapproval action.

IV. Proposed Action

EPA is proposing to disapprove the submittals made on January 9, 1995 and May 17, 1995 by the Commonwealth of Virginia to satisfy the requirements for the operating permits program required by Title V of the Clean Air Act for the reasons outlined in this notice.

V. Administrative Requirements

A. Request for Public Comments

The EPA is requesting comments on all aspects of this proposed disapproval. Copies of the State's submittal and other information relied upon for the proposed disapproval are contained in a docket maintained at the EPA Regional Office. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the development of this proposed disapproval. The principal purposes of the docket are: (1) To allow interested parties a means to identify and locate documents so that they can effectively participate in the disapproval process; and (2) to serve as the record in case of judicial review. The EPA will consider any comments received by October 19, 1995.

B. Executive Order 12866

The Office of Management and Budget has exempted this action from Executive Order 12866 review.

C. Regulatory Flexibility Act

The EPA's actions under section 502 of the CAA do not create any new requirements, but simply address operating permits programs submitted to satisfy the requirements of 40 CFR Part 70. Because this action does not impose any new requirements, it does not have a significant impact on a substantial number of small entities.

D. Federal Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final action that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must consider the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule. EPA has determined that this proposed disapproval action of Virginia's Title V Operating Permits Program does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action disapproves pre-existing requirements under State or local law, and imposes no new Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, and Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401–7671q.

Dated: September 8, 1995.

W. Michael McCabe,

Regional Administrator, Region III.

[FR Doc. 95–23204 Filed 9–18–95; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 81

[AD–FRL–5297–9]

Clean Air Act Reclassification; Pennsylvania—Liberty Borough Nonattainment Area; PM–10

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to find that the Liberty Borough, Pennsylvania nonattainment area has not attained national ambient air quality standards (NAAQS) for particulate matter of nominal aerodynamic diameter smaller than 10 micrometers (PM–10) by the Clean Air Act (the Act) mandated attainment date for moderate nonattainment areas. The Act established an attainment date of no later than December 31, 1994 for areas classified as moderate nonattainment areas. This proposed finding is based on monitored air quality data for the PM–10 NAAQS during the years 1992–94. EPA is soliciting public comment on all relevant matters associated with this proposed action, including comment as to whether there are any mitigating facts or extenuating circumstances that it should consider in its review of the monitoring data used to propose to find that the area has not achieved the

NAAQS. All comments and information submitted, in writing, at the address and within the time frame specified below will be fully considered by EPA in determining its final action.

DATES: Comments must be received on or before October 19, 1995.

ADDRESSES: Comments may be mailed to Marcia L. Spink, Associate Director, Air Programs, Mailcode 3AT00, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107 and at the Allegheny County Health Department, Bureau of Environmental Quality, Division of Air Quality, 301 39th Street, Pittsburgh, Pennsylvania 15201.

FOR FURTHER INFORMATION CONTACT: Thomas A. Casey, U.S. EPA Region III, (215) 597–2746.

SUPPLEMENTARY INFORMATION:

I. Background

A. Health and Welfare Effects of Particulate Matter

Based on studies of human populations exposed to high concentrations of particles (at times in the presence of SO_2) and laboratory studies of animals and humans, there are major human health concerns associated with particulate matter. These include deleterious effects on breathing and respiratory systems, aggravation of existing respiratory and cardiovascular disease, alterations in the body's immune systems against foreign materials, damage to lung tissue, carcinogenesis, and premature death. The major subgroups of the population that appear to be most sensitive to the effects of particulate matter include individuals with chronic obstructive pulmonary or cardiovascular disease, those with influenza, asthmatics, the elderly, and children. Particulate matter also soils and damages materials, and fine particles are a major cause of visibility impairment in the United States.[1]

B. Clean Air Act Requirements Concerning Designation and Classification

On November 15, 1990, the date of enactment of the 1990 Clean Air Act Amendments, PM–10 areas meeting the criteria of section 107(d)(4)(B) of the Act were designated nonattainment by operation of law. Once an area is designated nonattainment, section 188 of the Act outlines the process for classification of the area and establishes the area's attainment date. Pursuant to section 188(a), all PM–10 nonattainment areas were initially classified as moderate by operation of law upon designation as nonattainment. These nonattainment designations and moderate area classifications were codified in 40 CFR Part 81 on November 6, 1991 (56 FR 56694).

C. Clean Air Act's Requirements for Moderate PM–10 Nonattainment Areas

States containing areas which were designated as moderate nonattainment by operation of law under section 107(d)(4)(B) were to develop and submit State Implementation Plans (SIPs) to provide for the attainment of the PM–10 NAAQS. Those SIPs were to include the adoption and implementation of PM–10 reduction requirements which constitute reasonably available control measures, (RACM), including reasonably available control technology (RACT). Pursuant to section 189(a)(2) of the Act, those SIP revisions were to be submitted to EPA by November 15, 1991. The Commonwealth of Pennsylvania submitted this SIP revision (developed and adopted by the Allegheny County Health Department) on January 11, 1994. On April 11, 1995 (60 FR 18385), in a rulemaking separate from today's action, EPA proposed approval of the Commonwealth's SIP revision for the Liberty Borough moderate PM–10 nonattainment area. EPA received numerous comments on its proposed action, some in support and some in opposition, and has yet to take final action on that SIP revision.

D. Reclassification to Serious Nonattainment

EPA has the responsibility, pursuant to sections 179(c) and 188(b)(2) of the Act, of determining within 6 months of the applicable attainment date, whether PM–10 nonattainment areas have attained the NAAQS. Section 179(c)(1) of the Act provides that these determinations are to be based upon an area's ''air quality as of the attainment date'', and section 188(b)(2) is consistent with this requirement. EPA makes the determination of whether an area's air quality is meeting the PM–10 NAAQS based upon air quality data gathered at monitoring sites in the nonattainment area and entered into the Aerometric Information Retrieval System (AIRS). These data are reviewed to determine the area's air quality status in accordance with 40 CFR Part 50, Appendix K.

Pursuant to Appendix K, attainment of the annual PM–10 standard is achieved when the expected annual arithmetic mean PM–10 concentration is equal to or less than 50 micrograms per cubic meter ($\mu g/m^3$). Attainment of the 24-hour standard is determined by calculating the expected number of exceedances of the 150 $\mu g/m^3$ limit per year. The 24-hour standard is attained when the expected number of exceedances is 1.0 or less. A total of 3 consecutive years of non-violating air quality data is generally necessary to show attainment of the 24-hour and annual standards for PM–10. A complete year of air quality data, as defined in 40 CFR Part 50, Appendix K, is comprised of all 4 calendar quarters with each quarter containing data from at least 75 percent of the scheduled sampling days.[2]

Under section 188(b)(2)(A), a moderate PM–10 nonattainment area is reclassified as serious by operation of law if the Administrator finds that the area has failed to attain the NAAQS by the statutory attainment date. Pursuant to section 188(b)(2)(B) of the Act, EPA must publish a notice in the Federal Register identifying those areas that failed to attain the standard and the resulting reclassifications. EPA is fulfilling its responsibility for this requirement via the federal rulemaking process initiated by today's action.

E. Clean Air Act's Requirements for Serious PM–10 Nonattainment Areas

PM–10 nonattainment areas reclassified as serious under section 188(b)(2) of the Act are required to submit, within 18 months of the area's reclassification, SIP revisions providing for, among other things, the adoption and implementation of best available control measures (BACM), including best available control technology (BACT), for PM–10 and PM–10 precursors no later than four years from the date of reclassification. The SIP also must contain a demonstration that its implementation will provide for attainment of the PM–10 NAAQS no later than December 31, 2001. EPA has provided specific guidance on developing serious area PM–10 SIP revisions in an addendum to the General Preamble to Title I of the Clean Air Act. See 59 FR 41998 (August 16, 1994). These requirements are in

[1] Air Quality Criteria for Particulate Matter (External Review Draft), EPA–600/AP–95/001a–c, April 1995 (NTIS #: PB95–22–1727, –1735, –1743).

[2] EPA is currently under court order to review the NAAQS for particulate matter (*American Lung Association* v. *Browner*, No. 93–643 D. Ariz., October 6, 1994).

addition to the moderate PM–10 nonattainment area requirements for RACT/RACM.

II. Rationale for EPA's Proposed Action

By today's action, EPA is proposing to find that the Liberty Borough area did not attain the PM–10 NAAQS by the required attainment date of December 31, 1994. As discussed below, this proposed finding is based upon air quality data which revealed violations of the PM–10 NAAQS during 1992–1994. If EPA takes final action on this proposed finding, the Liberty Borough nonattainment area (comprised of the City of Clairton and the Boroughs of Liberty, Lincoln, Glassport, and Port Vue) located in Allegheny County, Pennsylvania) will be reclassified by operation of law as a serious nonattainment area for PM–10 under section 188(b)(2)(A) of the Act.

A. Ambient Air Monitoring Data

Table 1 lists each of the monitoring sites in the Liberty Borough area where the 24-hour PM–10 NAAQS has been exceeded during 1992–1994 and the concentration, in micrograms per cubic meter, on the day of the exceedance.

TABLE 1

Year and date	Lincoln (high-volume sampler) (μg/m³)	Lincoln (continuous sampler) (μg/m³)	Liberty (high-volume sampler) (μg/m³)
1992:			
1/28	.....	.....	175
12/15	186	.....	.....
1993:			
5/10	167	.....	.....
11/23	223	195	.....
1994:			
2/19	163	.....	.....
3/7	157	.....	.....

The monitors in the nonattainment area that recorded exceedances of the PM–10 NAAQS have operated on varying sampling schedules with varying data capture rates. EPA requires the adjustment of observed exceedances to account for incomplete data pursuant to 40 CFR Part 50 Appendix K. In the case of the Lincoln high-volume sampler, five exceedances of the 24-hour NAAQS were observed from 1992 through 1994.[3] Before adjusting for incomplete sampling, the number of exceedances per year for the three year period would be 1.7. After adjusting for incomplete sampling, the number of expected exceedances of the NAAQS at this site during the three year period was 2.2.

According to 40 CFR Part 50, the 24-hour NAAQS is attained when the expected number of days per calendar year with a 24-hour average concentration above 150 μg/m3 is equal to or less than one. In the simplest case, the number of expected exceedances at a site is determined by recording the number of exceedances in each calendar year, accounting for incomplete data, and then averaging them over the past three calendar years. Therefore from 1992–1994, the number of expected exceedances at the Lincoln high-volume sampler is 2.2. This estimation of expected exceedances indicates that the Lincoln site had not attained the 24-hour PM–10 NAAQS during 1992–1994.

Only one exceedance of the annual NAAQS has been recorded in the Liberty Borough area from 1992–1994. (The Lincoln high-volume sampler recorded a weighted-average concentration of 52.5 μg/m³ in 1994.) No station in the Liberty Borough area recorded an annual average concentration, averaged (as prescribed in Appendix K) from 1992–1994, which exceeded the annual NAAQS.

III. Proposed Action

By today's action, EPA is proposing to find that the Liberty Borough area did not attain the PM–10 NAAQS by December 31, 1994. As discussed above, this proposed finding is based upon air quality data which revealed violations of the PM–10 NAAQS during 1992–1994. If EPA takes final action on this proposed finding, the Liberty Borough nonattainment area will be reclassified by operation of law as a serious nonattainment area for PM–10 under section 188(b)(2)(A) of the Act.

IV. Request for Public Comment

EPA is requesting comment on all aspects of today's proposal, including, but not limited to: The PM–10 control requirements adopted to date by the County and the timing and status of their implementation, the compliance status and history of the sources subject to the PM–10 control requirements, the efforts made to date to meet the requirements, air quality data and trends as they relate to implementation of the control requirements, and weather system occurrances (meteorology). EPA is also soliciting comment as to whether there are any mitigating facts or extenuating circumstances that it should consider in its review of the monitoring data used to propose to find that the area has not achieved the NAAQS, including any relevant comparison of the data collected from the ambient monitors. EPA is soliciting comment as to the relevancy of such information in determining whether the area has achieved the NAAQS.

As indicated earlier in this notice, EPA will consider any comments received, in writing, by October 19, 1995.

V. Executive Order (E.O.) 12866

Under E.O. 12866, 58 FR 51735 (October 4, 1993), EPA is required to determine whether regulatory actions are significant and therefore should be subject to OMB review, economic analysis, and the requirements of the Executive Order. The Executive Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may meet at least one of the four criteria identified in section 3(f), including, under paragraph (1), that the rule may ''have an annual effect on the economy of $100 million or more or adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.''

The Agency has determined that the finding of failure to attain proposed today would result in none of the effects identified in section 3(f). Under section 188(b)(2) of the Act, findings of failure to attain and reclassification of nonattainment areas are based upon air quality considerations and must occur by operation of law in light of certain air quality conditions. They do not, in-and-of-themselves, impose any new requirements on any sectors of the economy. In addition, because the statutory requirements are clearly defined with respect to the differently classified areas, and because those requirements are automatically triggered by classifications that, in turn, are triggered by air quality values, findings of failure to attain and reclassification cannot be said to impose a materially adverse impact on State, local, or tribal governments or communities.

VI. Regulatory Flexibility

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

[3] The Lincoln high volume sampler began operation in the Fall of 1992.

As discussed in section V of this notice, findings of failure to attain and reclassification of nonattainment areas under section 188(b)(2) of the Act do not in-and-of-themselves create any new requirements. Therefore, I certify that today's proposed action does not have a significant impact on small entities.

VII. Unfunded Mandates

Under sections 202, 203 and 205 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act), signed into law on March 22, 1995, EPA must assess whether various actions undertaken in association with proposed or final regulations include a Federal mandate that may result in estimated costs of $100 million or more to the private sector, or to State, local or tribal governments in the aggregate.

EPA believes, as discussed earlier in section V of this notice, that the proposed finding of failure to attain and reclassification of the Liberty Borough nonattainment area are factual determinations based upon air quality considerations and must occur by operation of law and, hence, do not impose any federal intergovernmental mandate, as defined in section 101 of the Unfunded Mandates Act.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter.

Authority: 42 U.S.C. 7401–7671q.

Dated: September 11, 1995.

W. Michael McCabe,

Regional Administrator, Region III.

[FR Doc. 95–23205 Filed 9–18–95; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 441 and 447

[MB–046–P]

RIN 0938–AF42

Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements With Manufacturers

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would specify requirements for State Medicaid agencies and conditions under which Federal payments would be made under Medicaid for covered outpatient prescription drugs. The rule would also specify the conditions for approval and renewal of rebate agreements with drug manufacturers participating in the Medicaid program.

The proposed rule would interpret sections 1902(a)(54), 1903(i)(10), and 1927 of the Social Security Act, as added by section 4401 of the Omnibus Budget Reconciliation Act of 1990, and amended by section 13602 of the Omnibus Budget Reconciliation Act of 1993, and section 601(b) of the Veterans Health Care Act of 1992. We consider this rule necessary to adequately implement the provisions of section 1927 of the Act.

DATES: Written comments will be considered if we receive them at the appropriate address, as provided in the ''Addresses'' section below, no later than 5:00 p.m. on November 20, 1995.

ADDRESSES: Mail written comments (an original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: MB–046–P, P.O. Box 7518, Baltimore, MD 21207–0518.

If you prefer, you may deliver your written comments (an original and 3 copies) to one of the following addresses: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C., or C5–09–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Due to staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code MB–046–P. Written comments received timely will be available for public inspection as they are received, beginning approximately 3 weeks after publication of this document, in room 309–G of the Department's offices at 200 Independence Ave., SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (telephone: (202) 690–7890).

If you wish to submit comments on the information collection requirements contained in this rule, you may submit written comments to: Office of Information and Regulatory Affairs, Attention: Laura Oliven, Office of Management and Budget, Room 3002, New Executive Office Building, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Estelle Chisholm, (410) 786–3286.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview of the Drug Rebate Provisions

Under section 1927 of the Social Security Act (the Act), manufacturers that have entered into a national rebate agreement must provide each State Medicaid program with rebate period payments (or other periodic rebate payments, as determined by the Secretary). The rebate must be calculated in accordance with sections 1927(b) and (c) of the Act, using manufacturing pricing data and State drug utilization information as outlined in the statute.

The requirements concerning rebate agreements apply to drugs dispensed and paid for under Medicaid on or after January 1, 1991. For manufacturers who entered into rebate agreements before March 1, 1991, section 1927(a)(1) of the Act provided for Federal financial participation (FFP) retroactively calculated as if the agreement had been entered into on January 1, 1991. For agreements that are entered into on or after March 1, 1991, Medicaid coverage and FFP begin, as specified in section 1927(a)(1), the first day of the rebate period that begins more than 60 days after the date the agreement is entered into. We are interpreting the term ''entered into'' to mean the date the agreement is postmarked by the U.S. Postal Service or other common mail carrier. We will not consider the date stamped by a postage meter to be a postmark.

Although the statute provides specific deadlines for manufacturers to sign rebate agreements, section 1927(a)(3) of the Act provides, in part, for payment of drugs not covered under rebate agreements if the Secretary determines that in the first calendar quarter of 1991 there were extenuating circumstances. Therefore, in light of the deadlines imposed by the statute for signing the agreement, and in accordance with the extenuating circumstances clause in section 1927(a)(3) of the Act, HCFA extended through April 30, 1991, the deadline for manufacturers to enter into Medicaid rebate agreements that are retroactive to January 1, 1991. Therefore, rebate agreements entered into on or after May 1, 1991, are effective on the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

The statute does not specify whether the drug provisions are applicable in areas other than the 50 States and the District of Columbia. However, in the