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[FR Doc. 05-17538 Filed 9-2-05; 8:45 am]

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Parts 52 and 81****[R09-OAR-2005-AZ-0003; FRL-7960-8]****Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; Arizona; Correction of Redesignation of Phoenix to Attainment for the Carbon Monoxide Standard****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Direct final rule.

**SUMMARY:** In today's action, EPA is taking direct final action to amend the regulations that identify revisions to the Arizona state implementation plan and the regulations that identify area designations within Arizona. In so doing, EPA is acting pursuant to the Agency's authority under the Clean Air Act to correct errors made in approving plan revisions and area redesignations. The purpose of this action is to correct an error in the adoption and submittal date shown for a revision to the implementation plan that EPA recently approved and to correct a transcription error in, and to make a more general correction to, the boundary description of the metropolitan Phoenix carbon monoxide area that EPA recently redesignated to attainment.

**EFFECTIVE DATE:** This rule is effective on November 7, 2005, without further notice, unless we receive adverse comments by October 6, 2005. If we receive adverse comments, we will publish a timely withdrawal in the *Federal Register* to notify the public that this rule will not take effect.

**ADDRESSES:** Submit comments, identified by docket number R09-OAR-2005-AZ-\_\_\_, by one of the following methods:

1. *Agency Web site:* <http://docket.epa.gov/rmepub/>. EPA prefers receiving comments through this electronic public docket and comment system. Follow the on-line instructions to submit comments.

2. *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions.

3. *E-mail:* [tax.wienke@epa.gov](mailto:tax.wienke@epa.gov).

4. *Mail or deliver:* Wienke Tax, Office of Air Planning (AIR-2), U.S. Environmental Protection Agency,

Region 9, 75 Hawthorne Street, San Francisco, CA 94105-3901.

**Instructions:** All comments will be included in the public docket without change and may be made available online at <http://docket.epa.gov/rmepub/>, including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through the agency Web site, eRulemaking portal, or e-mail. The agency Web site and eRulemaking portal are "anonymous access" systems, and EPA will not know your identify or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

**Docket:** The index to the docket for this action is available electronically at <http://docket.epa.gov/rmepub> and in hard copy at EPA Region 9, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** Wienke Tax, Air Planning Office (AIR-2), U.S. Environmental Protection Agency, Region 9, (520) 622-1622 or e-mail to [tax.wienke@epa.gov](mailto:tax.wienke@epa.gov).

**SUPPLEMENTARY INFORMATION:** Throughout this document, the terms "we," "us," and "our" refer to EPA.

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**I. Background**

On March 9, 2005, pursuant to the Clean Air Act (CAA), we published a final rulemaking action (1) approving various plan elements contained in two submittals of revisions to the Arizona state implementation plan (SIP) by the Arizona Department of Environmental Quality (ADEQ), (2) approving Arizona's request for the redesignation of the metropolitan Phoenix carbon monoxide

(CO) area to attainment for the carbon monoxide (CO) national ambient air quality standard (NAAQS), and (3) redesignating the boundary of the metropolitan Phoenix CO area to exclude the Gila River Indian Reservation. See 70 FR 11553 (March 9, 2005). Our March 9th final rulemaking contained amendments to 40 CFR part 52 relating to the two SIP submittals and amendments to 40 CFR part 81 relating to the redesignation actions. Three of these amendments were incorrect.

First, in the regulatory language we added as 40 CFR 52.120(c)(118), we incorrectly listed ADEQ's adoption and submittal date for the *Revised MAG 1999 Serious Area Carbon Monoxide Plan for the Maricopa County Nonattainment Area* (March 2001) as March 30, 2001. The correct date for both ADEQ's adoption and submittal of this plan (to EPA) as a revision to the Arizona SIP is April 18, 2001 and today's action revises 40 CFR 52.120(c)(118) accordingly.

Second, in 40 CFR 81.303, which contains a table describing in detail the metropolitan Phoenix CO area, we did not intend any change to paragraph 13 as codified prior to our March 9th final rule except for the added phrase at the end of the paragraph ("except that portion in the Gila River Indian Reservation"), but, through transcription error, we made other changes to that paragraph that were unintended. In today's notice, we are correcting paragraph 13 by reinstating the prior language.

Third, also in the CO table in 40 CFR 81.303, we codified our action to redesignate the boundary of the metropolitan Phoenix CO area to exclude the Gila River Indian Reservation by adding the phrase, "except that portion in the Gila River Indian Reservation," to the end of each of the 28 paragraphs that describe the metropolitan Phoenix CO area. In 40 CFR 81.303, the metropolitan Phoenix CO area is described by reference to a point of origin (paragraph 1) that lies at the southeast corner of the area followed by a series of 27 contiguous lines (paragraphs 2 through 28) that starts at the point of origin and proceeds in a counter-clockwise direction back to the point of origin. We now find that excluding "the portion in the Gila River Indian Reservation" from the point of origin and from each of the lines that collectively define the CO area was erroneous because the description, as revised in our March 9th final rule, is ambiguous as to its southern boundary.

We continue to believe that the redesignation of the boundary of the metropolitan Phoenix CO area to

exclude the Gila River Indian Reservation is appropriate and are taking action today to re-codify this redesignation in a manner that avoids the unintended ambiguity introduced by the regulatory text we used in our March 9th final rule. Specifically, in this action, we are revising each of the 28 paragraphs that define the metropolitan Phoenix CO area in 40 CFR 81.303 to remove the phrase that we added in our March 9th final rule (*i.e.*, “except that portion in the Gila River Indian Reservation”) and are instead adding a new paragraph 29 that states: “except that portion of the area defined by paragraphs 1 through 28 above that lies within the Gila River Indian Reservation.”

We are taking this action under our authority in CAA section 110(k)(6). Section 110(k)(6) provides, “Whenever the Administrator determines that the Administrator’s action approving, disapproving, or promulgating any plan or plan revision (or part thereof), area designation, redesignation, classification, or reclassification was in error, the Administrator may in the same manner as the approval, disapproval, or promulgation revise such action as appropriate without requiring any further submission from the State.” For the reasons stated above, we are correcting errors in the regulatory language we promulgated in approving a revision to the Arizona SIP, in redesignating the metropolitan Phoenix CO area to attainment, and in redesignating the boundary of the metropolitan Phoenix CO area to exclude the Gila River Indian Reservation.

## II. Final Action

In this action, EPA is correcting amendments to 40 CFR part 52, subpart D, and 40 CFR part 81, subpart C, that were contained in the final **Federal Register** notice published on March 9, 2005 approving submittals of revisions to the Arizona state implementation plan, redesignating the metropolitan Phoenix carbon monoxide area to attainment for the carbon monoxide National Ambient Air Quality Standards, and redesignating the boundary of the metropolitan Phoenix CO area to exclude the Gila River Indian Reservation. Specifically, this action amends 40 CFR 52.120 relating to the Arizona SIP and 40 CFR 81.303 describing the boundaries of the metropolitan Phoenix CO area.

The EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed

rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to correct the errors described herein should adverse comments be filed. This action will be effective November 7, 2005, without further notice unless the EPA receives relevant adverse comments by October 6, 2005.

If the EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on November 7, 2005 and no further action will be taken on the proposed rule. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule, and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

## III. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a “significant regulatory action” and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This action merely corrects a previous EPA action and imposes no additional requirements. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule corrects a previous EPA action and does not impose any additional enforceable duty, it 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).

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” are defined in the

Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.”

Under section 5(b) of Executive Order 13175, EPA may not issue a regulation that has tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by tribal governments, or EPA consults with tribal officials early in the process of developing the proposed regulation. Under section 5(c) of Executive Order 13175, EPA may not issue a regulation that has tribal implications and that preempts tribal law, unless the Agency consults with tribal officials early in the process of developing the proposed regulation.

As discussed above, in a previous action, EPA excluded the Gila River Indian Reservation from the metropolitan Phoenix CO area, and this action merely corrects the corresponding regulatory text. Consistent with EPA policy, EPA has discussed the need for correction of the previous action with representatives of the Gila River Indian Community. EPA finds that this action, which simply corrects an action that the Agency has previously taken, will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law. Thus, the requirements of sections 5(b) and 5(c) of the Executive Order do not apply to this rule.

This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely corrects a previous EPA rule, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this rule present a disproportionate risk to children.

This rule does not involve establishment of technical standards, and thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. section 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. section 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 7, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality

of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See CAA section 307(b)(2).)

#### List of Subjects

##### 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

##### 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: July 15, 2005.

**Laura Yoshii,**

*Deputy Regional Administrator, Region IX.*

■ Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

#### PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

#### Subpart D—Arizona

■ 2. Section 52.120 is amended by revising paragraph (c)(118) to read as follows:

##### § 52.120 Identification of plan.

\* \* \* \* \*

(c) \* \* \*  
(118) The following plan was submitted on April 18, 2001, by the Governor's designee.

(i) Incorporation by reference.

(A) Arizona Department of Environmental Quality.

(1) *Revised MAG 1999 Serious Area Carbon Monoxide Plan for the Maricopa County Nonattainment Area*, dated March 2001, adopted by the Maricopa Association of Governments on March 28, 2001, and adopted by the Arizona Department of Environmental Quality on April 18, 2001.

#### PART 81—[AMENDED]

■ 1. The authority citation for part 81 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

#### Subpart C—Section 107 Attainment Status Designations

■ 2. In § 81.303, the table entitled "Arizona—Carbon Monoxide" is amended by revising the entry for the Phoenix Area to read as follows:

##### § 81.303 Arizona.

\* \* \* \* \*

#### ARIZONA—CARBON MONOXIDE

| Designated area                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Designation |            | Classification |      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|------------|----------------|------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Date        | Type       | Date           | Type |
| Phoenix Area:<br>Maricopa County (part) .....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 4/8/2005    | Attainment |                |      |
| Phoenix nonattainment area boundary:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |             |            |                |      |
| 1. Commencing at a point which is the intersection of the eastern line of Range 7 East, Gila and Salt River Baseline and Meridian, and the southern line of point Township 2 South, said point is the southeastern corner of Maricopa Association of Governments Urban Planning Area, which is the point of beginning;                                                                                                                                                                                                                           |             |            |                |      |
| 2. thence, proceed northerly along the eastern line of Range 7 East, which is the common boundary between Maricopa and Pinal Counties, as described in Arizona Revised Statutes Section 11–109, to a point where the eastern line of Range 7 East intersects the northern line of Township 1 North, said point is also the intersection of the Maricopa County Line and the Tonto National Forest Boundary, as established by Executive Order 869 dated July 1, 1908, as amended and the shown on the U.S. Forest Service 1969 Planimetric Maps; |             |            |                |      |
| 3. thence, westerly along the northern line of Township 1 North to approximately the southwest corner of the southeast quarter of Section 35, Township 2 North, Range 7 East, said point being the boundary of the Tonto National Forest and Utery Mountain Semi-Regional Park;                                                                                                                                                                                                                                                                  |             |            |                |      |
| 4. thence, northerly along the Tonto National Forest Boundary, which is generally the western line of the east half of Sections 26 and 35 of Township 2 North, Range 7 East, to a point which is where the quarter section line intersects with the northern line of Section 26, Township 2 North, Range 7 East, said point also being the northeast corner of the Utery Mountain Semi-Regional Park;                                                                                                                                            |             |            |                |      |

## ARIZONA—CARBON MONOXIDE—Continued

| Designated area                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Date        | Type | Date           | Type |
| <p>5. thence, westerly along the Tonto National Forest Boundary, which is generally the south line of Sections 19, 20, 21 and 22 and the southern line of the west half of Section 23, Township 2 North, Range 7 East, to a point which is the southwest corner of Section 19, Township 2 North, Range 7 East;</p> <p>6. thence, northeasterly along the Tonto National Forest Boundary to a point where the Tonto National Forest Boundary intersects with the eastern boundary of the Salt River Indian Reservation, generally described as the center line of the Salt River Channel;</p> <p>7. thence, northeasterly and northerly along the common boundary of the Tonto National Forest and the Salt River Indian Reservation to a point which is the northeast corner of the Salt River Indian Reservation and the southeast corner of the Fort McDowell Indian Reservation, as shown on the plat dated July 22, 1902, and recorded with the U.S. Government on June 15, 1902;</p> <p>8. thence, northeasterly along the common boundary between the Tonto National Forest and the Fort McDowell Indian Reservation to a point which is the northeast corner of the Fort McDowell Indian Reservation;</p> <p>9. thence, southwesterly along the northern boundary of the Fort McDowell Indian Reservation, which line is a common boundary with the Tonto National Forest, to a point where the boundary intersects with the eastern line of Section 12, Township 4 North, Range 6 East;</p> <p>10. thence, northerly along the eastern line of Range 6 East to a point where the eastern line of Range 6 East intersects with the southern line of Township 5 North, said line is the boundary between the Tonto National Forest and the east boundary of McDowell Mountain Regional Park;</p> <p>11. thence, westerly along the southern line of Township 5 North to a point where the southern line intersects with the eastern line of Range 5 East which line is the boundary of Tonto National Forest and the north boundary of McDowell Mountain Regional Park;</p> <p>12. thence, northerly along the eastern line of Range 5 East to a point where the eastern line of Range 5 East intersects with the northern line of Township 5 North, which line is the boundary of the Tonto National Forest;</p> <p>13. thence, westerly along the northern line of Township 5 North to a point where the northern line of Township 5 North intersects with the easterly line of Range 4 East, said line is the boundary of Tonto National Forest;</p> <p>14. thence, northerly along the eastern line of Range 4 East to a point where the eastern line of Range 4 East intersects with the northern line of Township 6 North, which line is the boundary of the Tonto National Forest;</p> <p>15. thence, westerly along the northern line of Township 6 North to a point of intersection with the Maricopa-Yavapai County line, which is generally described in Arizona Revised Statutes Section 11–109 as the center line of the Aqua Fria River (Also the north end of Lake Pleasant);</p> <p>16. thence, southwesterly and southerly along the Maricopa-Yavapai County line to a point which is described by Arizona Revised Statutes Section 11–109 as being on the center line of the Aqua Fria River, two miles southerly and below the mouth of Humbug Creek;</p> <p>17. thence, southerly along the center line of Aqua Fria River to the intersection of the center line of the Aqua Fria River and the center line of Beardsley Canal, said point is generally in the northeast quarter of Section 17, Township 5 North, Range 1 East, as shown on the U.S. Geological Survey's Baldy Mountain, Arizona Quadrangle Map, 7.5 Minute series (Topographic), dated 1964;</p> <p>18. thence, southwesterly and southerly along the center line of Beardsley Canal to a point which is the center line of Beardsley Canal where it intersects with the center line of Indian School Road;</p> <p>19. thence, westerly along the center line of West Indian School Road to a point where the center line of West Indian School Road intersects with the center line of North Jackrabbit Trail;</p> <p>20. thence, southerly along the center line of Jackrabbit Trail approximately nine and three-quarter miles to a point where the center line of Jackrabbit Trail intersects with the Gila River, said point is generally on the north-south quarter section line of Section 8, Township 1 South, Range 2 West;</p> <p>21. thence, northeasterly and easterly up the Gila River to a point where the Gila River intersects with the northern extension of the western boundary of Estrella Mountain Regional Park, which point is generally the quarter corner of the northern line of Section 31, Township 1 North, Range 1 West;</p> <p>22. thence, southerly along the extension of the western boundary and along the western boundary of Estrella Mountain Regional Park to a point where the southern extension of the western boundary of Estrella Mountain Regional Park intersects with the southern line of Township 1 South;</p> |             |      |                |      |

## ARIZONA—CARBON MONOXIDE—Continued

| Designated area                                                                                                                                                                                                                                                                                                                                              | Designation |      | Classification |      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|------|----------------|------|
|                                                                                                                                                                                                                                                                                                                                                              | Date        | Type | Date           | Type |
| 23. thence, easterly along the southern line of Township 1 South to a point where the south line of Township 1 South intersects with the western line of Range 1 East, which line is generally the southern boundary of Estrella Mountain Regional Park;                                                                                                     |             |      |                |      |
| 24. thence, southerly along the western line of Range 1 East to the southwest corner of Section 18, Township 2 South, Range 1 East, said line is the western boundary of the Gila River Indian Reservation;                                                                                                                                                  |             |      |                |      |
| 25. thence, easterly along the southern boundary of the Gila River Indian Reservation which is the southern line of Sections 13, 14, 15, 16, 17, and 18, Township 2 South, Range 1 East, to the boundary between Maricopa and Pinal Counties as described in Arizona Revised Statutes Sections 11–109 and 11–113, which is the eastern line of Range 1 East; |             |      |                |      |
| 26. thence, northerly along the eastern boundary of Range 1 East, which is the common boundary between Maricopa and Pinal Counties, to a point where the eastern line of Range 1 East intersects the Gila River;                                                                                                                                             |             |      |                |      |
| 27. thence, southerly up the Gila River to a point where the Gila River intersects with the southern line of Township 2 South; and                                                                                                                                                                                                                           |             |      |                |      |
| 28. thence, easterly along the southern line of Township 2 South to the point of beginning which is a point where the southern line of Township 2 South intersects with the easter line Range 7 East;                                                                                                                                                        |             |      |                |      |
| 29. except that portion of the area defined by paragraphs 1 through 28 above that lies within the Gila River Indian Reservation.                                                                                                                                                                                                                             |             |      |                |      |

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[FR Doc. 05–17539 Filed 9–2–05; 8:45 am]

BILLING CODE 6560–50–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Part 414****CMS–1325–IFC2****RIN 0938–AN58****Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B: Interpretation and Correction****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Interim final rule; interpretation and correction.

**SUMMARY:** This interim final rule clarifies our timeline for implementation of the competitive acquisition program under section 1847B of the Social Security Act and corrects technical errors that appeared in the addenda to the interim final rule with comment period published in the **Federal Register** on July 6, 2005 entitled “Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B.”

**EFFECTIVE DATE:** This rule is effective September 6, 2005.**FOR FURTHER INFORMATION CONTACT:** Lia Prela, (410) 786–0548.**SUPPLEMENTARY INFORMATION:****I. Background***A. Clarification of Timeline for Implementation of CAP*

On July 6, 2005, we published an interim final rule with comment period (70 FR 39022) in the **Federal Register** with respect to provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that require the implementation of a competitive acquisition program (CAP) for certain Medicare Part B drugs not paid on a cost or prospective payment system basis. Physicians will generally be given a choice between obtaining these drugs from vendors selected through a competitive bidding process or directly purchasing these drugs and being paid under the average sales price (ASP) system.

In the July 6, 2005 interim final rule, we stated that implementation of the CAP would take place on January 1, 2006 to coordinate the CAP physician election process with the Medicare participating physician election process described in section 1842(h) of Social Security Act (the Act). Subsequent to the publication of the July 6, 2005 interim final rule, we received comments requesting a delay in implementation of the CAP from a variety of sources including written public comments as well as comments voiced during the conference call for potential vendors that we held on July 8, 2005.

Effective August 3, 2005, we suspended the vendor bidding process that began with publication of the interim final rule on July 6, 2005, to allow us more time to fully review public comments on the interim final rule and also to further refine the bidding process. We provided notification of the suspension on the CMS Web site <http://www.cms.hhs.gov/providers/drugs/compbid/> and through the pharmacy and physician Listservs. We will publish a final rule for implementing the CAP after we analyze the additional comments on the interim final rule and determine the best manner for improving the efficiency of the CAP and increasing potential participation of both vendors and physicians in the program.

We will announce the dates for the new vendor bidding period concurrent with the publication of the final rule. We also will be announcing a special physician election period. Currently, we expect that drugs will first be delivered through the CAP by July 2006. During the special election period, physicians will have the opportunity to elect to participate in the CAP from its start date in 2006 through the end of calendar year 2006.

As we specified in the July 2005 **Federal Register** document, we will continue to accept comments on the interim final rule until September 6, 2005.

In section II of this document, we provide clarification of the timeline for implementation of the CAP as well as further interpretation of what will