7–17–07 Tuesday
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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.

2. The relationship between the Federal Register and Code of Federal Regulations.

3. The important elements of typical Federal Register documents.

4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, July 17, 2007
9:00 a.m.–Noon

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

Contents

Federal Register

Vol. 72, No. 136

Tuesday, July 17, 2007

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Federal Register
Vol. 72, No. 136
Tuesday, July 17, 2007

Presidential Documents

Title 3—

The President

Proclamation 8162 of July 12, 2007

Death of Lady Bird Johnson

By the President of the United States of America

A Proclamation

As a mark of respect for the memory of Lady Bird Johnson, I hereby order, by the authority vested in me by the Constitution and laws of the United States of America, that on the day of her interment, the flag of the United States shall be flown at half-staff at the White House and upon all public buildings and grounds, at all military posts and naval stations, and on all naval vessels of the Federal Government in the District of Columbia and throughout the United States and its Territories and possessions until sunset on such day. I also direct that the flag shall be flown at half-staff for the same period at all United States embassies, legations, consular offices, and other facilities abroad, including all military facilities and naval vessels and stations.

IN WITNESS WHEREOF, I have hereunto set my hand this twelfth day of July, in the year of our Lord two thousand seven, and of the Independence of the United States of America the two hundred and thirty-second.

[FR Doc. 07–3498
Filed 7–16–07; 8:45 am]
Billing code 3195–01–P

Rules and Regulations

Federal Register
Vol. 72, No. 136
Tuesday, July 17, 2007

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2007–27837; Airspace Docket No. 07–ACE–5]

Modification of Class E Airspace; Bolivar, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; confirmation of effective date and correction.

SUMMARY: This document confirms the effective date of the direct final rule which revises Class E airspace at Bolivar, MO and corrects the airport reference point coordinates.

DATES: *Effective Date:* The direct final rule published at 72 FR 23768, May 1, 2007, is confirmed to be 0901 UTC, August 30, 2007.

FOR FURTHER INFORMATION CONTACT: Grant Nichols, System Support, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2522.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on May 1, 2007 (72 FR 23768). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on August 30, 2007. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date. The airport reference point coordinates are corrected to lat. 37°35′46″ N., long. 93°20′52″ W.

Issued in Fort Worth, Texas on June 27, 2007.

Donald R. Smith,

Manager, System Support Group, ATO Central Service Center.

[FR Doc. 07–3446 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2007–27838; Airspace Docket No. 07–ACE–6]

Modification of Class E Airspace; Hugoton, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of the direct final rule which revises Class E airspace at Hugoton, KS.

DATES: *Effective Date:* The direct final rule published at 72 FR 23767, May 1, 2007, is confirmed to be 0901 UTC, August 30, 2007.

FOR FURTHER INFORMATION CONTACT: Grant Nichols, System Support, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2522.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on May 1, 2007 (72 FR 23767). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on August 30, 2007. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Fort Worth, Texas on June 27, 2007.

Donald R. Smith,

Manager, System Support Group, ATO Central Service Center.

[FR Doc. 07–3445 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 730, 764 and 766

[Docket No. 0612242577–7145–01]

RIN 0694–AD63

Antiboycott Penalty Guidelines

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule sets forth BIS policy concerning voluntary self-disclosures of violations of part 760 (Restrictive Trade Practices or Boycotts) of the Export Administration Regulations (EAR) and violations of part 762 (Recordkeeping) of the EAR that relate to part 760. This rule also sets forth the factors that the Bureau of Industry and Security (BIS) considers when deciding whether to pursue administrative charges or settle allegations of such violations as well as the factors that BIS considers when deciding what level of penalty to seek in administrative antiboycott cases.

DATES: This rule is effective August 16, 2007.

FOR FURTHER INFORMATION CONTACT: Edward O. Weant III, Director, Office of Antiboycott Compliance, Bureau of Industry and Security, United States Department of Commerce, at (202) 482–2381.

SUPPLEMENTARY INFORMATION:

Background

Part 760 of the EAR—Restrictive Trade Practices or Boycotts—prohibits U.S. persons from taking or knowingly agreeing to take certain actions with intent to comply with, further, or support an unsanctioned foreign boycott. Part 760 of the EAR also requires U.S. persons who are recipients of requests ''* * * to take any action which has the effect of furthering or

supporting a restrictive trade practice or boycott fostered or imposed by a foreign country against a country friendly to the United States or against any United States person * * *'' to report receipt of those requests to BIS and whether they took the requested action. Part 762 of the EAR—Recordkeeping—requires, *inter alia,* retention of certain documents that contain information related to the prohibitions or reporting requirements of part 760. Collectively, these provisions of the EAR are referred to in this notice as the ''antiboycott provisions.'' BIS administers and enforces the antiboycott provisions through its Office of Antiboycott Compliance (OAC). On June 30, 2006, BIS published a proposed rule regarding specific procedures for voluntary self-disclosures of violations to OAC, guidance about how BIS responds to violations of the antiboycott provisions, and a description of how BIS makes penalty determinations in the settlement of administrative enforcement cases related to the antiboycott provisions. After reviewing the public comments on the proposed rule, BIS is publishing this final rule.

This rule does not address disclosure provisions or penalty determination factors in any other matters such as criminal prosecutions for violations of the antiboycott provisions or tax penalties that the Department of Treasury may impose for antiboycott violations that arise pursuant to the Ribicoff Amendment to the Tax Reform Act of 1976, as implemented by Section 999 of the Internal Revenue Code. Voluntary self-disclosure provisions and guidance on charging and penalty determinations in settlement of administrative enforcement cases that are not related to the antiboycott provisions are stated elsewhere in the EAR.

BIS received comments from two organizations regarding the proposed rule. Collectively, the two organizations raised seven issues. Three of the issues were general in nature and four addressed specific provisions of the proposed rule.

General Issues Raised by the Comments

One commenter suggested that BIS consult with industry and provide guidance on what a company's reporting structure should be. BIS concludes that this proposal is outside the scope of the issues raised by the proposed rule. BIS recognizes that among the entities that have reporting obligations, one could find myriad organizational structures. BIS believes that any tailoring of the manner of reporting to accommodate both an organization's structure and BIS's need to properly identify the source of reports can best be done through consultations between the organization and BIS rather than through an amendment to the regulations. BIS encourages organizations that have questions about how to submit reports to contact BIS for such consultations.

One commenter suggested that BIS develop a system to allow the public to submit boycott reports electronically. This suggestion is outside the scope of the proposed rule.

One commenter suggested that BIS update and publish its telephone advice guidance and look for other opportunities to provide practical written guidance for companies to use in complying with boycott requests. This comment is outside the scope of the proposed rule.

Comments Relating to Specific Features of the Proposed Rule

The comments address four specific issues in connection with the proposed rule. Those four issues are: The burden that would be imposed by new § 764.8 regarding voluntary self-disclosures; whether the provision of new § 764.8(f) regarding requests to take action that would otherwise violate § 764.2(e) is contrary to prior agency practice; whether new § 764.8 should allow verbal voluntary self-disclosures with written follow-up; and whether the rule should provide more concrete incentives to disclose by making a warning letter the maximum sanction for most voluntary self-disclosure cases.

Comment on Paperwork Burden

One commenter stated that BIS had underestimated the costs large global companies would incur in complying with the voluntary disclosure provisions. In particular, the commenter noted that a company with decentralized operations would incur costs measured in tens of thousands of dollars if it conducted the five-year review of all its operations recommended by BIS. Upon review, BIS acknowledges that the burden on large companies with decentralized operations would be greater than estimated in the proposed rule. However, BIS believes that such burden will be justified in many instances because of the risks to the firm involved if it performs a less comprehensive review. The risk of conducting a review covering a period shorter than five years or that does not include all business units is that some violations will be made known to OAC through other sources or during the course of an OAC investigation initiated in response to the voluntary self-disclosure. Such undisclosed violations would not receive the ''great weight'' mitigating factor that BIS would apply in settlement negotiations to voluntarily self-disclosed violations under this rule. The larger penalties imposed for such undisclosed violations might exceed the cost of doing a business-wide five-year search. Hence, BIS believes that it is appropriate to recommend a five-year period for this kind of review. BIS notes that the proposed rule and this final rule recommend but do not require a review extending back for a period of five years prior to the initial notification.

In the proposed rule, BIS stated that it intended to treat the collection of information related to the voluntary self-disclosure procedures in this rule as an extension of the scope of the collection approved under OMB control number 0694–AD58. Based on this comment, BIS re-evaluated the burden hours associated with this information collection and concluded that the burden is large enough to justify a separate collection authorization. Therefore, BIS sought and obtained separate OMB authorization for the collection related to the voluntary self-disclosure procedure in this rule. The collection related to the voluntary self-disclosure procedure in this rule explicitly accounts for the larger burden that would be imposed on large companies with decentralized locations and is authorized under OMB control number 0694–0132 for which the estimated annual burden hours and costs are 1,280 and $51,200, respectively.

Comment on § 764.8(f) and Prior Agency Practice

One commenter raised an issue concerning the implication of proposed § 764.8(f). Proposed § 764.8(f) would have provided a procedure by which a person making a voluntary self-disclosure of a violation of the antiboycott provision may request authorization to take certain actions with respect to the transaction. The commenter expressed a belief that ''the current OAC practice is not to require companies to seek BIS authorization to continue with a transaction after filing a voluntary disclosure.'' The commenter went on to state that ''[t]he proposed rule, however, would impose such a requirement * * * if a company were to commit a Category B or C violation it seems unreasonable that the company would have to file a voluntary disclosure and then seek BIS authorization to continue with the transaction. A more reasonable approach would be to require BIS

authorization only in those instances where the company voluntarily discloses a Category A violation.''

BIS agrees that, in the past, OAC has advised members of the public who contacted OAC via its telephone advice line a violation of part 760 does not preclude exporting in connection with the same commercial transaction. Upon review, BIS has decided to remove paragraph (f) from § 764.8 because it is not consistent with prior agency practice.

Comment Proposing Allowing Verbal Voluntary Self-Disclosures

BIS received one comment expressing the opinion that the Bureau of Customs and Border Protection self-disclosure procedure set forth in 19 CFR 162.74(a) is better than the procedure in the proposed rule. The procedure in 19 CFR 162.74(a) allows an importer to make a verbal disclosure to a Customs officer of a violation with the requirement that the disclosure be followed up in writing within 10 days. The commenter suggested that this Customs procedure encourages more disclosures by allowing the importer to disclose the violation at the earliest possible moment. The ten day written follow-up deadline encourages accurate and complete disclosures. BIS has reviewed 19 CFR 162.74(a) and the commenter's rationale. BIS notes that 19 CFR 162.74(a) applies to penalties for certain violations related to tariffs on imports into the United States. Compliance with the disclosure requirements in § 162.74 can allow the importer to pay a reduced penalty as compared with violations for which no such disclosure takes place. The penalties are set forth in 19 CFR 162.73 and 19 CFR 162.73a. Generally, the penalties are expressed as a percentage of value of the merchandise that was the subject of the violation. BIS believes that violations of the antiboycott provisions are substantively different from the violations addressed by 19 CFR 162.74(a). As noted in the preamble to the proposed rule, BIS believes that written initial notifications reduce the possibility of confusion as to whether a particular communication was intended to be a voluntary self-disclosure and are likely to produce more complete disclosures than would oral disclosures. In addition, BIS believes that preparing and submitting a written submission of the information required in an initial notification, *i.e.*, the name of the person making the disclosure and a brief description of the suspected violations and their general nature and extent, is not an onerous task. Therefore, this final rule makes no changes to the provisions of the proposed rule that required initial notifications to be in writing.

Comment Regarding Incentives to Self-Disclose Violations

One commenter recommended that BIS provide more concrete incentives for making disclosures of violations of the antiboycott provisions. This commenter noted that although new Supplement No. 2 to part 764 provides that voluntary self-disclosures be given ''GREAT WEIGHT'' as a mitigating factor, other language in the supplement concerning the effect of other factors as well as language in new § 764.8(b) stating that ''[t]he weight given to a voluntary self-disclosure is solely within discretion of BIS and the effect of voluntary self-disclosure may be outweighed by aggravating factors'' makes the benefits of voluntary self-disclosure almost speculative and could affect decisions to disclose. That commenter stated that BIS's proposal ''contrasts sharply with * * * customs law administration. [Where] * * * definite advantages always flow from disclosing violations * * *.'' The commenter recommended that BIS at least adopt a position of resolving all voluntary self-disclosure cases with a warning letter unless the ''violation involves serious anti-boycott concerns—*e.g.*, complying with boycott requests to discriminate on the basis of race, religion, sex, or national origin, or where there are significant aggravating factors.''

BIS notes that as stated in § 764.8, the weight to be given to any factor is solely within the discretion of BIS. Supplement No. 2 to part 764 describes how BIS exercises that discretion. BIS's statement in the supplement that voluntary self-disclosure made in accordance with § 764.8 be given great weight and that factors of great weight ordinarily should be given considerably more weight than other factors reflects the policy that BIS has followed and intends to follow in settling administrative enforcement actions involving the antiboycott provisions. However, given the myriad possible combinations of facts that may be present in any given case, including a range of possible aggravating and mitigating factors, BIS believes that it cannot determine in advance the maximum sanction that would be appropriate for a particular violation or combination of violations. Moreover, attempting to do so could create incentives to violate the antiboycott provisions in cases where the potential economic benefit to the violator is large relative to the maximum monetary penalty. Such incentives could occur, for example, in a situation in which a single violation provides the violator with access to a very large market.

Changes to the EAR in This Rule

This rule creates a new § 764.8 setting forth the procedures for voluntary self-disclosure of violations of the antiboycott provisions. It also creates a new supplement No. 2 to part 764 that describes how BIS responds to violations of the antiboycott provisions and how BIS makes penalty determinations in the settlement of antiboycott administrative enforcement cases. The rule also makes technical and conforming changes to part 766.

This rule provides specific criteria with respect to what constitutes a voluntary self-disclosure and how voluntary self-disclosures relate to other sources of information that OAC may have concerning violations of the antiboycott provisions. The rule also informs the public of the factors that BIS usually considers to be important when settling antiboycott administrative enforcement cases. BIS believes that publishing this information in the EAR will tend to place all potential respondents on a more equal footing because procedures for making voluntary self-disclosures, information about how BIS responds to violations and how BIS makes penalty determinations in the settlement of antiboycott administrative enforcement cases will all be matters of public record. BIS also believes such publication will make settlement of antiboycott administrative cases more efficient, as respondents and BIS will be able to focus on the important factors in antiboycott administrative enforcement cases and OAC generally expends fewer resources to obtain information received through voluntary self-disclosure than information obtained by other means.

This rule also revises Supp. No. 1 to part 730 of the EAR to display the OMB control number of the newly approved collection of information that relates to § 764.8 of the EAR, which is created by this rule.

Creation of § 764.8—Voluntary Self-Disclosure of Boycott Violations

The new § 764.8 both defines what constitutes a voluntary self-disclosure and provides the procedures for making such disclosures. Compliance with the provisions of § 764.8 is important because a voluntary self-disclosure ''satisfying the requirements of § 764.8'' is designated as a mitigating factor of ''GREAT WEIGHT'' in the settlement of administrative cases as set forth in the new Supplement No. 2 to part 764. Supplement No. 2 provides that such

factors ''will ordinarily be given considerably more weight than a factor that is not so designated.'' In addition to providing such an incentive for the submission of voluntary self-disclosures, BIS anticipates that § 764.8 will promote more effective use of OAC resources, as the receipt of voluntary self-disclosures will reduce the time that OAC must spend identifying and investigating possible violations. The rule provides the benefit of a mitigating factor to those who self-disclose before OAC has invested resources to investigate violations based on information it might receive from another source.

Section 764.8 requires, among other things, that voluntary self-disclosures be in writing and that they be received by OAC before OAC learns of the same or substantially similar information from ''another source'' and has commenced an investigation or inquiry in connection with that information. Section 764.8 provides that a person may make an initial written notification followed by submission of a more detailed narrative account and supporting documents. For purposes of determining whether a voluntary self-disclosure was received before OAC learned of the same or substantially similar information from another source, the date of the voluntary self-disclosure will be deemed to be the date that OAC received the initial notification if the person making the disclosure subsequently submits the required narrative account and supporting documentation.

BIS recognizes that two features of its existing regulations and practices may impact the requirement that a voluntary self-disclosure be received before OAC learns of the same or substantially similar information from another source. The first such feature is the set of reporting requirements in § 760.5. The second such feature is OAC's practice of encouraging persons with questions about the EAR to contact OAC by telephone or e-mail for advice.

Section 760.5 of the EAR requires any ''U.S. person who receives a request to take any action that would have the effect of furthering or supporting a restrictive trade practice or boycott fostered or imposed by a foreign country against a country friendly to the United States or against any United States person'' to report to OAC both receipt of the request and the action that the person took in response to that request. In some instances, taking the requested action would be a violation of § 760.2. BIS recognizes that, in such instances, the reporting requirements of § 760.5 would have the effect of requiring a person to disclose a violation that it had committed. Section 764.8(b)(3)(i) provides that reports filed pursuant to § 760.2 constitute ''information received from another source.'' Thus, a person who wishes to make a voluntary self-disclosure of a violation that is based on an action that § 760.5 requires that person to report would have to make sure that OAC receives the written initial notification portion of the voluntary self-disclosure before OAC began an investigation or inquiry based on the information received in the required report. The report itself would not serve as the initial notification. However, if OAC received the report and the initial notification simultaneously, it would be deemed to have received the initial notification before it had begun an investigation or inquiry based on the report. That person would then have to comply with the remaining requirements of § 764.8, but once that person complied with those requirements, the voluntary self-disclosure would be treated as having been received at the time that the initial notification was received.

OAC has, for a number of years, provided advice about the antiboycott provisions to persons requesting such advice via telephone or e-mail. In some instances, the persons requesting such advice may disclose that they have committed a violation. OAC's practice has been to encourage such persons to make voluntary self-disclosures. OAC wants to continue to encourage persons with questions about the antiboycott provisions to disclose fully all relevant facts when making telephone or e-mail inquiries for advice concerning the antiboycott provisions. Therefore, § 764.8(b)(3)(ii) provides that violations revealed in telephone or e-mail requests for advice concerning the antiboycott provisions are not information received from another source for purposes of § 764.8. Section 764.8(b)(3)(ii) also states that the information provided over the telephone or via e-mail while seeking advice would not constitute a voluntary self-disclosure or even an initial notification of a voluntary self-disclosure. OAC's practice is to inform persons who reveal violations in the course of seeking such advice of their opportunity to make a voluntary self-disclosure.

Section 764.8 also provides that for a firm to be deemed to have made a voluntary self-disclosure under that section, the individual making the disclosure must do so with the ''full knowledge and authorization of the firm's senior management or of an officer or employee who is authorized to make such disclosures on behalf of the firm.'' BIS believes that approval of a person with such authority is needed to make clear that a firm may not claim the benefits of a voluntary self-disclosure when a subordinate employee acting on his or her own initiative has disclosed wrongdoing. The proposed rule did not include the phrase ''or of an officer or employee who is authorized to make such disclosures on behalf of the firm.'' Upon review, BIS does not believe that knowledge and approval of ''senior management'' are needed so long as someone with authority to make such disclosures on behalf of the firm has approved the disclosure on behalf of the firm.

Creation of Supplement No. 2 to Part 766

This rule creates a new supplement to part 766 of the EAR to set forth publicly BIS's practice with respect to violations of the antiboycott provisions. The supplement describes the ways that BIS responds to violations, the types of administrative sanctions that may be imposed for violations, the factors that BIS considers in determining what sanctions are appropriate, the factors that BIS considers in determining the appropriate scope of the denial or exclusion order sanctions, and the factors BIS considers when deciding whether to suspend a sanction.

Paragraph (a) of the supplement contains introductory material that defines the scope and limitations of the supplement as well as sets forth BIS's policy of encouraging any party in settlement negotiations with BIS to provide all information that the party believes is relevant to the application of the guidance in the supplement as well as information that is relevant to determining whether a violation has, in fact, occurred and whether the party has a defense to any potential charges.

Paragraph (b) of the supplement sets forth the three actions that BIS may take in response to a violation, namely, issuing a warning letter, pursuing an administrative case, and referring a case to the Department of Justice for criminal prosecution. This paragraph also lists the factors that often cause BIS to issue a warning letter. Additionally, it notes BIS's ability to issue *proposed* administrative charging letters rather than actual administrative charging letters. Proposed charging letters are issued informally to provide an opportunity for settlement before initiation of a formal administrative proceeding. As noted in paragraph (b), BIS is not required to issue a proposed charging letter. Finally, paragraph (b) notes that BIS may refer a case to the Department of Justice for criminal

prosecution in addition to pursuing an administrative enforcement action.

Paragraph (c) of the supplement lists the types of administrative sanctions that may be imposed in antiboycott administrative enforcement cases. Those sanctions are: A monetary penalty, a denial of export privileges and an order excluding the party from practice before BIS.

Paragraph (d) provides information about how BIS determines what sanctions are appropriate in settlement of antiboycott administrative enforcement cases. The paragraph describes the general factors that BIS believes are important in cases concerning violations of the antiboycott provisions. The paragraph then describes specific mitigating and aggravating factors. BIS typically looks to the presence or absence of the specific factors, alongside the general factors, in determining what sanctions should apply in a given settlement.

Paragraph (d) begins by listing seven general factors to which BIS looks in determining what administrative sanctions are appropriate in each settlement. Those seven general factors are: Degree of seriousness, category of violation, whether multiple violations arise from related transactions, whether multiple violations arise from unrelated transactions, the timing of a settlement, whether there are related civil or criminal violations, and the party's familiarity with the antiboycott provisions. The supplement provides general guidance on how BIS applies each of these seven general factors.

Paragraph (d) then addresses the role of eight specific mitigating and nine specific aggravating factors whose presence or absence BIS generally considers when determining what sanctions should apply. The listed factors are not exhaustive and BIS may consider other factors as well in a particular case. However, the listed factors are those that BIS's experience indicates are commonly relevant to penalty determinations in cases that are settled. Factors identified by the term ''GREAT WEIGHT'' will ordinarily be given considerably more weight than other factors.

The eight specific mitigating factors in paragraph (d) are: Voluntary self-disclosure, effective compliance program, limited business with or in boycotted or boycotting countries, history of compliance with the antiboycott provisions, exceptional cooperation with the investigation, (lack of) clarity of request to furnish prohibited information or take prohibited action, violations arising out of a party's ''passive'' refusal to do business in connection with an agreement, and isolated occurrence. The proposed rule contained a statement in paragraph (d)(2)(i)(B)(*2*), to the effect that deliberate or intentional destruction of records may be an issue in settlement. Paragraph (d)(2)(i)(B)(*2*) is part of a discussion of mitigating factors of great weight. Upon review BIS removed the sentence about intentional or deliberate destruction of records because it pertains to aggravating factors and would be subsumed in the serious disregard for compliance issues provision in paragraph (d)(2)(ii)(B).

The nine specific aggravating factors in paragraph (d) are: Concealment or obstruction, serious disregard for compliance responsibilities, history of (lack of) compliance with the antiboycott provisions, familiarity with the type of transaction at issue in the violation, prior history of business with or in boycotted countries or boycotting countries, long duration or high frequency of violations, clarity of request to furnish prohibited information or take prohibited action, violation relating to information concerning a specific individual or entity, and violations relating to ''active'' conduct concerning an agreement to refuse to do business.

The specific mitigating and aggravating factors are set forth in more detail in the supplement. BIS believes that in most cases evaluating these factors provides a fair basis for determining the penalty that is appropriate when settling an antiboycott administrative enforcement case. However, these mitigating and aggravating factors are not exclusive. BIS may consider other factors that are relevant in a particular case and respondents in settlement negotiations may submit other relevant factors for BIS's consideration.

Paragraph (e) sets forth the factors that BIS considers to be particularly relevant when deciding whether to impose a denial or exclusion order in the settlement of antiboycott administrative enforcement cases. Certain factors in paragraph (d)—the four factors that are given great weight, degree of seriousness, and history of prior violations and their seriousness—are included in paragraph (e). In addition, BIS considers the extent to which a firm's senior management participated in or was aware of the conduct that gave rise to the violation, the likelihood of future violations, and whether a monetary penalty could be expected to have a sufficient deterrent effect to be particularly relevant in determining whether a monetary penalty is appropriate.

Paragraph (f) provides examples of factors that BIS may consider in deciding whether to suspend or defer a monetary penalty or suspend an order denying export privileges or an order providing for exclusion from practice. With respect to suspension or deferral of monetary penalties, BIS may consider whether the party has demonstrated a limited ability to pay a penalty that would be appropriate for such violation so that suspended or deferred payment can be expected to have sufficient deterrent value, and whether the impact of the penalty would be consistent with the impact of penalties on other parties who commit similar violations. When deciding whether to suspend denial or exclusion orders, BIS may consider the adverse economic consequences of the order on the party, its employees, and other persons, as well as on the national interest in the competitiveness of U.S. businesses. However, such orders will be suspended for adverse economic consequences only if future violations are unlikely and if there are adequate measures (usually a substantial civil penalty) to achieve the necessary deterrent effect.

Rulemaking Requirements

1. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid Office of Management and Budget Control Number. This rule contains a new collection of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) that has been approved by the Office of Management and Budget under control number 0694–0132 which carries a burden hour estimate of 1,280 and a cost estimate of $51,200.

Send comments about this collection, including suggestions for reducing the burden, to David Rostker, Office of Management and Budget, by e-mail to *David_Rostker@omb.eop.gov*, or by fax to (202) 395–7285; and to the Office of Administration, Bureau of Industry and Security, Department of Commerce, 14th and Pennsylvania Avenue, NW., Room 6883, Washington, DC 20230.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The Chief Counsel for Regulation at the Department of Commerce certified

to the Chief Counsel for Advocacy at the Small Business Administration that this rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis was published in the proposed rule and is not repeated here. BIS received only one comment that addressed the economic impact of this rule. That comment addressed the rule's economic impact on large businesses with multiple operating units in many countries and did not address the rule's impact on small entities. BIS has included that comment in its Paperwork Reduction Act submission to OMB and addressed it under the heading ''Comment on Paperwork Burden'' earlier in this preamble. Therefore, BIS has not prepared a final regulatory flexibility analysis for this rule.

List of Subjects

15 CFR Part 730

Administrative practice and procedure, Advisory committees, Exports, Reporting and recordkeeping requirements, Strategic and critical materials.

15 CFR Part 764

Administrative practice and procedure, Exports, Law enforcement, Penalties.

15 CFR Part 766

Administrative practice and procedure, Confidential business information, Exports, Law enforcement, Penalties.

■ For the reasons set forth above, the Export Administration Regulations (15 CFR 730–774) are amended as follows:

PART 730—[AMENDED]

■ 1. The authority citation for part 730 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note, Pub. L. 108–175; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 12002, 42 FR 35623, 3 CFR, 1977 Comp., p.133; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12214, 45 FR 29783, 3 CFR, 1980 Comp., p. 256; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 179; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 12981, 60 FR 62981, 3 CFR, 1995 Comp., p. 419; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp. p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; E.O. 13338, 69 FR 26751, May 13, 2004; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of October 27, 2006, 71 FR 64109 (October 31, 2006).

■ 2. In Supp. No. 1 to part 730, add a new row to the table of approved information collections immediately following the row that begins with ''0694–0129'' and immediately preceding the row that begins with ''0607–0152'' to read as follows:

Supplement No. 1 to Part 730—Information Collection Requirements Under the Paperwork Reduction Act: OMB Control Numbers

* * * * *

Collection No.	Title	Reference in the EAR
* * *	* *	* *
0694–0132	Voluntary Self-Disclosure of Antiboycott Violations ...	§ 764.8.
* * *	* *	* *

PART 764—[AMENDED]

■ 3. The authority citation for part 764 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006).

■ 4. Add a new § 764.8 to read as follows:

§ 764.8 Voluntary self-disclosures for boycott violations.

This section sets forth procedures for disclosing violations of part 760 of the EAR—Restrictive Trade Practices or Boycotts and violations of part 762—Recordkeeping—with respect to records related to part 760. In this section, these provisions are referred to collectively as the ''antiboycott provisions.'' This section also describes BIS's policy regarding such disclosures.

(a) *General policy.* BIS strongly encourages disclosure to the Office of Antiboycott Compliance (OAC) if you believe that you may have violated the antiboycott provisions. Voluntary self-disclosures are a mitigating factor with respect to any enforcement action that OAC might take.

(b) *Limitations.* (1) This section does not apply to disclosures of violations relating to provisions of the EAR other than the antiboycott provisions. Section 764.5 of this part describes how to prepare disclosures of violations of the EAR other than the antiboycott provisions.

(2) The provisions of this section apply only when information is provided to OAC for its review in determining whether to take administrative action under parts 764 and 766 of the EAR for violations of the antiboycott provisions.

(3) *Timing.* The provisions of this section apply only if OAC receives the voluntary self-disclosure as described in paragraph (c)(2) of this section before it commences an investigation or inquiry in connection with the same or substantially similar information it received from another source.

(i) *Mandatory Reports.* For purposes of this section, OAC's receipt of a report required to be filed under § 760.5 of the EAR that discloses that a person took an action prohibited by part 760 of the EAR constitutes the receipt of information from another source.

(ii) *Requests for Advice.* For purposes of this section, a violation that is revealed to OAC by a person who is seeking advice, either by telephone or e-mail, about the antiboycott provisions does not constitute the receipt of information from another source. Such revelation also does not constitute a voluntary self-disclosure or initial notification of a voluntary self-disclosure for purposes of this section.

(4) Although a voluntary self-disclosure is a mitigating factor in determining what administrative sanctions, if any, will be sought by BIS, it is a factor that is considered together with all other factors in a case. The weight given to voluntary self-disclosure is solely within the discretion of BIS, and the mitigating effect of voluntary self-disclosure may be outweighed by aggravating factors. Voluntary self-disclosure does not

prevent transactions from being referred to the Department of Justice for criminal prosecution. In such a case, BIS would notify the Department of Justice of the voluntary self-disclosure, but the decision as to how to consider that factor is within the discretion of the Department of Justice.

(5) A firm will not be deemed to have made a disclosure under this section unless the individual making the disclosure did so with the full knowledge and authorization of the firm's senior management or of a person with authority to make such disclosures on behalf of the firm.

(6) The provisions of this section do not, nor should they be relied on to, create, confer, or grant any rights, benefits, privileges, or protection enforceable at law or in equity by any person, business, or entity in any civil, criminal, administrative, or other matter.

(c) *Information to be provided.* (1) *General.* Any person wanting to disclose information that constitutes a voluntary self-disclosure should, in the manner outlined below, initially notify OAC as soon as possible after violations are discovered, and then conduct a thorough review of all transactions where violations of the antiboycott provisions are suspected.

(2) *Initial notification.* The initial notification must be in writing and be sent to the address in § 764.8(c)(7) of this part. The notification should include the name of the person making the disclosure and a brief description of the suspected violations. The notification should describe the general nature and extent of the violations. If the person making the disclosure subsequently completes the narrative account required by § 764.8(c)(3) of this part, the disclosure will be deemed to have been made on the date of the initial notification for purposes of § 764.8(b)(3) of this part.

(3) *Narrative account.* After the initial notification, a thorough review should be conducted of all business transactions where possible antiboycott provision violations are suspected. OAC recommends that the review cover a period of five years prior to the date of the initial notification. If your review goes back less than five years, you risk failing to discover violations that may later become the subject of an investigation. Any violations not voluntarily disclosed do not receive the same mitigation as the violations voluntarily self-disclosed under this section. However, the failure to make such disclosures will not be treated as a separate violation unless some other section of the EAR or other provision of law enforced by BIS requires disclosure. Upon completion of the review, OAC should be furnished with a narrative account that sufficiently describes the suspected violations so that their nature and gravity can be assessed. The narrative account should also describe the nature of the review conducted and measures that may have been taken to minimize the likelihood that violations will occur in the future. The narrative account should include:

(i) The kind of violation involved, for example, the furnishing of a certificate indicating that the goods supplied did not originate in a boycotted country;

(ii) An explanation of when and how the violations occurred, including a description of activities surrounding the violations (*e.g.*, contract negotiations, sale of goods, implementation of letter of credit, bid solicitation);

(iii) The complete identities and addresses of all individuals and organizations, whether foreign or domestic, involved in the activities giving rise to the violations; and

(iv) A description of any mitigating factors.

(4) Supporting documentation.

(i) The narrative account should be accompanied by copies of documents that explain and support it, including:

(A) Copies of boycott certifications and declarations relating to the violation, or copies of documents containing prohibited language or prohibited requests for information;

(B) Other documents relating to the violation, such as letters, facsimiles, telexes and other evidence of written or oral communications, negotiations, internal memoranda, purchase orders, invoices, bid requests, letters of credit and brochures;

(ii) Any relevant documents not attached to the narrative account must be retained by the person making the disclosure until the latest of the following: the documents are supplied to OAC; BIS informs the disclosing party that it will take no action; BIS issues a warning letter for the violation; BIS issues an order that constitutes the final agency action in the matter and all avenues for appeal are exhausted; or the documents are no longer required to be kept under part 762 of the EAR.

(5) *Certification.* A certification must be submitted stating that all of the representations made in connection with the voluntary self-disclosure are true and correct to the best of that person's knowledge and belief. Certifications made by a corporation or other organization should be signed by an official of the corporation or other organization with the authority to do so. Section 764.2(g) of this part relating to false or misleading representations applies in connection with the disclosure of information under this section.

(6) *Oral presentations.* OAC believes that oral presentations are generally not necessary to augment the written narrative account and supporting documentation. If the person making the disclosure believes otherwise, a request for a meeting should be included with the disclosure.

(7) *Where to make voluntary self-disclosures.* The information constituting a voluntary self-disclosure or any other correspondence pertaining to a voluntary self-disclosure should be submitted to: Office of Antiboycott Compliance, 14th and Pennsylvania Ave., NW., Room 6098, Washington, DC 20230, tel: (202) 482–2381, facsimile: (202) 482–0913.

(d) *Action by the Office of Antiboycott Compliance.* After OAC has been provided with the required narrative and supporting documentation, it will acknowledge the disclosure by letter, provide the person making the disclosure with a point of contact, and take whatever additional action, including further investigation, it deems appropriate. As quickly as the facts and circumstances of a given case permit, BIS may take any of the following actions:

(1) Inform the person making the disclosure that, based on the facts disclosed, it plans to take no action;

(2) Issue a warning letter;

(3) Issue a proposed charging letter and attempt to settle the matter pursuant to § 766.18 of the EAR;

(4) Issue a charging letter pursuant to § 766.3 of the EAR if a settlement is not reached or BIS otherwise deems appropriate; and/or

(5) Refer the matter to the Department of Justice for criminal prosecution.

(e) *Criteria.* Supplement No. 2 to part 766 of the EAR describes how BIS typically exercises its discretion regarding whether to pursue an antiboycott administrative enforcement case under part 766 and what administrative sanctions to seek in settling such a case.

PART 766—[AMENDED]

■ 5. The authority citation for part 766 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006).

■ 6. In § 766.3, paragraph (a) the second sentence is revised to read as follows:

§ 766.3 Institution of administrative enforcement proceedings.

(a) *Charging letters.* * * * Supplements Nos. 1 and 2 to this part describe how BIS typically exercises its discretion regarding the issuance of charging letters. * * *

* * * * *

■ 5. In § 766.18 paragraph (f) is revised to read as follows:

§ 766.18 Settlement.

* * * * *

(f) Supplements Nos. 1 and 2 to this part describe how BIS typically exercises its discretion regarding the terms under which it is willing to settle particular cases.

■ 6. Add Supplement No. 2 to part 766 to read as follows:

Supplement No. 2 to Part 766—Guidance on Charging and Penalty Determinations in Settlement of Administrative Enforcement Cases Involving Antiboycott Matters

(a) *Introduction.*

(1) *Scope.* This Supplement describes how the Office of Antiboycott Compliance (OAC) responds to violations of part 760 of the EAR ''Restrictive Trade Practices or Boycotts'' and to violations of part 762 ''Recordkeeping'' when the recordkeeping requirement pertains to part 760 (together referred to in this supplement as the ''antiboycott provisions''). It also describes how BIS makes penalty determinations in the settlement of administrative enforcement cases brought under parts 764 and 766 of the EAR involving violations of the antiboycott provisions. This supplement does not apply to enforcement cases for violations of other provisions of the EAR.

(2) *Policy Regarding Settlement.* Because many administrative enforcement cases are resolved through settlement, the process of settling such cases is integral to the enforcement program. BIS carefully considers each settlement offer in light of the facts and circumstances of the case, relevant precedent, and BIS's objective to achieve in each case an appropriate level of penalty and deterrent effect. In settlement negotiations, BIS encourages parties to provide, and will give serious consideration to, information and evidence that the parties believe is relevant to the application of this guidance to their cases, to whether a violation has in fact occurred, and to whether they have a defense to potential charges.

(3) *Limitation.* BIS's policy and practice is to treat similarly situated cases similarly, taking into consideration that the facts and combination of mitigating and aggravating factors are different in each case. However, this guidance does not confer any right or impose any obligation regarding what posture or penalties BIS may seek in settling or litigating a case. Parties do not have a right to a settlement offer or particular settlement terms from BIS, regardless of settlement postures BIS has taken in other cases.

(b) *Responding to Violations.* OAC within BIS investigates possible violations of Section 8 of the Export Administration Act of 1979, as amended (''Foreign Boycotts''), the antiboycott provisions of EAR, or any order or authorization related thereto. When BIS has reason to believe that such a violation has occurred, BIS may issue a warning letter or initiate an administrative enforcement proceeding. A violation may also be referred to the Department of Justice for criminal prosecution.

(1) *Issuing a warning letter.* Warning letters represent BIS's belief that a violation has occurred. In the exercise of its discretion, BIS may determine in certain instances that issuing a warning letter, instead of bringing an administrative enforcement proceeding, will fulfill the appropriate enforcement objective. A warning letter will fully explain the violation.

(i) BIS may issue warning letters where:

(A) The investigation commenced as a result of a voluntary self-disclosure satisfying the requirements of § 764.8 of the EAR; or

(B) The party has not previously committed violations of the antiboycott provisions.

(ii) BIS may also consider the category of violation as discussed in paragraph (d)(2) of this supplement in determining whether to issue a warning letter or initiate an enforcement proceeding. A violation covered by Category C (failure to report or late reporting of receipt of boycott requests) might warrant a warning letter rather than initiation of an enforcement proceeding.

(iii) BIS will not issue a warning letter if it concludes, based on available information, that a violation did not occur.

(iv) BIS may reopen its investigation of a matter should it receive additional evidence or if it appears that information previously provided to BIS during the course of its investigation was incorrect.

(2) *Pursuing an administrative enforcement case.* The issuance of a charging letter under § 766.3 of this part initiates an administrative proceeding.

(i) Charging letters may be issued when there is reason to believe that a violation has occurred. Cases may be settled before or after the issuance of a charging letter. *See* § 766.18 of this part.

(ii) Although not required to do so by law, BIS may send a proposed charging letter to a party to inform the party of the violations that BIS has reason to believe occurred and how BIS expects that those violations would be charged. Issuance of the proposed charging letter provides an opportunity for the party and BIS to consider settlement of the case prior to the initiation of formal enforcement proceedings.

(3) *Referring for criminal prosecution.* In appropriate cases, BIS may refer a case to the Department of Justice for criminal prosecution, in addition to pursuing an administrative enforcement action.

(c) *Types of administrative sanctions.* Administrative enforcement cases generally are settled on terms that include one or more of three administrative sanctions:

(1) A monetary penalty may be assessed for each violation as provided in § 764.3(a)(1) of the EAR;

Note to paragraph (c)(1): The maximum penalty is subject to adjustments under the Federal Civil Penalties Adjustment Act of 1990 (28 U.S.C. 2461, note (2000)), which are codified at 15 CFR 6.4. For violations that occurred before March 9, 2006, the maximum monetary penalty per violation is $11,000. For violations occurring on or after March 9, 2006, the maximum monetary penalty per violation is $50,000.

(2) An order denying a party's export privileges under the EAR may be issued, under § 764.3(a)(2) of the EAR; or

(3) Exclusion from practice under § 764.3(a)(3) of the EAR.

(d) *How BIS determines what sanctions are appropriate in a settlement.*

(1) *General Factors.* BIS looks to the following general factors in determining what administrative sanctions are appropriate in each settlement.

(i) *Degree of seriousness.* In order to violate the antiboycott provisions of the EAR, a U.S. person does not need to have actual ''knowledge'' or a reason to know, as that term is defined in § 772.1 of the EAR, of relevant U.S. laws and regulations. Typically, in cases that do not involve knowing violations, BIS will seek a settlement for payment of a civil penalty (unless the matter is resolved with a warning letter). However, in cases involving knowing violations, conscious disregard of the antiboycott provisions, or other such serious violations (*e.g.,* furnishing prohibited information in response to a boycott questionnaire with knowledge that such furnishing is in violation of the EAR), BIS is more likely to seek a denial of export privileges or an exclusion from practice, and/or a greater monetary penalty as BIS considers such violations particularly egregious.

(ii) *Category of violations.* In connection with its activities described in paragraph (a)(1) of this supplement, BIS recognizes three categories of violations under the antiboycott provisions of the EAR. (*See* § 760.2, § 760.4 and § 760.5 of the EAR for examples of each type of violation other than recordkeeping). These categories reflect the relative seriousness of a violation, with Category A violations typically warranting the most stringent penalties, including up to the maximum monetary penalty, a denial order and/or an exclusion order. Through providing these categories in this penalty guidelines notice, BIS hopes to give parties a general sense of how it views the seriousness of various violations. This guidance, however, does not confer any right or impose any obligation as to what penalties BIS may impose based on its review of the specific facts of a case.

(A) The Category A violations and the sections of the EAR that set forth their elements are:

(*1*) Discriminating against U.S. persons on the basis of race, religion, sex, or national origin—§ 760.2(b);

(*2*) Refusing to do business or agreeing to refuse to do business—§ 760.2(a);

(*3*) Furnishing information about race, religion, sex, or national origin of U.S. persons including, but not limited to, providing information in connection with a boycott questionnaire about the religion of employees—§ 760.2(c);

(*4*) Evading the provisions of part 760—§ 760.4;

(*5*) Furnishing information about business relationships with boycotted countries or blacklisted persons—§ 760.2(d); and

(*6*) Implementing letters of credit—§ 760.2(f).

(B) The Category B violations and the sections of the EAR that set forth their elements are:

(*1*) Furnishing information about associations with charitable or fraternal organizations which support a boycotted country—§ 760.2(e); and

(*2*) Making recordkeeping violations—part 762.

(C) The Category C violation and the section of the EAR that sets forth its elements is: Failing to report timely receipt of boycott requests—§ 760.5.

(iii) *Violations arising out of related transactions.* Frequently, a single transaction can give rise to multiple violations. Depending on the facts and circumstances, BIS may choose to impose a smaller or greater penalty per violation. In exercising its discretion, BIS typically looks to factors such as whether the violations resulted from conscious disregard of the requirements of the antiboycott provisions; whether they stemmed from the same underlying error or omission; and whether they resulted in distinguishable or separate harm. The three scenarios set forth below are illustrative of how BIS might view transactions that lead to multiple violations.

(A) *First scenario.* An exporter enters into a sales agreement with a company in a boycotting country. In the course of the negotiations, the company sends the exporter a request for a signed statement certifying that the goods to be supplied do not originate in a boycotted country. The exporter provides the signed certification. Subsequently, the exporter fails to report the receipt of the request. The exporter has committed two violations of the antiboycott provisions, first, a violation of § 760.2(d) for furnishing information concerning the past or present business relationships with or in a boycotted country, and second, a violation of § 760.5 for failure to report the receipt of a request to engage in a restrictive trade practice or boycott. Although the supplier has committed two violations, BIS may impose a smaller mitigated penalty on a per violation basis than if the violations had stemmed from two separate transactions.

(B) *Second scenario.* An exporter receives a boycott request to provide a statement that the goods at issue in a sales transaction do not contain raw materials from a boycotted country and to include the signed statement along with the invoice. The goods are shipped in ten separate shipments. Each shipment includes a copy of the invoice and a copy of the signed boycott-related statement. Each signed statement is a certification that has been furnished in violation of § 760.2(d)'s bar on the furnishing of prohibited business information. Technically, the exporter has committed ten separate violations of § 760.2(d) and one violation of § 760.5 for failure to report receipt of the boycott request. Given that the violations arose from a single boycott request, however, BIS may treat the violations as related and impose a smaller penalty than it would if the furnishing had stemmed from ten separate requests.

(C) *Third scenario.* An exporter has an ongoing relationship with a company in a boycotting country. The company places three separate orders for goods on different dates with the exporter. In connection with each order, the company requests the exporter to provide a signed statement certifying that the goods to be supplied do not originate in a boycotted country. The exporter provides a signed certification with each order of goods that it ships to the company. BIS has the discretion to penalize the furnishing of each of these three items of information as a separate violation of § 760.2(d) of the EAR for furnishing information concerning past or present business relationships with or in a boycotted country.

(iv) *Multiple violations from unrelated transactions.* In cases involving multiple unrelated violations, BIS is more likely to seek a denial of export privileges, an exclusion from practice, and/or a greater monetary penalty than in cases involving isolated incidents. For example, the repeated furnishing of prohibited boycott-related information about business relationships with or in boycotted countries during a long period of time could warrant a denial order, even if a single instance of furnishing such information might warrant only a monetary penalty. BIS takes this approach because multiple violations may indicate serious compliance problems and a resulting risk of future violations. BIS may consider whether a party has taken effective steps to address compliance concerns in determining whether multiple violations warrant a denial or exclusion order in a particular case.

(v) *Timing of settlement.* Under § 766.18 of this part, settlement can occur before a charging letter is served, while a case is before an administrative law judge, or while a case is before the Under Secretary for Industry and Security under § 766.22 of this part. However, early settlement—for example, before a charging letter has been filed—has the benefit of freeing resources for BIS to deploy in other matters. In contrast, for example, the BIS resources saved by settlement on the eve of an adversary hearing under § 766.13 of this part are fewer, insofar as BIS has already expended significant resources on discovery, motions practice, and trial preparation. Given the importance of allocating BIS resources to maximize enforcement of the EAR, BIS has an interest in encouraging early settlement and will take this interest into account in determining settlement terms.

(vi) *Related criminal or civil violations.* Where an administrative enforcement matter under the antiboycott provisions involves conduct giving rise to related criminal charges, BIS may take into account the related violations and their resolution in determining what administrative sanctions are appropriate under part 766 of the EAR. A criminal conviction indicates serious, willful misconduct and an accordingly high risk of future violations, absent effective administrative sanctions. However, entry of a guilty plea can be a sign that a party accepts responsibility for complying with the antiboycott provisions and will take greater care to do so in the future. In appropriate cases where a party is receiving substantial criminal penalties, BIS may find that sufficient deterrence may be achieved by lesser administrative sanctions than would be appropriate in the absence of criminal penalties. Conversely, BIS might seek greater administrative sanctions in an otherwise similar case where a party is not subjected to criminal penalties. The presence of a related criminal or civil disposition may distinguish settlements among civil penalty cases that appear to be otherwise similar. As a result, the factors set forth for consideration in civil penalty settlements will often be applied differently in the context of a ''global settlement'' of both civil and criminal cases, or multiple civil cases involving other agencies, and may therefore be of limited utility as precedent for future cases, particularly those not involving a global settlement.

(vii) *Familiarity with the Antiboycott Provisions.* Given the scope and detailed nature of the antiboycott provisions, BIS will consider whether a party is an experienced participant in the international business arena who may possess (or ought to possess) familiarity with the antiboycott laws. In this respect, the size of the party's business, the presence or absence of a legal division or corporate compliance program, and the extent of prior involvement in business with or in boycotted or boycotting countries, may be significant.

(2) *Specific mitigating and aggravating factors.* In addition to the general factors described in paragraph (d)(1) of this supplement, BIS also generally looks to the presence or absence of the specific mitigating and aggravating factors in this paragraph in determining what sanctions should apply in a given settlement. These factors describe circumstances that, in BIS's experience, are commonly relevant to penalty determinations in settled cases. However, this listing of factors is not exhaustive and BIS may consider other factors that may further indicate the blameworthiness of a party's conduct, the actual or potential harm associated with a violation, the likelihood of future violations, and/or other considerations relevant to determining what sanctions are appropriate. The assignment of mitigating or aggravating factors will depend upon the attendant circumstances of the party's conduct. Thus, for example, one prior violation should be given less weight than a history of multiple violations, and a previous violation reported in a voluntary self-disclosure by a party whose overall compliance efforts are of high quality should be given less weight than previous violation(s) not involving such mitigating factors. Some of the mitigating factors listed in this paragraph are designated as having ''great weight.'' When present, such a factor should ordinarily be given considerably more weight than a factor that is not so designated.

(i) *Specific mitigating factors.*

(A) *Voluntary self-disclosure.* (GREAT WEIGHT) The party has made a voluntary self-disclosure of the violation, satisfying the requirements of § 764.8 of the EAR.

(B) *Effective compliance program.* (GREAT WEIGHT)

(*1*) *General policy or program pertaining to Antiboycott Provisions.* BIS will consider whether a party's compliance efforts uncovered a problem, thereby preventing further violations, and whether the party has taken steps to address compliance concerns raised by the violation, including steps to prevent recurrence of the violation, that are reasonably calculated to be effective. The focus is on the party's demonstrated compliance with the antiboycott provisions. Whether a party has an effective export compliance program covering other provisions of the EAR is not relevant as a mitigating factor. In the case of a party that has done previous business with or in boycotted countries or boycotting countries, BIS will examine whether the party has an effective antiboycott compliance program and whether its overall antiboycott compliance efforts have been of high quality. BIS may deem it appropriate to review the party's internal business documents relating to antiboycott compliance (*e.g.*, corporate compliance manuals, employee training materials).

(*2*) *Compliance with reporting and recordkeeping requirements.* In the case of a party that has received reportable boycott requests in the past, BIS may examine whether the party complied with the reporting and recordkeeping requirements of the antiboycott provisions.

(C) *Limited business with or in boycotted or boycotting countries.* The party has had little to no previous experience in conducting business with or in boycotted or boycotting countries. Prior to the current enforcement proceeding, the party had not engaged in business with or in such countries, or had only transacted such business on isolated occasions. BIS may examine the volume of business that the party has conducted with or in boycotted or boycotting countries as demonstrated by the size and dollar amount of transactions or the percentage of a party's overall business that such business constitutes.

(D) *History of compliance with the Antiboycott Provisions of the EAR.*

(*1*) BIS will consider it to be a mitigating factor if:

(*i*) The party has never been convicted of a criminal violation of the antiboycott provisions;

(*ii*) In the past 5 years, the party has not entered into a settlement or been found liable in a boycott-related administrative enforcement case with BIS or another U.S. government agency;

(*iii*) In the past 3 years, the party has not received a warning letter from BIS relating to the antiboycott provisions; or

(*iv*) In the past 5 years, the party has not otherwise violated the antiboycott provisions.

(*2*) Where necessary to ensure effective enforcement, the prior involvement in violations of the antiboycott provisions of a party's owners, directors, officers, partners, or other related persons may be imputed to a party in determining whether these criteria are satisfied. When an acquiring firm takes reasonable steps to uncover, correct, and disclose to BIS conduct that gave rise to violations that the acquired business committed before the acquisition, BIS typically will not take such violations into account in applying this factor in settling other violations by the acquiring firm.

(E) *Exceptional cooperation with the investigation.* The party has provided exceptional cooperation to OAC during the course of the investigation.

(F) *Clarity of request to furnish prohibited information or take prohibited action.* The party responded to a request to furnish information or take action that was ambiguously worded or vague.

(G) *Violations arising out of a party's ''passive'' refusal to do business in connection with an agreement.* The party has acquiesced in or abided by terms or conditions that constitute a prohibited refusal to do business (*e.g.*, responded to a tender document that contains prohibited language by sending a bid). *See* ''active'' agreements to refuse to do business in paragraph (d)(2)(ii)(I) of this supplement.

(H) *Isolated occurrence of violation.* The violation was an isolated occurrence. (Compare to long duration or high frequency of violations as an aggravating factor in paragraph (d)(2)(ii)(F) of this supplement.)

(ii) *Specific Aggravating Factors.*

(A) *Concealment or obstruction.* The party made a deliberate effort to hide or conceal the violation. (GREAT WEIGHT)

(B) *Serious disregard for compliance responsibilities.* (GREAT WEIGHT] There is evidence that the party's conduct demonstrated a serious disregard for responsibilities associated with compliance with the antiboycott provisions (*e.g.:* knowing violation of party's own compliance policy or evidence that a party chose to treat potential penalties as a cost of doing business rather than develop a compliance policy).

(C) *History of compliance with the Antiboycott Provisions.*

(*1*) BIS will consider it to be an aggravating factor if:

(*i*) The party has been convicted of a criminal violation of the antiboycott provisions;

(*ii*) In the past 5 years, the party has entered into a settlement or been found liable in a boycott-related administrative enforcement case with BIS or another U.S. government agency;

(*iii*) In the past 3 years, the party has received a warning letter from BIS relating to the antiboycott provisions; or

(*iv*) In the past 5 years, the party has otherwise violated the antiboycott provisions.

(*2*) Where necessary to ensure effective enforcement, the prior involvement in violations of the antiboycott provisions of a party's owners, directors, officers, partners, or other related persons may be imputed to a party in determining whether these criteria are satisfied.

(*3*) When an acquiring firm takes reasonable steps to uncover, correct, and disclose to BIS conduct that gave rise to violations that the acquired firm committed before being acquired, BIS typically will not take such violations into account in applying this factor in settling other violations by the acquiring firm.

(D) *Familiarity with the type of transaction at issue in the violation.* For example, in the case of a violation involving a letter of credit or related financial document, the party routinely pays, negotiates, confirms, or otherwise implements letters of credit or related financial documents in the course of its standard business practices.

(E) *Prior history of business with or in boycotted countries or boycotting countries.* The party has a prior history of conducting business with or in boycotted and boycotting countries. BIS may examine the volume of business that the party has conducted with or in boycotted and boycotting countries as reflected by the size and dollar amount of transactions or the percentage of a party's overall business that such business constitutes.

(F) *Long duration or high frequency of violations.* Violations that occur at frequent intervals or repeated violations occurring over an extended period of time may be treated more seriously than a single violation or related violations that are committed within a brief period of time, particularly if the violations are committed by a party with a history of business with or in boycotted and boycotting countries. (Compare to isolated occurrence of violation in paragraph (d)(2)(i)(H) of this supplement.)

(G) *Clarity of request to furnish prohibited information or take prohibited action.* The request to furnish information or take other prohibited action (*e.g.*, enter into agreement to refuse to do business with a boycotted country or entity blacklisted by a boycotting country) is facially clear as to its intended purpose.

(H) *Violation relating to specific information concerning an individual entity or individual.* The party has furnished prohibited information about business relationships with specific companies or individuals.

(I) *Violations relating to ''active'' conduct concerning an agreement to refuse to do business.* The party has taken action that involves altering, editing, or enhancing prohibited terms or language in an agreement to refuse to do business, including a letter of credit, or drafting a clause or provision including prohibited terms or language in the course of negotiating an agreement to refuse to do business, including a letter of credit. *See* ''passive'' agreements to refuse to do business in paragraph (d)(2)(i)(G) of this supplement.

(e) *Determination of Scope of Denial or Exclusion Order.* In deciding whether and what scope of denial or exclusion order is appropriate, the following factors are particularly relevant: The presence of mitigating or aggravating factors of great weight; the degree of seriousness involved; the extent to which senior management participated in or was aware of the conduct in question; the number of violations; the existence and seriousness of prior violations; the likelihood of future violations (taking into account relevant efforts to comply with the antiboycott provisions); and whether a civil monetary penalty can be expected to have a sufficient deterrent effect.

(f) *How BIS Makes Suspension and Deferral Decisions.*

(1) *Civil Penalties.* In appropriate cases, payment of a civil monetary penalty may be

deferred or suspended. See § 764.3(a)(1)(iii) of the EAR. In determining whether suspension or deferral is appropriate, BIS may consider, for example, whether the party has demonstrated a limited ability to pay a penalty that would be appropriate for such violations, so that suspended or deferred payment can be expected to have sufficient deterrent value, and whether, in light of all the circumstances, such suspension or deferral is necessary to make the impact of the penalty consistent with the impact of BIS penalties on other parties who committed similar violations.

(2) *Denial of Export Privileges and Exclusion from Practice.* In deciding whether a denial or exclusion order should be suspended, BIS may consider, for example, the adverse economic consequences of the order on the party, its employees, and other persons, as well as on the national interest in maintaining or promoting the competitiveness of U.S. businesses. An otherwise appropriate denial or exclusion order will be suspended on the basis of adverse economic consequences only if it is found that future violations of the antiboycott provisions are unlikely and if there are adequate measures (usually a substantial civil monetary penalty) to achieve the necessary deterrent effect.

Dated: July 9, 2007.

Christopher A. Padilla,

Assistant Secretary for Export Administration.

[FR Doc. E7–13717 Filed 7–16–07; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 774

[Docket No. 070426097–7099–01]

RIN 0694–AE02

Export Licensing Jurisdiction for Microelectronic Circuits

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule provides clarifying guidance for distinguishing the export and reexport licensing jurisdiction of the U.S. Department of State from that of the U.S. Department of Commerce concerning microelectronic circuits. In this same issue of the **Federal Register**, the U.S. Department of State is amending the International Traffic in Arms Regulations (ITAR) with respect to radiation-hardened microelectronic circuits in Category XV(d) of the United States Munitions List (USML). The Bureau of Industry and Security (BIS) is publishing this rule to assist readers of the Export Administration Regulations (EAR) in evaluating agency licensing jurisdiction over microelectronic circuits while taking into account the new standard in Category XV(d) of the USML.

DATES: *Effective Date:* This rule is effective July 17, 2007.

ADDRESSES: Although this is a final rule, comments are welcome and should be sent to *publiccomments@bis.doc.gov,* fax (202) 482–3355, or to Regulatory Policy Division, Bureau of Industry and Security, Room H2705, U.S. Department of Commerce, Washington, DC 20230. Please refer to regulatory identification number (RIN) 0694–AE02 in all comments, and in the subject line of e-mail comments. Comments on the collection of information should also be sent to David Rostker, Office of Management and Budget (OMB), by e-mail to *David_Rostker@omb.eop.gov*, or by fax to (202) 395–7285.

FOR FURTHER INFORMATION CONTACT: Brian Baker, Deemed Exports and Electronics Division, Office of National Security and Technology Transfer Controls, by telephone at 202–482–5534 or by e-mail at *bbaker@bis.doc.gov.*

SUPPLEMENTARY INFORMATION: Entries for certain Export Control Classification Numbers (ECCNs) contain ''Related Controls'' paragraphs that alert readers to the possible application of export controls administered by other U.S. government agencies or that of export controls set forth in other similar ECCNs. The ''Related Controls'' paragraph of ECCN 3A001 currently provides guidance on the licensing jurisdiction of the Directorate of Defense Trade Controls of the U.S. Department of State with respect to certain ''space qualified'' and certain radiation-hardened commodities.

Concurrent with this final rule, the U.S. Department of State is publishing a final rule amending the ITAR with respect to State's jurisdiction over radiation-hardened microelectronic circuits in Category XV(d) of the USML (22 CFR part 121). Within Category XV(d) of the USML, the U.S. Department of State is changing the measurement for the single event upset rate parameter. As a result, radiation-hardened microelectronic circuits that meet or exceed the four unchanged parameters in Category XV(d) and whose single event upset rate parameter lies between the old and new standard will be moved to the Commerce Control List (CCL) under ECCN 3A001.a.1.

To reflect the new licensing jurisdiction standard in the USML, this rule adds language to the ''Related Controls'' paragraph of ECCN 3A001 to assist readers in correctly determining whether certain microelectronic circuits are covered by the CCL and subject to the licensing jurisdiction of the Bureau of Industry and Security of the U.S. Department of Commerce, or are on the USML and subject to the licensing jurisdiction of the Directorate of Defense Trade Controls of the U.S. Department of State.

Specifically, the language added to ECCN 3A001 states that the following are subject to the licensing jurisdiction of the Department of State, Directorate of Defense Trade Controls: Radiation-hardened microelectronic circuits controlled by Category XV(d) of the United States Munitions List (USML) and all specifically designed or modified systems or subsystems, components, parts, accessories, attachments, and associated equipment controlled by Category XV(e) of the USML.

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as extended by the Notice of August 3, 2006, 71 FR 44551 (August 7, 2006), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act.

Rulemaking Requirements

1. This final rule has been determined to be not significant for purposes of E.O. 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule involves a collection of information subject to the requirements of the PRA. This collection has previously been approved by OMB under control number 0694–0088 (Multi-Purpose Application), which carries a burden hour estimate of 58 minutes to prepare and submit form BIS–748. Miscellaneous and recordkeeping activities account for 12 minutes per submission. BIS expects that this rule will not change that burden hour estimate.

3. This rule does not contain policies with Federalism implications as that term is defined under E.O. 13132.

4. BIS finds that there is good cause under 5 U.S.C. 553 (b)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment

because it is unnecessary. The revisions made by this rule are clarifying in nature and do not affect the rights and obligations of the public because they merely provide a cross reference to related regulations of another administrative agency. Because these revisions are not substantive changes to the EAR, it is unnecessary to provide notice and opportunity for public comment. In addition, the 30-day delay in effectiveness required by 5 U.S.C. 553(d) is not applicable because this rule is not a substantive rule. No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because notice of proposed rulemaking and opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Therefore, this regulation is issued in final form.

List of Subjects in 15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

■ Accordingly, part 774 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 774—[AMENDED]

■ 1. The authority citation for 15 CFR part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*, 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006).

■ 2. In Supplement No. 1 to part 774 (the Commerce Control List), Category 3—Electronics, ECCN 3A001 is amended by adding a note (3) to the ''Related Controls'' paragraph in the ''List of Items Controlled'' section before the phrase ''*See also* 3A101, 3A201, and 3A991'' to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

Category 3—Electronics

* * * * *

3A001 Electronic components, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Unit: * * *

Related Controls: * * * (3) The following commodities are under the export licensing authority of the Department of State, Directorate of Defense Trade Controls (22 CFR part 121): (a) Radiation-hardened microelectronic circuits controlled by Category XV (d) of the United States Munitions List (USML); and (b) All specifically designed or modified systems or subsystems, components, parts, accessories, attachments, and associated equipment controlled by Category XV (e) of the USML. * * *

* * * * *

Dated: July 5, 2007.

Christopher A. Padilla,

Assistant Secretary for Export Administration.

[FR Doc. E7–13364 Filed 7–16–07; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF STATE

22 CFR Part 121

[Public Notice 5867]

Amendment to the International Traffic in Arms Regulations: United States Munitions List

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State, in consultation with the Departments of Defense and Commerce, is amending the text of the United States Munitions List (USML), Category XV—Spacecraft Systems and Associated Equipment to clarify the coverage and to alter one of the five performance characteristics that define radiation-hardened microelectronic circuits that are subject to the licensing jurisdiction of the International Traffic in Arms Regulations (ITAR).

DATES: *Effective Date:* This rule is effective July 17, 2007.

ADDRESSES: Interested parties are invited to submit comments at any time by the following methods:

- *Mail:* Department of State, Directorate of Defense Trade Controls, Office of Defense Trade Controls Policy, ATTN: Regulatory Change, USML Part 121, Category XV, 12th Floor, SA–1, Washington DC 20522–0112.
- *E-mail:* *DTCPResponseTeam@state.gov* with the subject line: USML Review—Category XV.

Persons with access to the Internet may also view this notice by going to the regulations.gov Web site at: *http://www.regulations.gov/index.cfm.* Comments will be accepted at any time.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Tomchik, Office of Defense Trade Controls Policy, Department of State, Telephone (202) 663–2799 or Fax (202) 261–8199. ATTN: Regulatory Change, USML Part 121, Category XV.

SUPPLEMENTARY INFORMATION: The specific results of the Department of State-led interagency review are as follows:

1. Category XV. One substantive change is made to the characteristics defining radiation hardened microelectronic circuits in paragraph (d). The exponential measure describing the single event upset rate described in (d)(4) is changed from 1×10^{-7} to 1×10^{-10}. This change reflects the minimal performance standard for space applications, and addresses the outcome of evolving refinements in the manufacturing process for these circuits.

2. Several additional textual clarifications are made to the five characteristics. The word ''threshold'' is inserted in (d)(2) and (d)(4) for purposes of technical clarity. In (d)(3) the insertion of the expression ''1 MeV Equivalent'' describes the energetic activity of neutrons. Finally, in (d)(4) an expression is added to clarify the representative environment for performance in space.

3. It is stressed that any microelectronic circuit that is specifically designed, developed, configured, adapted, or modified for a military or space application, to include its incorporation into any defense article described on the United States Munitions List (USML) remains subject to the licensing requirements of the International Traffic in Arms Regulations (ITAR).

4. Manufacturers and exporters are responsible for compliance with the controls of this subchapter. Consequently, the Department of State advises that companies must be able to demonstrate, either through testing, statistical analyses, design analyses, or other means, whether semiconductors meet or fail to meet the parameters established in USML Category XV(d). Records of such testing, analyses, or other means must be retained and made available as appropriate to demonstrate compliance.

Regulatory Analysis and Notices

Administrative Procedure Act

This amendment involves a foreign affairs function of the United States and, therefore, is not subject to the procedures required by 5 U.S.C. 553 and 554.

Regulatory Flexibility Act

This rule does not require analysis under the Regulatory Flexibility Act.

Unfunded Mandates Act of 1995

This rule does not require analysis under the Unfunded Mandates Reform Act.

Small Business Regulatory Enforcement Fairness Act of 1996

This amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996. It will not have substantial direct effects on the States, the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Orders 12372 and 13132

It is determined that this rule does not have sufficient federalism implications to warrant application of the consultation provisions of Executive Orders 12372 and 13132.

Executive Order 12866

This amendment is exempt from review under Executive Order 12866, but has been reviewed internally by the Department of State to ensure consistency with the purposes thereof.

Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 121

Arms and munitions, Exports.

■ Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, part 121 is amended as follows:

PART 121—UNITED STATES MUNITIONS LIST

■ 1. The authority citation for part 121 continues to read as follows:

Authority: Sec. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2278, 2797); E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2658; Pub. L. 105–261, 112 Stat. 1920.

■ 2. In § 121.1, paragraph (c), Category XV—Spacecraft Systems and Associated Equipment is amended by revising paragraph (d) to read as follows:

§ 121.1 General. The United States Munition List.

* * * * *

Category XV—Spacecraft Systems and Associated Equipment

* * * * *

(d) Radiation-hardened microelectronic circuits that meet or exceed all five of the following characteristics:

(1) A total dose of 5×10^5 Rads (Si);

(2) A dose rate upset threshold of 5×10^8 Rads (Si)/sec;

(3) A neutron dose of 1×10^{14} n/cm^2 (1 MeV equivalent);

(4) A single event upset rate of 1×10^{-10} errors/bit-day or less, for the CREME96 geosynchronous orbit, Solar Minimum Environment;

(5) Single event latch-up free and having a dose rate latch-up threshold of 5×10^8 Rads (Si).

* * * * *

Dated: July 11, 2007.

Frank J. Ruggiero,

Acting Deputy Assistant Secretary, Political Military Affairs, Department of State.

[FR Doc. E7–13826 Filed 7–16–07; 8:45 am]

BILLING CODE 4710–25–P

POSTAL SERVICE

39 CFR Parts 230, 233, 273

Authority of Office of Inspector General and Postal Inspection Service

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Postal Service is revising portions of title 39, Code of Federal Regulations, to clarify the division of investigatory responsibilities between the Office of the Inspector General of the Postal Service and the Postal Inspection Service.

DATES: Effective July 17, 2007.

FOR FURTHER INFORMATION CONTACT: Gladis C. Griffith, Deputy General Counsel, Office of the Inspector General, United States Postal Service, 703–248–4683.

SUPPLEMENTARY INFORMATION: To promote efficient use of resources, and prevent unnecessary duplication of effort, the Postal Service has determined it is appropriate to clarify the division of investigative authority between the Office of the Inspector General and the Postal Inspection Service. Most notably, it has been determined that the Office of the Inspector General should investigate allegations of violations of postal laws or misconduct by postal employees, including mail theft, and the Inspection Service should investigate allegations of violations or postal laws or misconduct by all other persons. This delineation of responsibilities reflects agreement between the Postmaster General and the Chairman of the Board of Governors.

List of Subjects

39 CFR Part 230

Authority delegations (Government agencies), Freedom of information, Organization and functions (Government agencies), Privacy

39 CFR Part 233

Administrative practice and procedure, Banks, banking, Credit, Crime, Infants and children, Law enforcement, Penalties.

39 CFR part 273

False claims and statements, Law enforcement, Penalties, Program fraud.

■ In view of the considerations discussed above, the Postal Service adopts the following amendments to parts 230, 233, and 273 of title 39 of the Code of Federal Regulations.

PART 230—OFFICE OF INSPECTOR GENERAL

■ 1. The authority citation for part 230 continues to read as follows:

Authority: 5 U.S.C. App. 3; 39 U.S.C. 401(2) and 1001.

■ 2. Section 230.1 is amended by revising paragraph (d) to read as follows:

§ 230.1 Establishment and authority.

* * * * *

(d) The Office of Inspector General is responsible for detecting and preventing fraud, waste, and abuse in the programs and operations of the Postal Service, including, investigating all allegations of violations of postal laws or misconduct by postal employees, including mail theft, and for reviewing existing and proposed legislation and regulations relating to the programs and operations of the Postal Service.

* * * * *

PART 233—INSPECTION SERVICE AUTHORITY

■ 3. The authority citation for part 233 continues to read as follows:

Authority: 39 U.S.C. 101, 102, 202, 204, 401, 402, 403, 404, 406, 410, 411, 1003, 3005(e)(1); 12 U.S.C. 3401–3422; 18 U.S.C. 981, 1956, 1957, 2254, 3061; 21 U.S.C. 881; Omnibus Reconciliation Act of 1996, sec. 662 (Pub. L. 104–208).

■ 4. Section 233.1 is amended by revising paragraphs (b) introductory text and (b)(1) to read as follows:

§ 233.1 Arrest and investigative powers of Postal Inspectors.

* * * * *

(b) *Limitations.* The powers granted by paragraph (a) of this section shall be exercised only—

(1) In the enforcement of laws regarding property in the custody of the Postal Service, property of the Postal Service, the use of the mails, and other postal offenses. With the exception of enforcing laws related to the mails:

(i) The Office of Inspector General will investigate all allegations of violations of postal laws or misconduct by postal employees, including mail theft; and

(ii) The Inspection Service will investigate all allegations of violations of postal laws or misconduct by all other persons.

* * * * *

■ 5. Section 233.7 is amended by paragraph (a) to read as follows:

§ 233.7 Forfeiture authority and procedures.

(a) *Designation of officials having forfeiture authority.* The Chief Postal Inspector is authorized to perform all duties and responsibilities necessary on behalf of the Postal Service and the Office of Inspector General to enforce 18 U.S.C. 981, 2254, and 21 U.S.C. 881, to delegate all or any part of this authority to Deputy Chief Inspectors, Inspectors in Charge, and Inspectors of the Postal Inspection Service, and to issue such instructions as may be necessary to carry out this authority.

* * * * *

PART 273—ADMINISTRATION OF PROGRAM FRAUD CIVIL REMEDIES ACT

■ 6. The authority citation for part 273 continues to read as follows:

Authority: 31 U.S.C. Chapter 38; 39 U.S.C. 401.

■ 7. Section 273.2 is amended by revising paragraph (c) to read as follows:

§ 273.2 Definitions.

* * * * *

(c) *Investigating Official* refers to the Inspector General of the Postal Service or any designee within the United States Office of the Inspector General who serves in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS–15 under the General Schedule.

* * * * *

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. E7–13740 Filed 7–16–07; 8:45 am]

BILLING CODE 7710–12–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 192 and 195

[Docket No. PHMSA–04–18938; Amdt. Nos. 192–104, 195–87]

RIN 2137–AE07

Pipeline Safety: Integrity Management Program Modifications and Clarifications

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the integrity management regulations for hazardous liquid and natural gas transmission pipelines. The modifications include adding an eight-month window to the period for reassessing hazardous liquid pipelines; modifying notification requirements for operators of hazardous liquid and natural gas pipelines; repealing a requirement for gas operators to notify local authorities; and allowing alternatives in calculating pressure reduction when making an immediate repair on a hazardous liquid pipeline. This action is intended to improve pipeline safety by clarifying the integrity management regulations and providing operators with increased flexibility in implementing their integrity management (IM) programs.

DATES: This rule is effective August 16, 2007.

FOR FURTHER INFORMATION CONTACT: Mike Israni by phone at (202) 366–4571 or by e-mail at *mike.israni@dot.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Statutory and Regulatory Requirements

PHMSA is the Federal regulatory agency responsible for promoting the safe, reliable, and environmentally sound operation of over two million miles of natural gas and hazardous liquid pipelines in the United States. PHMSA has broad authority under 49 U.S.C. 60102 to issue regulations establishing standards for pipeline facility design, installation, inspection, emergency planning and response, testing, construction, extension, operation, replacement, and maintenance. By law, PHMSA pipeline safety standards must be both practicable and designed to meet the need for environmental safety and protection, taking account of specified criteria (49 U.S.C. 60102(b)(1–2)). Our rulemaking actions are reviewed by one or both of two statutorily-mandated advisory committees—the Technical Pipeline Safety Standards Committee, and the Technical Hazardous Liquid Pipeline Safety Standards Committee—which provide peer review of all proposed pipeline safety rules to assure technical feasibility, reasonableness, cost-effectiveness, and practicability.

Integrity Management Program

Since 2000, PHMSA has issued IM requirements for pipeline operators. PHMSA's pipeline IM regulations require operators of hazardous liquid and gas transmission pipelines to assess, evaluate, repair, and validate through comprehensive analyses the integrity of pipeline segments in areas where a leak or failure would do the most damage. These areas are referred to as ''High Consequence Areas'' and include populated, unusually sensitive environmental areas, and other areas defined by the IM regulations.

On December 1, 2000, PHMSA issued IM program regulations at 49 CFR 195.452 for operators with more than 500 miles of hazardous liquid pipeline (65 FR 75378). On January 14, 2002, PHMSA issued IM program repair criteria (67 FR 1650). On January 16, 2002, the IM program regulations were extended to operators with less than 500 miles of hazardous liquid pipeline (67 FR 2136). On December 15, 2003, PHMSA issued IM program regulations for gas transmission pipelines at 49 CFR Part 192, Subpart O (68 FR 69778).

Petition for Rulemaking

The American Petroleum Institute (API) and the Association of Oil Pipelines (AOPL) represent members who operate more than 85 percent of the U.S hazardous liquid infrastructure. On June 18, 2004, API and AOPL jointly submitted a petition for rulemaking seeking changes to the hazardous liquid pipeline IM regulations.

API and AOPL requested the rule changes to benefit pipeline safety and provide operators additional flexibility in the following three areas: Adding flexibility to reassessment intervals; adding flexibility to scheduling repairs, and providing for notification to PHMSA when an operator is unable to make a repair because of permitting or other problems.

An important concept in IM is that an operator's program is to evolve into a more detailed and comprehensive program as the operator gains information about its pipeline system. An operator is required to continually improve its IM program. Similarly, as

PHMSA gains experience in enforcing the IM regulations, we see ways that the regulations can be clarified and improved. Based on our experience and the operators' experience with IM, PHMSA considers how the IM regulations can be improved to benefit public safety and provide operators the flexibility they need in carrying out effective IM programs.

PHMSA published a notice of proposed rulemaking (NPRM) on December 15, 2005 (70 FR 74265), proposing to revise its pipeline IM regulations to address the API and AOPL petition to improve the IM regulations and to get additional information about reasons for repair delays. In the NPRM, PHMSA proposed four revisions. First, we proposed to allow more flexibility in the integrity reassessment intervals for hazardous liquid pipelines by adding an eight-month window to the five-year time frame for operators to complete reassessments. Second, we proposed to require hazardous liquid pipeline and gas transmission pipeline operators to notify us of repair-related reductions in operating pressure. The proposal would require operators to notify us whenever they reduce pipeline pressure to make a repair, to provide reasons for any pressure reduction, and to provide further notice and explanation when a pressure reduction exceeds 365 days. Third, we proposed to repeal as unnecessary an existing regulation requiring gas operators to provide notice of pressure reductions to local authorities. Lastly, PHMSA proposed to amend an existing provision for calculating a pressure reduction when making an immediate repair on a hazardous liquid pipeline. The proposal would allow use of an alternative method to calculate reduced operating pressure when the prescribed formula is not applicable or results in a calculated pressure higher than the operating pressure.

II. Disposition of NPRM Comments

PHMSA received comments from 12 parties: API and AOPL; the American Gas Association; Texas Pipeline Association; Kinder Morgan Energy Partners, L.P.; Southwest Gas Corporation; Paiute Pipeline Company; Orange and Rockland Utilities, Inc.; Duke Energy Gas Transmission Corporation; Magellan Midstream Partners, L.P.; Panhandle Energy; Puget Sound Energy; and Enbridge Energy Company, Inc.—Liquids Transportation Segment.

(1) Flexibility in Reassessment Intervals

Current regulations require hazardous liquid pipeline operators to set up intervals not to exceed five years for continually assessing pipeline integrity (§ 195.452(j)(3)). The NPRM proposed adding an eight-month window to the five-year time frame for operators to complete reassessments.

Comment: No commenter opposed this proposal. Commenters supported the proposed revision, stating they would benefit from flexibility to allow for unforeseeable events that could affect intervals. Commenters asserted added flexibility would not materially affect pipeline safety. They noted that adding the proposed window to the prescribed reassessment interval would comport with similar latitude provided in other periodic intervals under the pipeline safety regulations (e.g., for patrolling). One commenter suggested PHMSA develop an approach for extending reassessment intervals based on sound engineering, technical studies, and IM principles. Commenters also recognized operators may establish shorter reassessment intervals as a result of risk prioritization.

A commenter also requested that PHMSA extend similar flexibility to gas transmission pipeline operators, maintaining that the current reassessment time frames on gas transmission pipelines do not have a technical basis. The commenter offered RSTRENG, a means of predicting the effects of metal loss on the remaining strength of the corroded pipe, and other industry-accepted methods as alternatives that could be useful in setting reassessment time frames on gas transmission pipelines.

PHMSA Response: Adding an eight-month window to the hazardous liquid pipeline five-year reassessment interval in § 195.452(j)(3) gives operators flexibility in scheduling and completing reassessments without compromising pipeline safety. Operators must allow time in their schedules for unforeseen problems or contingencies that could delay assessments. In practice, operators must thus schedule their assessments on intervals of less than five years in order to assure compliance with a five-year regulatory requirement. This was never PHMSA's intent. This final rule maintains a nominal five-year interval while recognizing that unexpected contingencies can arise. This change is consistent with other pipeline safety regulations specifying compliance intervals.

PHMSA agrees that reassessment intervals should be adjusted over time based on engineering, technical studies, and integrity management principles. At this point, we do not have sufficient scientific and technical data to support modifying the five-year interval in regulation.

Nevertheless, section § 195.452(j)(4) of the IM regulations allows hazardous liquid operators to seek a variance from the five-year interval for particular pipeline facilities based on engineering data or if needed technology is not available. In these instances, operators notify PHMSA and provide scientific and technical justifications and alternate intervals for variation requests. PHMSA (and States where pipelines are under State jurisdiction) reviews the documentation to ensure sufficient justification has been provided for the proposed interval. This approach has been adequate to cover situations in which longer intervals are needed.

Both PHMSA and the U.S. General Accountability Office have testified that assessment intervals for natural gas transmission pipelines should be established based on technical data, risk factors, and engineering analyses. However, making those changes to the gas IM regulations in this action is outside the scope of the NPRM.

(2) Scheduling Repairs

In the NPRM, PHMSA requested submission of data and comments on operators' experience with identification of defect characteristics needing short-term (60 and 180-day) remediation. The NPRM allowed a longer period to submit these analyses, and API and AOPL responded to this request by submitting engineering analysis produced by Kiefner and Associates, Inc. on April 13, 2006. This analysis required detailed technical review.

PHMSA contracted with Oak Ridge National Laboratory to review the API/AOPL analysis. The Oak Ridge review documented which of the proposed changes in the API analysis could lead to improvements in safety and which could lead to reduced safety. It attempted neither to evaluate the significance to safety of each proposed change, nor to describe the composite impact on safety of the group of proposed changes. The Oak Ridge review did identify the technical factors that a comprehensive evaluation of the proposed changes should consider. PHMSA is currently evaluating operator treatment of many of these factors in ongoing IMP inspections.

DOT's Inspector General issued an audit in September 2006 addressing, among other issues, uncertainties in the characterization of defects using in-line inspection (ILI). Although uncertainties,

both modest under-sizing and over-sizing of defects, in ILI readings are a fact of life, improvements in technology are continuing to reduce these uncertainties. ILI vendors and pipeline operators must account for potential inaccuracies in tool indications in their evaluation of ILI results. PHMSA inspections are evaluating approaches being used by operators to assure prudent decisions are made in the light of these uncertainties. The PHMSA inspection approach has been evaluated by the IG, and the issue closed satisfactorily. PHMSA is collecting additional data to better characterize the extent to which ILI has mischaracterized actual pipeline defects. PHMSA's ongoing inspection process is providing the necessary assurance that operators are addressing in a responsible way the impact of various sources of uncertainty on key decisions, including whether to excavate, timing of repairs, and timing of reassessment interval PHMSA will address potential changes to repair schedules in a future rulemaking action.

(3) Notification of Special Circumstances—Pressure Reduction

Both the hazardous liquid (§ 195.452(h)) and gas transmission (§ 192.933) pipeline IM remediation criteria require operators to reduce pressure or to shut down the pipeline until they can remediate all anomalous conditions. The IM regulations do not require notification when an operator reduces pressure unless the operator cannot meet its schedule for evaluating and remediating conditions and cannot provide safety through a temporary decrease in operating pressure. If a pressure reduction exceeds 365 days, a gas transmission pipeline operator must provide technical justification that the continued pressure reduction will not jeopardize the pipeline's integrity, and a hazardous liquid pipeline operator must take further remedial action to ensure the safety of the pipeline.

PHMSA proposed amending its regulations to require an operator of a gas transmission or hazardous liquid pipeline to notify PHMSA when it reduces pressure on an IM program segment (to remediate a defect), and to provide a justification for the pressure reduction. If a repair was not completed within 365 days, the operator would again be required to notify PHMSA and provide an explanation for the delay. PHMSA intended the proposed notification to provide better information on what causes schedule delays (permitting, scheduling, other); and where and under what circumstances PHMSA would be in a position to help streamline the permit process.

For gas transmission pipeline operators, PHMSA proposed repealing the requirement for notification of local pipeline safety authorities. PHMSA is not aware of any instance where an intrastate gas transmission pipeline is regulated by a local, rather than a State or Federal, authority.

Comment: The commenters supported efforts to better understand repair delays and supported efforts to improve pipeline IM. Nevertheless, the commenters opposed the notifications as proposed, stating that PHMSA needs to provide a clear statement of issues, analysis of possible solutions, and the expected costs and benefits of such a regulatory solution. Commenters contended the proposed notifications would impose a significant, undue, and problematic administrative burden on industry. Commenters said many discretionary pressure reductions are part of voluntary, normal, and circumstantial events unrelated to remediation scheduling requirements.

Some commenters recommended a demonstration project and suggested PHMSA collect and review the proposed notification data over a two-year period before making a final determination on the need for continued notification. Commenters also suggested collecting the information through annual reporting for any case where operators could not meet the remediation schedule requirements of § 195.452(h).

Other commenters suggested pressure reduction notifications should apply where remediation requirements cannot be met due to circumstances beyond the operator's control, when events impact energy supply, or when the operator cannot meet the remediation time limits and the pressure reduction exceeds 365 days. Notifications in these situations would provide PHMSA with more information on conditions interfering with repair attempts and help PHMSA recognize patterns potentially affecting pipeline safety.

Commenters also requested PHMSA clarify that the notifications requested are for pressure reductions related to IM remediation and not for other situations, such as pressure reductions done as safety precautions.

PHMSA Response: After analyzing the comments, PHMSA agrees that adding a requirement to notify PHMSA (and States, when applicable) of every pressure reduction would add a significant burden and likely would not result in commensurate useful information. Temporary pressure reductions add extra safety margin and serve to mitigate the safety impacts of repair delays, making early notifications unnecessary. PHMSA believes the current notification requirements address most cases where, for safety reasons, notification is important—those instances when an operator is unable to make repairs within the required time frames and cannot provide safety through pressure reductions. Thus, this existing notification requirement will remain unchanged.

In addition to the existing requirement, PHMSA has added a requirement for notification when a pressure reduction exceeds 365 days. PHMSA believes that notification of extended delay, with justification for the pressure reduction, will provide important information on conditions interfering with the operator's ability to complete defect remediation without placing an undue burden on the operator. This notification will enable PHMSA to intervene if necessary in order to facilitate needed repairs (e.g., by assisting in resolving permitting delays) and to evaluate the necessity for additional safety measures until remediation can be completed.

PHMSA expects that greater understanding of the causes of repair delays will help identify where extra actions can help. We are particularly interested in whether any delays are due to permitting problems. We also agree that periodic information collection, as part of the annual report, would reduce the paperwork burden without compromising safety. In the future, PHMSA will consider revising requirements for annual reports to include the number of times repairs required by IM regulations are delayed, beyond required repair times, because of permitting issues.

PHMSA has clarified that the notification requirements apply to certain pressure reductions made for purposes of IM remediation requirements. We have also modified the wording in §§ 192.933(c) and 195.452(h)(3) to make it clearer and consistent with wording in the IM notification requirements. There is no change in the requirement. With the revised wording, this section will now require an operator to explain why it cannot meet its schedule for evaluation and remediation of a condition and that the changed schedule will not jeopardize public safety (gas transmission) or public safety or environmental protection (hazardous liquid).

We received favorable comments on the proposal to eliminate the notification provisions for local pipeline safety authorities. Accordingly, we are

repealing this requirement as proposed. For gas transmission pipeline operators, State notification requirements will continue for intrastate pipelines regulated by that State or for interstate gas transmission pipelines in States where PHMSA has an interstate agent agreement.

(4) Formula for Reducing Operating Pressure

Section 195.452(h)(4) requires a hazardous liquid pipeline operator to calculate a temporary reduction in operating pressure using the formula in section 451.7 of ASME/ANSI B 31.4 when making an immediate repair. The requirement is to ensure an extra safety margin. However, this formula only applies to metal loss anomalies, not to all immediate repair conditions, and can result in a calculated pressure higher than the original operating pressure.

PHMSA proposed revising the provision by allowing hazardous liquid pipeline operators to use the ASME/ANSI B 31.4 formula, if applicable. If not applicable to the anomaly, or if the formula results in a calculated pressure higher than the original operating pressure, operators could use an alternative acceptable method to calculate pressure reductions.

Comment: Commenters supported PHMSA's proposal to allow operators to use alternative methods to address anomalies and pipeline operating conditions. No commenter opposed the proposal.

PHMSA Response: We are adopting the proposal with minor wording changes. This final rule provides flexibility in methods an operator may use to calculate a pressure reduction when making immediate repairs on a hazardous liquid pipeline.

III. Advisory Committee Recommendations

The amendments adopted in this final rule have been reviewed and approved by both of our pipeline safety standards advisory committees, the Technical Pipeline Safety Standards Committee, and the Technical Hazardous Liquid Pipeline Safety Standards Committee. On June 28, 2006, PHMSA held a joint meeting of the Committees and two concurrent public workshops in Alexandria, VA. PHMSA presented the proposed changes to the committees for a vote. Following a brief discussion, the committee members unanimously carried a motion to accept the rule changes.

IV. Regulatory Analyses and Notices

A. Privacy Act

Anyone can search the electronic form of all comments received in response to any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). DOT's complete Privacy Act Statement was published in the **Federal Register** on April 11, 2000 (65 FR 19477) and is available on the Web at *http://dms.dot.gov.*

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

This final rule is not considered a significant regulatory action under section 3(f) of Executive Order 12866 (58 FR 51735; Oct. 4, 1993) or the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034; Feb. 26, 1979). A final regulatory evaluation is in the docket for this rulemaking.

The rule's provision concerning scheduling continued integrity assessments will yield benefits in the form of additional flexibility, and will have no cost effects. PHMSA believes the change to the notification requirement for pressure reductions exceeding 365 days will add minimally to the annual average cost to each operator, and to the number of operators affected. PHMSA expects the benefits will offset costs. Together, PHMSA expects these changes to IM regulations for hazardous liquid and gas transmission pipelines to create positive net benefits.

C. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act (5 U.S.C. 601–611) requires agencies to review each new regulation and assess its impact on small businesses and other small entities to determine whether the final rule will have a significant impact on a substantial number of small entities. This rule imposes minimal new costs of compliance on the regulated community. The requirements do not apply to a substantial number of small entities. The revisions to the IM rules will affect hazardous liquid pipeline operators and gas transmission pipeline operators. PHMSA expects notification costs per operator to be significantly less than $3.04 annually, a non-significant burden on any pipeline operator, large or small. The changes to add scheduling flexibility to the integrity reassessments will create positive benefits and impose minimal additional costs. The changed notification requirements for pressure reductions exceeding 365 days will also create benefits, and negligible added costs. Together, PHMSA expects these changes to the IM regulations for hazardous liquid and gas transmission pipelines to create positive net benefits to the affected industry. Based on the cost benefit analysis the regulatory changes will not have a significant impact on a substantial number of small entities.

PHMSA developed this final rule in accordance with Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'') and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that the potential impact of rules on small entities are properly considered. The Small Business Administration's small business definition is either $6 million in revenue (for natural gas pipelines under North American Industry Classification System (NAICS) 486210) or 1,500 employees (for crude oil and refined petroleum product pipelines under NAICS 486110 and 486910). Based on a review of data collected from the hazardous liquid pipeline industry, PHMSA estimates there are 10–20 small entities. PHMSA does not have an estimate of the number of gas transmission pipeline operators that meet the small business definition. Information collection determining pipeline operator staffing or revenue would require separate Office of Management and Budget (OMB) approval. However, as stated above, compliance with this regulation requires a trivial expenditure and imposes a minimal burden on small businesses.

I certify this final rule would not have a significant economic impact on a substantial number of small entities. The costs associated with this final rule will be offset with benefits such as increased flexibility for operators. The changed notification requirements for pressure reductions exceeding 365 days would create benefits and negligible added costs.

D. Executive Order 13132

PHMSA analyzed this rule under the principles and criteria contained in Executive Order 13132 (Federalism). None of the changes in this final rule: (1) Have a substantial direct effect on States, relationships between the Federal government and the States, or on distribution of power and responsibilities among various levels of government; (2) imposes substantial direct compliance costs on States and local governments; or (3) preempts State law. Therefore, the consultation and funding requirements of Executive

Order 13132 (64 FR 43255; August 10, 1999) do not apply.

E. Executive Order 13175

PHMSA analyzed this rule under the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments'') (63 FR 27655; November 9, 2000). Because this rule will not significantly or uniquely affect the communities of the Indian tribal governments, the funding and consultation requirements of this Executive Order do not apply.

F. Executive Order 13211

This rule is not a ''significant energy action'' under Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use). It is not likely to have a significant adverse effect on energy supply, distribution, or use. This rule does not change the pressure reduction restrictions in the IM regulations. It only changes the notification requirements associated with those pressure reductions.

G. Unfunded Mandates

This rule does not impose unfunded mandates under the 1995 Unfunded Mandates Reform Act. It does not result in costs of $100 million or more to either State, local, or tribal governments, in aggregate, or to the private sector, and is the least burdensome alternative for achieving the objectives.

H. Paperwork Reduction Act

PHMSA evaluated the rule, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), and believes the rule will impose no significant paperwork burden on industry or individual operators. Industry commenters to the rule supported the revised notification requirements. As required, PHMSA presented a separate paperwork analysis to OMB for review and will file a copy of the analysis in the docket.

This rule imposes minimal information collection requirements. Based on information currently available to PHMSA, 26 operators filed 74 pressure reduction notifications over the last three years. The revised notification requirements will likely result in minimal additional paperwork burden. The estimated average time to prepare a notification request is 30 minutes. PHMSA does not know how many more notifications will result from the requirement but estimates, on average, less than $3.04 per affected operator per year. Therefore, there should be no significant cost or hourly burden on individual operators or the industry because of the notification requirement in this rule.

I. National Environmental Policy Act

PHMSA analyzed this rule under section 102(2)(c) of the National Environmental Policy Act (42 U.S.C. 4332), the Council on Environmental Quality regulations (40 CFR 1500–1508), and DOT Order 5610.1C, and determined this action will not significantly affect the quality of the human environment. PHMSA did not receive comments on the environmental assessment prepared on the proposed rule. The final environmental assessment is in the Docket.

List of Subjects

49 CFR Part 192

Pipeline safety, Reporting and recordkeeping requirements.

49 CFR Part 195

Pipeline safety, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, PHMSA amends 49 CFR parts 192 and 195 as follows:

PART 192—TRANSPORTATION OF NATURAL AND OTHER GAS BY PIPELINE: MINIMUM FEDERAL SAFETY STANDARDS

■ 1. The authority citation for part 192 continues to read as follows:

Authority: 49 U.S.C. 5103, 60102, 60104, 60108, 60109, 60110, 60113, and 60118; and 49 CFR 1.53.

■ 2. Amend § 192.933 by revising paragraphs (a) and (c), to read as follows:

§ 192.933 What actions must an operator take to address integrity issues?

(a) *General requirements.* An operator must take prompt action to address all anomalous conditions the operator discovers through the integrity assessment. In addressing all conditions, an operator must evaluate all anomalous conditions and remediate those that could reduce a pipeline's integrity. An operator must be able to demonstrate that the remediation of the condition will ensure the condition is unlikely to pose a threat to the integrity of the pipeline until the next reassessment of the covered segment.

(1) *Temporary pressure reduction.* If an operator is unable to respond within the time limits for certain conditions specified in this section, the operator must temporarily reduce the operating pressure of the pipeline or take other action that ensures the safety of the covered segment. An operator must determine any temporary reduction in operating pressure required by this section using ASME/ANSI B31G (incorporated by reference, *see* § 192.7) or AGA Pipeline Research Committee Project PR–3–805 (''RSTRENG,'' incorporated by reference, *see* § 192.7) or reduce the operating pressure to a level not exceeding 80 percent of the level at the time the condition was discovered. (See appendix A to this part for information on availability of incorporation by reference information.) An operator must notify PHMSA in accordance with § 192.949 if it cannot meet the schedule for evaluation and remediation required under paragraph (c) of this section and cannot provide safety through temporary reduction in operating pressure or other action. An operator must also notify a State pipeline safety authority when either a covered segment is located in a State where PHMSA has an interstate agent agreement, or an intrastate covered segment is regulated by that State.

(2) *Long-term pressure reduction.* When a pressure reduction exceeds 365 days, the operator must notify PHMSA under § 192.949 and explain the reasons for the remediation delay. This notice must include a technical justification that the continued pressure reduction will not jeopardize the integrity of the pipeline. The operator also must notify a State pipeline safety authority when either a covered segment is located in a State where PHMSA has an interstate agent agreement, or an intrastate covered segment is regulated by that State.

* * * * *

(c) *Schedule for evaluation and remediation.* An operator must complete remediation of a condition according to a schedule prioritizing the conditions for evaluation and remediation. Unless a special requirement for remediating certain conditions applies, as provided in paragraph (d) of this section, an operator must follow the schedule in ASME/ANSI B31.8S (incorporated by reference, see § 192.7), section 7, Figure 4. If an operator cannot meet the schedule for any condition, the operator must explain the reasons why it cannot meet the schedule and how the changed schedule will not jeopardize public safety.

* * * * *

PART 195—TRANSPORTATION OF HAZARDOUS LIQUIDS BY PIPELINE

■ 3. The authority citation for part 195 continues to read as follows:

Authority: 49 U.S.C. 5103, 60102, 60104, 60108, 60109, 60118; and 49 CFR 1.53.

■ 4. Amend § 195.452 by revising paragraphs (h)(1), (h)(3), (h)(4), and (j)(3) to read as follows:

§ 195.452 Pipeline integrity management in high consequence areas.

* * * * *

(h) * * * (1) *General requirements.* An operator must take prompt action to address all anomalous conditions the operator discovers through the integrity assessment or information analysis. In addressing all conditions, an operator must evaluate all anomalous conditions and remediate those that could reduce a pipeline's integrity. An operator must be able to demonstrate that the remediation of the condition will ensure the condition is unlikely to pose a threat to the long-term integrity of the pipeline. An operator must comply with § 195.422 when making a repair.

(i) *Temporary pressure reduction.* An operator must notify PHMSA, in accordance with paragraph (m) of this section, if the operator cannot meet the schedule for evaluation and remediation required under paragraph (h)(3) of this section and cannot provide safety through a temporary reduction in operating pressure.

(ii) *Long-term pressure reduction.* When a pressure reduction exceeds 365 days, the operator must notify PHMSA in accordance with paragraph (m) of this section and explain the reasons for the delay. An operator must also take further remedial action to ensure the safety of the pipeline.

* * * * *

(3) *Schedule for evaluation and remediation.* An operator must complete remediation of a condition according to a schedule prioritizing the conditions for evaluation and remediation. If an operator cannot meet the schedule for any condition, the operator must explain the reasons why it cannot meet the schedule and how the changed schedule will not jeopardize public safety or environmental protection.

(4) *Special requirements for scheduling remediation.* (i) *Immediate repair conditions.* An operator's evaluation and remediation schedule must provide for immediate repair conditions. To maintain safety, an operator must temporarily reduce the operating pressure or shut down the pipeline until the operator completes the repair of these conditions. An operator must calculate the temporary reduction in operating pressure using the formula in section 451.7 of ASME/ANSI B31.4 (incorporated by reference, see § 195.3), if applicable. If the formula is not applicable to the type of anomaly or would produce a higher operating pressure, an operator must use an alternative acceptable method to calculate a reduced operating pressure. An operator must treat the following conditions as immediate repair conditions:

* * * * *

(3) *Assessment intervals.* An operator must establish five-year intervals, not to exceed 68 months, for continually assessing the line pipe's integrity. An operator must base the assessment intervals on the risk the line pipe poses to the high consequence area to determine the priority for assessing the pipeline segments. An operator must establish the assessment intervals based on the factors specified in paragraph (e) of this section, the analysis of the results from the last integrity assessment, and the information analysis required by paragraph (g) of this section.

* * * * *

Issued in Washington, DC, on July 6, 2007.

Thomas J. Barrett,

Administrator.

[FR Doc. E7–13772 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–60–P

Proposed Rules

Federal Register
Vol. 72, No. 136
Tuesday, July 17, 2007

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS–2006–0075]

RIN 0579–AC46

Gypsy Moth Regulations; Updates and Clarifications

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the gypsy moth regulations by making editorial and nonsubstantive changes to several terms and providing necessary updates throughout the regulations. These actions would improve the clarity and consistency of the regulations while continuing to provide protection against the artificial spread of gypsy moth into noninfested areas of the United States.

DATES: We will consider all comments that we receive on or before September 17, 2007.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov,* select ''Animal and Plant Health Inspection Service'' from the agency drop-down menu, then click ''Submit.'' In the Docket ID column, select APHIS–2006–0075 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. APHIS–2006–0075, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2006–0075.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Weyman Fussell, Program Manager, Emergency and Domestic Programs, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1236; (301) 734–5705.

SUPPLEMENTARY INFORMATION:

Background

The regulations in ''Subpart-Gypsy Moth'' (7 CFR 301.45 through 301.45–12, referred to below as the regulations) restrict the interstate movement of regulated articles from generally infested areas of States quarantined for gypsy moth in order to prevent the artificial spread of gypsy moth into noninfested areas of the United States.

The gypsy moth, *Lymantria dispar* (Linnaeus), is an introduced, highly destructive pest of trees that, during its caterpillar stage, poses a serious threat to hundreds of species of trees and shrubs. A female gypsy moth lays a cluster of eggs (called an egg mass) on and near trees. Up to a thousand caterpillars can hatch from a single egg mass. The caterpillars feed on nearby trees and shrubs, removing much, if not all, foliage. This defoliation, when combined with other forms of stress such as drought and soil compaction, may ultimately result in the death of the tree.

The first major outbreak of gypsy moth in the United States occurred in Massachusetts in 1889. Since then, the gypsy moth has infested 19 States and the District of Columbia and has defoliated thousands of acres of hardwood forests across the northeastern United States. The infestation continues to move south and west despite ongoing eradication and control efforts.

We are proposing to amend the regulations by making editorial and nonsubstantive changes to several terms and providing necessary updates throughout the regulations. These actions would improve the clarity and consistency of the regulations, while continuing to provide protection against the spread of gypsy moth into noninfested areas of the United States.

Definitions

Section 301.45–1 defines certain terms used in the regulations. We are proposing to make nonsubstantive changes to several of these definitions to improve the clarity and consistency of the regulations. These proposed change are described below.

The current definition of *certificate* describes a document issued to allow the movement of regulated articles to any destination. We would amend this definition to clarify that a certificate can be a form, stamp, or document approved by Plant Protection and Quarantine (PPQ) and that the purpose of a certificate is to affirm that a regulated article is eligible for interstate movement under the regulations, rather than the current ''to allow the movement'' description in the definition. We believe this definition would more accurately convey what constitutes a certificate.

The current definition of *compliance agreement* is rather circular, i.e., it describes a compliance agreement as a written agreement in which a person agrees to comply with the requirements of the compliance agreement. In actuality, a compliance agreement in the context of our domestic quarantines is an agreement in which a person engaged in growing, moving, or handling regulated articles agrees to comply with the requirements of the regulations. We would amend the definition of *compliance agreement* in § 301.45–1 to reflect this.

Inspector is currently defined as ''Any employee of APHIS, a State government, or any other person, authorized by the Administrator in accordance with the law to enforce the provisions of the quarantine and regulations in this subpart.'' To eliminate any possible confusion, we would add a sentence to that definition stating that a person operating under a compliance agreement is not an inspector. While

persons operating under a compliance agreement are authorized to take certain actions, e.g., issuing certificates, they are not authorized to enforce the regulations.

Limited permit is currently defined as ''A document issued by an inspector to allow the interstate movement of regulated articles to a specified destination.'' In actuality, persons operating under a compliance agreement may also issue limited permits. Further, the regulated articles moving under a limited permit must be moved in accordance with conditions specified on the permit to a specified destination, rather than simply ''to a specified destination,'' as mentioned in the current definition. We would amend the definition of *limited permit* in § 301.45–1 to more accurately convey what constitutes a limited permit.

The definition of *qualified certified applicator* refers to ''restricted pesticides.'' The correct term is ''restricted use pesticides.'' We would amend the definition accordingly. We would also update the definition's citation to provisions of the Federal Insecticide, Fungicide, and Rodenticide Act.

We are also proposing to revise footnote 1 in the definition of *qualified certified applicator.* Because PPQ no longer maintains a list of qualified certified applicators as stated in the footnote, we would revise the footnote to refer the reader to officials of the various State departments of agriculture for the names of qualified certified applicators.

Similarly, footnote 2 in the definition of *treatment manual* is outdated. We no longer provide pamphlets describing methods from the Gypsy Moth Program Manual, and the appendix to the regulations mentioned in the footnote no longer exists. We would remove these outdated references and instead provide a Web site address for viewing the Gypsy Moth Program Manual on the Internet.

We are also proposing to add a definition for *OHA document.* We mention throughout the regulations that an OHA document may be issued by the owner of an outdoor household article (OHA) for the interstate movement of the article, but we do not provide a definition for OHA document anywhere in the regulations. To improve the clarity and consistency of the regulations, we would add a definition of *OHA document.*

Safeguarding Methods for Interstate Movement

Section 301.45–4, paragraph (b), specifies that any regulated article moved interstate from a noninfested area through a generally infested area during certain months of the year ''must be in an enclosed vehicle, or completely enclosed by a covering adequate to prevent access by gypsy moths, such as canvas, plastic, or closely woven cloth.'' We are proposing to revise this paragraph by removing the references to specific types of enclosures and coverings, and put in its place a more general requirement that the regulated articles ''must be safeguarded by a covering adequate to prevent access by any gypsy moth life stages.'' We believe that moving to a more performance-based standard would offer more flexibility in meeting the requirements for the interstate movement of regulated articles, while continuing to provide protection against the artificial spread of gypsy moth into noninfested areas of the United States.

Disqualification of Qualified Certified Applicators

Section 301.45–12 pertains to the disqualification of qualified certified applicators. In the regulations, a qualified certified applicator may be disqualified if he or she is not certified by a State and/or Federal government to use specific pesticides, fails to comply with the provisions in the regulations, or fails to attend and complete a recertification workshop approved by the Administrator on the identification and treatment of life stages of gypsy moth on outdoor household articles and mobile homes. We are proposing to amend § 301.45–12, paragraph (a)(1), by removing the references to specific pesticides. What would remain would be the simple requirement that a person be certified as a qualified certified applicator under the Federal Insecticide, Fungicide, and Rodenticide Act in a category allowing the use of restricted use pesticides. That basic requirement renders the citing of specific pesticides by name unnecessary. For consistency, we are also proposing to amend paragraph (a)(2) of § 301.45–12 by adding the requirement that qualified certified applicators must also comply ''* * * with stipulations agreed on in the compliance agreement between the certified applicator and the Administrator.'' We are also proposing to remove paragraph (a)(3) of this section, which states that qualified certified applicators may be disqualified from issuing certificates if they fail to attend and complete a recertification workshop approved by the Administrator on the identification and treatment of life stages of gypsy moth on outdoor household articles and mobile homes. We would remove this paragraph in its entirety because we have not offered, or approved, the referenced recertification workshops for several years.

Other Miscellaneous Updates

The regulations in § 301.45–2(a)(1) refer to the Integrated Pest Management (IPM) alternative of the March 1985 Final Environmental Impact Statement (FEIS) on Gypsy Moth Suppression and Eradication Projects. The March 1985 FEIS has been superseded by an updated FEIS that was filed February 15, 1996. In the 1996 FEIS, the IPM alternative was replaced by the Eradication, Suppression, and Slow the Spread alternative. We would update this paragraph so that it refers to the most recent FEIS and alternative.

Section 301.45–7 addresses the assembly and inspection of regulated articles and outdoor household articles prior to interstate movement. The section refers to inspectors and qualified certified applicators examining regulated articles. However, § 301.45–5(e) authorizes an individual to self-certify outdoor household articles for interstate movement if that person has inspected the outdoor household article and has found it to be free of any life stage of gypsy moth. To ensure that § 301.45–7 includes references to all the possible certification options, we would amend the section to included a reference to the self-certification provisions of § 301.45–5(e).

Finally, because the APHIS ''officer in charge'' position title has been changed to ''State Plant Health Director,'' we would update § 301.45–8 to reflect the position name change.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We are proposing to amend the gypsy moth regulations by making editorial and nonsubstantive changes to several terms and providing necessary updates throughout the regulations. These actions would improve the clarity and consistency of the regulations, while continuing to provide protection against the artificial spread of gypsy moth into noninfested areas of the United States.

The gypsy moth is a pest of concern for the U.S. forest industry. Defoliation of trees by gypsy moths often results in the death of the trees, which leads to economic loss, changes in ecosystems and wildlife habitat, and disturbed

water flow and water quality. Economic costs to the U.S. forest industry, in addition to the costs of timber losses and pest control, can also arise from trade reductions as importing countries impose protective restrictions on access to their markets for wood products. Gypsy moths are already causing losses in quarantined areas in the United States. Annual losses attributable to gypsy moths are estimated to be about $22 million.[1] Any spread of gypsy moth to noninfested areas could have a negative economic and environmental impact.

The Small Business Administration (SBA) has established size standards based on the North American Industry Classification System (NAICS) to determine and to classify which economic entities can be considered small entities. Entities potentially affected by our gypsy moth regulations include sawmills, pulp mills, nursery and tree production farms and nurseries and garden centers that are involved in the interstate movement of Christmas trees, nursery products, household products, and bark and bark products from gypsy moth generally infested areas. The effects on all these entities of the proposed updates to the regulations would be positive.

The SBA classifies nursery and tree production (floriculture, nursery, Christmas trees, etc.) farms (NAICS code 111421) small if their annual receipts are not more than $750,000.[2] Sawmills (NAICS code 321113) are regarded small if they employ 500 or fewer employees, and pulp mills (NAICS code 322110) are small if they employ 750 or fewer employees. Nursery and garden centers (NAICS code 444220) are considered small if their annual sales are less than $6.5 million. In 2002, the most recent year for which data are available, there were 17,300 nursery and tree production farms, 1,215 sawmills, 7 pulp mills, and 4,093 nursery and garden centers in generally infested areas of the United States.[3] Approximately 93 percent of all these entities are considered to be small under the SBA's standards. Although the majority of these establishments are small entities, the economic effect of the proposed changes would be negligible. The proposed changes would not impose additional restrictions or requirements; rather, they would help ensure that the existing regulations are as up to date, clear, consistent, and as flexible as possible.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we propose to amend 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for part 301 would continue to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 issued under Sec. 204, Title II, Public Law 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 issued under Sec. 203, Title II, Public Law 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

2. Section 301.45–1 would be amended as follows:

a. By adding a definition of *OHA document,* and by revising the definitions of *certificate, compliance agreement,* and *limited permit* to read as set forth below.

b. In the definition of *inspector,* by adding a new second sentence to read as set forth below.

c. In the definition of *qualified certified applicator,* by removing the citation ''86 Stat. 983; 7 U.S.C. 136b'' and adding the citation ''7 U.S.C. 136i'' in its place, by adding the word ''use'' before the word ''pesticides'', and by revising footnote 1 to read as set forth below.

d. In the definition of *treatment manual,* by revising footnote 2 to read as set forth below.

§ 301.45–1 Definitions.

* * * * *

Certificate. A Plant Protection and Quarantine-approved form, stamp, or document issued and signed by an inspector, or by a qualified certified applicator or by any other person operating in accordance with a compliance agreement, affirming that a specified regulated article is eligible for interstate movement in accordance with this subpart.

Compliance agreement. A written agreement between APHIS and a person engaged in growing, handling, or moving regulated articles, in which the person agrees to comply with the provisions of this subpart.

* * * * *

Inspector. * * * A person operating under a compliance agreement is not an inspector.

* * * * *

Limited permit. A document in which an inspector or a person operating under a compliance agreement affirms that the regulated article identified on the document is eligible for interstate movement in accordance with § 301.45–5 only to the specified destination and only in accordance with the specified conditions.

* * * * *

OHA document. The self-inspection checklist portion of USDA–APHIS Program Aid Number 1329, ''Don't Move Gypsy Moth,'' completed and signed by the owner of an outdoor household article (OHA) affirming that the owner has inspected the OHA for life stages of gypsy moth in accordance with the procedures in the program aid.

* * * * *

Qualified certified applicator. * * * [1]

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[1] David Pimentel, Lori Latch, Rodolfo Zuniga, and Doug Morrison, ''Environmental and Economic Costs Associated with Non-indigenous Species in the United States,'' College of Agriculture and Life Sciences, Cornell University, Ithaca, NY 14850–0901, June 12, 1999.

[2] SBA, Small Business Size Standards matched to North American Industry Classification System 2002, Effective January 2006 (*http://www.sba.gov/size/sizetable2002.html*).

[3] U.S. Census Bureau, 2002 Economic Census Geographic Area Series: Manufacturing and Wholesale Trade, Revised January 2006 (*http://www.census.gov/prod/ec02/ec0231sq1t.pdf*). Information on the number of sawmills, pulp mills, nursery and garden centers is available at the State level only. County information is withheld to avoid disclosing data for individual establishments. This may result in an overestimate of the number of affected entities because not all counties within quarantined States are in generally infested areas.

[1] Names of qualified certified applicators may be obtained from State departments of agriculture.

* * * * *

Treatment Manual. * * *[2]

[2] The Gypsy Moth Program Manual may be viewed on the Internet at *http://www.aphis.usda.gov/ppq/manuals/online_manuals.html*.

* * * * *

3. In § 301.45–2, paragraph (a)(1) would be revised to read as follows:

§ 301.45–2 Authorization to designate and terminate designation of generally infested areas.

(a) * * *

(1) The area is subject to a gypsy moth eradication program conducted by the Federal government or a State government in accordance with the Eradication, Suppression, and Slow the Spread alternative of the Final Environmental Impact Statement (FEIS) on Gypsy Moth Suppression and Eradication Projects that was filed with the United States Environmental Protection Agency on January 16, 1996; and,

* * * * *

4. In § 301.45–4, paragraph (b) would be amended by revising the last sentence to read as follows:

§ 301.45–4 Conditions governing the interstate movement of regulated articles and outdoor household articles from generally infested areas.

* * * * *

(b) * * * The articles must be safeguarded by a covering adequate to prevent access by any gypsy moth life stages.

* * * * *

5. In § 301.45–7, a new sentence would be added after the last sentence to read as follows:

§ 301.45–7 Assembly and inspection of regulated articles and outdoor household articles.

* * * An owner who wants to move outdoor household articles interstate may self-inspect the articles and issue an OHA document in accordance with § 301.45–5(e).

§ 301.45–8 [Amended]

6. In § 301.45–8, paragraph (c) would be amended by removing the words ''officer in charge'' and adding the words ''State Plant Health Director'' in their place.

7. Section 301.45–12 would be amended as follows:

a. By revising paragraph (a)(1) to read as set forth below.

b. In paragraph (a)(2), by removing the word ''; or,'' from the end of the sentence and adding the words ''or with stipulations agreed on in the compliance agreement between the certified applicator and the Administrator.'' in its place.

c. By removing paragraph (a)(3).

§ 301.45–12 Disqualification of qualified certified applicator to issue certificates.

(a) * * *

(1) Such person is not certified by a State and/or the Federal government as a commercial certified applicator under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136i) in a category allowing the application of restricted use pesticides.

* * * * *

Done in Washington, DC, this 11th day of July 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–13774 Filed 7–16–07; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. APHIS–2006–0112]

RIN 0579–AC31

Introduction of Organisms and Products Altered or Produced Through Genetic Engineering

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability of draft environmental impact statement and request for comments.

SUMMARY: We are evaluating our regulatory program to determine whether we should revise our regulations regarding the importation, interstate movement, and environmental release of genetically engineered organisms. We are seeking public comment on the draft environmental impact statement (DEIS) we have prepared relative to the regulatory revisions we are considering. The DEIS evaluates the alternatives we have identified in terms of their potential effects on the human environment compared to the effects of our current regulatory program. We believe our ongoing evaluation of these alternatives would benefit from the submission of additional views and data from the public, and we are especially interested in receiving comments on the subset of DEIS alternatives described in this notice.

DATES: We will consider all comments that we receive on or before September 17, 2007.

ADDRESSES: You may submit comments addressing the draft environmental impact statement by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*, select ''Animal and Plant Health Inspection Service'' from the agency drop-down menu, then click ''Submit.'' In the Docket ID column, select APHIS–2006–0112 to submit or view public comments and to view supporting and related materials, including the DEIS, that are available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Postal Mail/Commercial Delivery*: Please send four copies of your comment (an original and three copies) to Docket No. APHIS–2006–0112, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2006–0112.

Issues in the DEIS are organized using 10 numbered issue areas developed through the scoping process. When possible, please relate each point in your comment to one of these 10 issue areas.

Public Meetings: APHIS intends to hold public meetings to encourage additional public comment on the DEIS. The locations and dates of the public meetings will be announced on the APHIS Web site (*http://www.aphis.usda.gov/brs/brs_meetings.html*) and in a future **Federal Register** notice.

Reading Room: You may read any comments that we receive on this notice and the DEIS in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. Michael Wach, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–0485.

SUPPLEMENTARY INFORMATION:

Background

Under the Plant Protection Act (PPA) (7 U.S.C. 7701 *et seq.*), the Secretary of Agriculture may prohibit or restrict the importation, entry, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction or the dissemination of a plant pest or noxious weed into the United States. The Secretary's authority under the PPA has been delegated to the Administrator of the Animal and Plant Health Inspection Service (APHIS).

Under that authority, APHIS administers regulations in 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests'' (referred to below as the regulations). The regulations govern the introduction (importation, interstate movement, or release into the environment) of any organism or product altered or produced through genetic engineering that is a plant pest or that there is reason to believe may be a plant pest, or any product that contains such an organism that is unclassified and/or whose classification is unknown. The regulations refer to such genetically engineered organisms as ''regulated articles.''

Current APHIS Regulations

Current APHIS regulations for genetically engineered organisms are based on authority in the PPA to regulate the introduction of organisms that are plant pests or for which there is reason to believe may be plant pests. Applicants must submit required information for review by APHIS scientists who evaluate the potential risks posed by the introduction and the procedures that the applicant will use to minimize those risks. Depending on the nature of the genetically engineered organism, an applicant applies for either a permit or a notification. APHIS authorizes introductions after considering the organism, the nature of the genetic engineering, and the ways in which the genetically engineered organism is likely to interact with the environment.

A notification is a more streamlined authorization process that is used only for plants with traits considered to be low risk. To qualify for a notification, the genetically engineered plant must meet strict eligibility requirements to ensure that it poses a minimal plant pest risk. The genetically engineered plant must also be grown under conditions designed to meet performance standards ensuring confinement of the regulated material. The remaining organisms—including plants that are genetically engineered to produce pharmaceutical or industrial compounds—are subject to the permitting process.

The permit process is designed to ensure the safe introduction of any genetically engineered organism over which APHIS has authority. All required information submitted in a permit application is reviewed by APHIS scientists. Permits will prescribe confinement conditions and standard operating procedures tailored on a case-by-case basis to maintain confinement of the genetically engineered organism throughout the course of the introduction. APHIS requires that all plants genetically engineered to produce pharmaceutical or industrial compounds be grown under extremely strict management protocols. These plants are required to be grown in a way that maintains confinement of the plant to the release area, with additional precautions taken to prevent the escape of pollen, seeds, or plant parts from the field test site.

After a genetically engineered organism has been field tested extensively and the developer demonstrates that the organism does not pose a plant pest risk, the developer may request the deregulation of the organism by filing a petition for a ''determination of nonregulated status.'' After the applicant submits the required data and it has been carefully evaluated, APHIS prepares an environmental assessment or, if warranted, an environmental impact statement (EIS) to analyze the potential impacts the plant may have on the human environment and seeks public comment. APHIS approves a petition only when it reaches the conclusion that the genetically engineered organism does not pose a plant pest risk. Once APHIS has deregulated an organism, it may be freely moved and planted without the requirement of permits or other regulatory oversight by APHIS. Deregulated status may be extended to genetically engineered organisms which APHIS determines are similar to previously deregulated organisms. Conversely, given new information, APHIS may determine that a previously deregulated genetically engineered organism poses a plant pest risk and should, therefore, be brought back under Agency oversight.

The Draft Environmental Impact Statement

APHIS is evaluating its regulatory program to determine if there is a need to revise its regulations in light of our current knowledge and experience and advances in science and technology. It is important that any regulations we may develop effectively carry out the purposes of the PPA, ensure environmental protection, provide regulatory processes that are transparent to stakeholders and the public, efficiently use Agency resources, minimize regulatory burdens, adhere to the principles of E.O. 12866, and are consistent with our international agreements, such as the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures.

We have prepared a draft EIS (DEIS) evaluating all of the regulatory alternatives we are currently considering for a future proposed rule to revise our biotechnology regulations. A copy of the DEIS may be obtained through the Federal eRulemaking Portal as described under **ADDRESSES** above. When commenting on the DEIS, please identify which of the 10 issue areas identified in the DEIS each point in your comment addresses.

While we invite comments on all alternatives in the DEIS, this notice identifies specific areas where we are particularly interested in further public input and data that will assist us in evaluating and refining these regulatory alternatives. We are requesting data on specific topics for some of the alternatives listed below, and we also welcome comments on how each alternative would affect areas such as the overall effectiveness of our biotechnology program, its operational efficiency, industry compliance, and other issues that would be associated with the development, adoption, and implementation of an alternative.

The DEIS alternatives highlighted in this notice are discussed in depth in the DEIS, and readers should refer to that document in preparing comments in response to this notice. The issues from the DEIS for which we are especially seeking additional public comment are listed below, with some notes on the particular types of data or views we believe would be most helpful.

DEIS Issue 1 and 5—Scope of the Program

Given the rapid advances in biotechnology, the present scope of the regulations may not be of sufficient breadth to cover the full range of genetically engineered organisms and

the full range of potential agricultural and environmental risks posed by these organisms, including risks to public health. Historically, the Agency has relied exclusively on its authority to protect against plant pests as the basis for regulating genetically engineered organisms. This authority, which is found in the PPA, was derived from the Federal Plant Pest Act and the Plant Quarantine Act. The PPA, however, consolidated and redefined the Agency's plant health authorities. The PPA authorizes the regulation of noxious weeds—defined as any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment—and biological control organisms—defined as any enemy, antagonist, or competitor used to control a plant pest or noxious weed. Regulatory alternatives are now being considered with due regard for the revised plant health authorities of the PPA and in light of the many advances in biotechnology.

Based on our evaluation of several alternatives in the DEIS, APHIS has made a preliminary determination that regulatory oversight should be enhanced by expanding the scope of regulations to utilize the range of authorities in the PPA, not just the plant pest provision, to include the authority over noxious weeds and biological control organisms. The noxious weed provision would allow oversight of genetically engineered plants by expanding the scope of what is regulated and by allowing a broader consideration of potential risks, including risks to public health. This would allow APHIS to consider what is known about the potential hazards of the introduced proteins and other substances to humans or animals, if inadvertently consumed or released. This information could, in turn, be used to develop appropriate regulatory safeguards in connection with introductions of genetically engineered organisms.

APHIS has also made a preliminary determination that it would be beneficial to regulate nonviable plant material originating from field tests when there is reason to believe, based on scientific review, that such debris might be harmful to the environment if it were allowed to remain. Such an approach would allow the Agency to maintain regulatory control if nonviable material poses a hazard (e.g., potential food contamination).

APHIS is interested in receiving comment on these preliminary determinations and the other alternatives discussed in the DEIS. In particular, APHIS requests comment on whether APHIS should broaden the scope of its regulations to reflect its authority over noxious weeds and biological control organisms. If APHIS does propose to broaden its regulatory scope to include consideration of noxious weed risk, how should oversight and evaluation of genetically engineered plants differ from what is done under the current plant pest risk-oriented regulations? If APHIS does propose to establish regulations regarding genetically engineered biological control organisms, on what risks should the regulations be focused? Should APHIS tailor the scope of such regulations to focus on specific risks? If so, how?

DEIS Issue 2—Transparent, Risk Based Permit System

APHIS has always used a risk-based approach in regulating genetically engineered organisms. The Agency has concluded that there is public interest in biotechnology regulation and how APHIS regulates various types of organisms based on to risk and Agency familiarity with a given organism. In addition, there is a trend toward more highly varied organisms and the regulatory process may need greater flexibility and rigor to more appropriately regulate the increasing variety of organisms. Accordingly, the Agency is considering revising the regulations to make the Agency's use of risk-based categories—where genetically engineered organisms are classified according to risk and familiarity so that oversight and confinement vary by category—more refined, more explicit and more transparent to the industry and the public. Redefined risk categories, we believe, can provide added flexibility, improving the Agency's ability to regulate diverse organisms and new types of traits, and provide better clarity to the regulated community and to the public, which may in turn promote greater confidence in the regulatory system.

Accordingly, APHIS' has made a preliminary determination to adopt an expanded tiered permitting system based on potential environmental risk and Agency familiarity with the organism. A detailed example of such a system is described in this DEIS. The goals of such a tiered system would be to increase transparency with respect to how the Agency regulates various types of genetically engineered organisms and to increase regulatory flexibility such that the Agency could move genetically engineered organisms among the tiers as new information becomes available. For well characterized low-risk genetically engineered organisms, APHIS would continue to use a process similar to the current notification process found in 7 CFR 340.3; however, the term notification would no longer be used. Such a process would become the lowest risk ''permit.'' This change would, we believe, increase transparency and avoid any potential confusion about the status of these organisms as regulated articles.

APHIS is interested in receiving comment on this alternative, and, in particular, requests comment on the criteria that should be used to establish risk-based categories. What characteristics of genetically engineered plants should be considered in establishing such categories? How many categories should there be? Which types or species of plants should be assigned to which categories? What specific regulatory requirements or restrictions would be appropriate for each such category and why would they be appropriate?

DEIS Issue 3—Nonregulated Status

Once an article has been deregulated, APHIS does not place any restrictions or requirements on its use. Restrictions have not been deemed necessary because BRS risk assessments have concluded that the genetically engineered plants APHIS has deregulated pose no plant pest risk. APHIS recognizes, however, that future development and commercialization of plants with less familiar traits may pose new challenges for the Agency because even a thorough and comprehensive assessment may not resolve all unknowns regarding an article proposed for deregulation. These unresolved issues may justify continued scrutiny and data collection or use restrictions, but be of such a minor nature and minimal risk or concern that allowing planting of the article without a permit would be appropriate. APHIS is exploring the concept of a system that could give increased flexibility for handling special cases involving less familiar traits by creating provisions that allow for imposition of conditions for unconfined release. This could facilitate commercialization, while requiring appropriate restrictions or monitoring.

APHIS has made a preliminary determination to propose a new feature for its regulatory system whereby the Agency would retain oversight in specific cases as appropriate. We envision, of course, that the vast

majority of organisms would be fully deregulated and that this determination would be identical to deregulation under our current regulations. The new system could include processes and criteria to allow release and use, with some restrictions, for special cases where there were minor risks that could be mitigated with conditions to ensure safe commercial use.

We are therefore interested in receiving comments on how to manage genetically engineered organisms that present only minor unresolved risks that can be mitigated effectively, and on what factors should be considered in establishing appropriate mitigations. APHIS is also considering the use of new terminology to describe both deregulation as it currently exists and the more limited deregulation where some oversight would be retained. One possibility is to use the term ''approval'' to indicate that specific genetically engineered organisms are ''unconditionally approved.'' This would be synonymous with full deregulation under our current regulations. Other genetically engineered organisms could be ''approved with conditions'' but would remain subject to continuing regulatory oversight in some respects. Alternatively, APHIS could retain the term ''deregulation'' and use ''deregulation in part'' or another term to refer to situations where genetically engineered organisms remain subject to regulatory oversight in some respects. We are interested in receiving comment on this potential change in terminology.

DEIS Issue 4—Oversight of Pharmaceuticals and Industrial Substances

Genetic engineering technology has advanced to the point where organisms can be developed that produce novel proteins and other substances with biological activity or industrial utility. Because the gene products made by such pharmaceutical and industrial compound producing plants may pose hazards not associated with proteins and other substances commonly found in the food supply, it is particularly important to ensure effective confinement measures for these plants. At the same time, however, the confinement measures prescribed for plants producing pharmaceutical and industrial compounds would be based on risk, not on the type of plant alone.

The Agency has considered various alternatives with respect to the regulation of genetically engineered plants producing pharmaceutical compounds, including whether food crops should be used and whether they should be allowable for open air introductions. We have made a preliminary determination that under stringent conditions and with rigorous oversight, including due consideration of substantive food safety issues, food crops can be safely used for production of these compounds.

In connection with this preliminary determination, the Agency seeks input on the need for and development of new or additional regulatory mechanisms to ensure that genetically engineered organisms producing pharmaceutical or industrial compounds are subject to requirements and oversight commensurate with the potential risks. We are also interested in comments regarding the biological characteristics that the Agency should consider in imposing safeguards. What should be done to ensure that such crops are commercialized under appropriate safeguards?

DEIS Issue 6—Commercialization Under Multi-Year Permits

For organisms that might be commercialized but that do not meet the criteria for deregulation, APHIS is considering whether a new type of permitting system would be more appropriate in terms of efficiency and effectiveness than the current system. In addition, there is much public and State interest in these types of plantings and a new mechanism may increase transparency and allow for greater State involvement.

Based on considerations more fully described in the DEIS, APHIS has made a preliminary determination to create a multi-year permit for genetically engineered organisms, with stringent oversight, in cases where developers are not interested or would not qualify for deregulation but plan to produce under permit. This would cover situations where producers are able to commercialize with relatively small plantings (e.g., industrial and pharmaceutical plants). Regulatory rigor would remain high to protect the environment, but efficiency and transparency would increase. The State partnership would be strengthened under this new system. The system would rely on multiyear permits and intensive reviews of standard operating procedures (SOPs), as well as audits and inspections. Though the new system under consideration could be used for pharmaceutical and industrial plants, the Agency might also find it appropriate for other types of genetically engineered plants.

We are seeking comments on such a system and are particularly interested in comments regarding new or additional regulatory mechanisms to ensure that genetically engineered organisms produced under multi-year permits would be subject to effective requirements and oversight commensurate with the potential risks.

DEIS Issue 7—Low Levels of Biotechnology-Derived Genes and Gene Products Occurring in Commerce That Have Not Gone Through All Applicable Regulatory Reviews

As with traditional plant breeding, large scale annual field testing of genetically engineered plants that have not completed all applicable reviews may result in materials from these trials occasionally being detected at low levels in commercial commodities and seeds. Current regulations do not expressly allow for such occurrences, though experience continues to show that such occurrences can occur. In a notice published in the **Federal Register** on August 2, 2002 (67 FR 50577–50580), by the Office of Science and Technology Policy, APHIS committed to conducting a risk-based regulatory program that minimizes the occurrence of these materials but includes safety criteria under which these materials would be allowed at low levels in commercial commodities and seeds. On March 29, 2007, APHIS published a policy statement in the **Federal Register** (72 FR 14649–14651, Docket No. APHIS–2006–0167) to clarify how it currently handles cases of low-level presence of regulated materials in commodities and seeds.

Based on our evaluation and assessment of alternatives in the DEIS, APHIS has made a preliminary determination to establish in regulations criteria under which the occurrence of regulated articles would be allowable, that is, considered not actionable by APHIS. The occasional detection of regulated material in commercial crops as seeds can occur as a result of field tests conducted under confinement conditions appropriate for notifications. This is due to cross-pollination and also commingling from shared equipment and facilities. In addition, such incidents will inevitably result from the importation of seeds and commodities from countries where such material has been fully approved but has not completed all U.S. reviews. In the majority of cases, this low-level occurrence of regulated articles will be of minimal risk, and this fact should be accounted for in any regulatory scheme since oversight should be commensurate with risk.

APHIS is interested in receiving comment on this alternative, but in particular, requests comment on whether APHIS should establish a new

regulatory approach to address such incidents of low-level presence of genetically engineered plant material. If low-level presence incidents occur, what criteria should the Agency use to determine whether remedial action will be required, and to determine the nature and scope of any such remedial action?

DEIS Issue 8—Importation of Genetically Engineered Commodities Not Intended for Propagation

APHIS anticipates an increasing number of requests to import regulated genetically engineered organisms that are not intended for propagation, such as organisms that are intended for direct use as food, feed, or for processing. The current system of permits and notifications was not designed to handle such requests on a case-by-case basis. However, in anticipation of this increase, APHIS' goal is to design an efficient system that protects U.S. agriculture and human health without erecting unnecessary trade barriers. To that end, the Agency has evaluated several different alternatives.

Based on considerations more fully described in the DEIS, APHIS has made a preliminary determination to have a new regulatory mechanism to allow for imports of commodities for nonpropagative use, that is, for food, feed, or processing, in cases where these commodities might not have been deregulated in the United States. With this approach, we could establish criteria to ensure safety and allow for additional environmental review when appropriate. Allowing such imports without prior deregulation would not obviate the need to comply with requirements at other agencies, such as FDA and EPA.

APHIS is interested in receiving comment on this alternative and, more specifically, comments as to the commodity characteristics and other data that APHIS should consider when determining the appropriate safeguards for commodities coming in for processing or to be used directly as food or feed.

DEIS Issue 9—Interstate Movement of Well-Studied, Low Risk Organisms

Currently, genetically engineered *Arabidopsis* spp. and a few other organisms are exempt from interstate movement restrictions under 7 CFR 340.2 because they are well understood and extensively used in research. Based on considerations more fully described in the DEIS, APHIS is considering whether to expand the current exemption from interstate movement restrictions to other well-studied, low-risk, genetically engineered research organisms. Such a change would create a consistent, risk based approach to organisms with similar risk profiles.

Are there other genetically engineered organisms that should also be exempt from regulation in the same or similar manner as genetically engineered *Arabidopsis* spp.? Which organisms, if any, should be considered for such an exemption? Should the quantity of seeds or plant material being moved be considered in any exemption? In connection with such an exemption, should there continue to be some limited regulatory oversight, and what should be the nature and scope of such oversight?

As noted above, we are interested in receiving comments on all of the issues presented in the DEIS and particularly on the issues and alternatives outlined above.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 12th day of July 2007.

Bruce Knight,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 07–3474 Filed 7–13–07; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 354

9 CFR Parts 130 and 156

[Docket No. APHIS–2006–0028]

RIN 0579–AC44

User Fees; Updates and Clarifications

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend our Agricultural Quarantine and Inspection Services user fee regulations to update an address that appears in several places. We are also proposing to make several nonsubstantive changes to the Veterinary Services user fees regulations to correct errors and to clarify the services covered by certain existing user fees. These proposed changes, which do not affect any existing fees, are necessary to ensure that the user fee regulations are up-to-date and ensure their clarity.

DATES: We will consider all comments that we receive on or before September 17, 2007.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov,* select ''Animal and Plant Health Inspection Service'' from the agency drop-down menu, then click ''Submit.'' In the Docket ID column, select APHIS–2006–0028 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to APHIS–2006–0028, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to APHIS–2006–0028.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Kris Caraher, User Fees Section Head, Financial Services Branch, Financial Management Division, MRBPS, APHIS, 4700 River Road, Unit 54, Riverdale, MD 20737–1232; (301) 734–5901.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR, chapter III, and 9 CFR, chapter I, subchapter D, require inspection, laboratory testing, certification, or quarantine of certain plants, plant products, animals, animal products, or other commodities intended for importation into, or exportation from, the United States.

Section 2509(a) of the Food, Agriculture, Conservation, and Trade Act of 1990 (21 U.S.C. 136a), referred to below as the FACT Act, authorizes the Secretary of Agriculture to collect user fees for agricultural quarantine and inspection (AQI) services. The FACT Act was amended on April 4, 1996, and May 13, 2002.

The user fees to reimburse the Animal and Plant Health Inspection Service (APHIS) for the costs of providing inspections for AQI services are contained in 7 CFR part 354. In this document, we propose to amend the AQI international services user fee regulations by correcting and updating the remittance addresses in § 354.3 to reflect the proper addresses for mailings. All current customers have already received notices regarding these changes; however, we need to correct the information that appears in the regulations.

The FACT Act also authorizes the Secretary of Agriculture to, among other things, prescribe and collect fees to reimburse the Secretary for the cost of carrying out the provisions of the Federal animal quarantine laws that relate to the importation, entry, and exportation of animals, articles, or means of conveyance. The Secretary is also authorized to prescribe and collect fees to recover the costs of carrying out certain veterinary diagnostics services.

The user fee regulations in 9 CFR part 130 (referred to below as the regulations) prescribe user fees that APHIS collects for various services that we provide. The regulations currently include fees for: (1) Endorsing export certificates for animals; (2) providing quarantine services within the United States for imported animals; (3) providing certain inspection and supervision services within the United States for animals intended for export; (4) conducting certain veterinary inspections outside the United States; and (5) conducting certain veterinary diagnostics services.

We would make several nonsubstantive changes to the regulations. These proposed changes are explained below.

In § 130.4, *User fees for processing import permit applications,* we would add a sentence at the end of the introductory text of the section in order to clarify for our customers that user fees for processing applications for permits to import certain animals and animal products (using VS forms 16–3 and 17–129) are nonrefundable. While none of our user fees are refundable, the user fees in this case pertain to the processing of the import permit application, not to the permit itself. Because the user fees in this case apply whether or not import permits are issued to the applicants, some customers ask for clarification regarding the nonrefundability of the fees.

In § 130.7, *User fees for import or entry services for live animals at land border ports along the United States-Canada border,* we would clarify that if a service must be conducted on a Sunday or holiday or at any other time outside the normal tour of duty of the employee, then reimbursable overtime, as provided for in 9 CFR part 97, must be paid for each service in addition to the user fee listed in this section. Because we currently charge reimbursable overtime in the abovementioned circumstances, as provided for in § 97.1, we believe it would be helpful to include this reference in the user fee regulations.

In § 130.11, *User fees for inspecting and approving import/export facilities and establishments,* we would amend paragraph (a), which applies user fees for inspecting and approving import/export facilities and establishments, by clarifying that these user fees do not apply to inspection activities covered in § 130.30(a)(2), which pertains to inspections required either to obtain import permits for animal products, aquaculture products, or organisms or vectors, or to maintain compliance with import permits. We provide these facility inspection services frequently and customers regularly ask for clarification as to which user fee applies. Conversely, we would amend § 130.30(a)(2), which sets out the hourly rate for laboratory and facility inspections, by clarifying that the hourly rate in this paragraph also applies to inspections of biosecurity level two facilities, and that this hourly rate does not apply to inspection activities covered in § 130.11. We provide these services frequently and customers regularly ask for clarification as to which user fees apply. We currently charge the hourly rate for inspections of biosecurity level two facilities, so there will not be any change in fees.

In § 130.20, *User fees for endorsing export certificates,* paragraph (b)(1) pertains to user fees for the endorsement of export health certificates that require APHIS to verify tests or vaccinations. In the table in that paragraph, we would amend the entry for nonslaughter horses to Canada by replacing the word ''animal'' with ''horse'' for the sake of clarity. Additionally, because the applicable user fee increases with the number of tests and vaccinations that must be verified, we would add a footnote to the chart to clarify that rabies vaccinations are not counted in this number. Almost all domesticated animals and livestock in the United States are vaccinated for rabies, and we do not spend a significant amount of time looking at the rabies vaccination paperwork.

We would also amend § 130.30, paragraph (a)(4), which applies hourly rate fees to services provided for imported birds or ratites that are not subject to quarantine, by specifically mentioning that these hourly rate fees cover services such as monitoring birds, including but not limited to pet birds, between flights. We provide this service frequently and customers regularly need clarification as to which user fees apply. We currently charge the hourly rate to monitor birds between flights, so there will not be any change in fees.

We would also amend § 130.30, paragraph (a), by specifically identifying additional services for which APHIS charges an hourly rate. These services are currently covered under the general catch-all text of paragraph (a)(13)—i.e., under ''other import-or export-related services for which there is no flat rate user fee specified elsewhere in this part''—but we provide these services frequently and customers regularly request clarification as to which user fees apply.

The specific services we would add are:

- Import or entry services for feeder animals including, but not limited to, feeder goats and feeder bison not covered by a flat rate user fee in § 130.7;
- Bird banding for identification;
- Inspection and approval of pet food facilities, including laboratories that perform pet food testing;
- Services provided at animal auctions, such as signing export health certificates; and
- Various facility inspections, including, but not limited to, fertilizer plants that utilize poultry waste, rendering plants, and potential embarkation facilities.

Finally, we would clarify that user fees for services under part 130 (specifically, user fees in §§ 130.2 through 130.8) apply whenever APHIS provides the services, be it through APHIS employees, contract veterinarians, or other personnel. We would do this by adding language to the regulations stating that user fees are payable for any service rendered by an APHIS representative, which is defined in § 130.1 as: ''An individual, including but not limited to, an animal health technician or veterinarian, authorized by the Administrator to perform services for which the user fees in this part are charged.'' This change is necessary to clarify for our customers that when APHIS provides services through an APHIS representative, such as contract veterinarians or other personnel, user fees still apply.

Changes in Part 156: Voluntary Inspection and Certification Service

The regulations in 9 CFR part 156 govern the inspection and certification of animal byproducts. Within these regulations, there are provisions regarding cooperative agreements between the Department and some other Federal or State agency, board of trade, chamber of commerce, or other agency, association, organization, person, or corporation as provided for in section 205 of the Agricultural Marketing Act of 1946 (7 U.S.C. 1624) to provide services under part 156.

In this document, we are proposing to remove those references to cooperative agreements because the export product endorsement and inspection services formerly covered by those agreements are now covered by user fees in 9 CFR part 130.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This proposed rule would amend our AQI user fee regulations by updating an address that appears in several places. We would also make several nonsubstantive changes to the Veterinary Services user fees regulations to correct errors and to clarify existing user fee services. The proposed changes to the regulations are administrative in nature and will not result in any new fees being charged or any additional entities becoming subject to user fees.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects

7 CFR Part 354

Animal diseases, Exports, Government employees, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Travel and transportation expenses.

9 CFR Part 130

Animals, Birds, Diagnostic reagents, Exports, Imports, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Tests.

9 CFR Part 156

Exports, Livestock, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 7 CFR part 354 and 9 CFR parts 130 and 156 as follows:

TITLE 7—[AMENDED]

PART 354—OVERTIME SERVICES RELATING TO IMPORTS AND EXPORTS; AND USER FEES

1. The authority citation for part 354 continues to read as follows:

Authority: 7 U.S.C. 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 49 U.S.C. 80503; 7 CFR 2.22, 2.80, and 371.3.

§ 354.3 [Amended]

2. In § 354.3, paragraphs (d)(4) introductory text, (d)(5), (d)(6), (e)(3)(i), (e)(3)(ii) introductory text, (e)(4), (f)(5)(i), (f)(5)(ii), (f)(5)(iii) introductory text, (f)(6), and (f)(7), remove the words ''Box 952181, St. Louis, MO 63195–2181'' and add the words ''Box 979044, St. Louis, MO 63197–9000'' in their place.

TITLE 9—[AMENDED]

PART 130—USER FEES

3. The authority citation for part 130 continues to read as follows:

Authority: 5 U.S.C. 5542; 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 3701, 3716, 3717, 3719, and 3720A; 7 CFR 2.22, 2.80, and 371.4.

§ 130.2 [Amended]

4. In § 130.2, paragraph (a), the first sentence is amended by adding the words ''for any service rendered by an APHIS representative'' after the word ''fees''.

§ 130.3 [Amended]

5. In § 130.3, paragraph (c)(3) is amended by removing the words ''for those services'' and adding the words ''for any service rendered by an APHIS representative'' in their place.

§ 130.4 [Amended]

6. In § 130.4, the first sentence of the section is amended by adding the words ''for any service rendered by an APHIS representative'' after the word ''fees'', and the sentence ''These fees are nonrefundable.'' is added after the second sentence.

§ 130.5 [Amended]

7. In § 130.5, paragraph (a), the first sentence is amended by adding the words ''for any service rendered by an APHIS representative'' after the word ''fees''.

§ 130.6 [Amended]

8. In § 130.6, paragraph (a), the first sentence is amended by adding the words ''for any service rendered by an APHIS representative'' after the word ''fees''.

9. Section 130.7 is amended as follows:

a. In paragraph (a), first sentence, by adding the words ''for any service rendered by an APHIS representative'' after the word ''fees''.

b. By adding paragraph (b) to read as set forth below.

§ 130.7 User fees for import or entry services for live animals at land border ports along the United States-Canada border.

* * * * *

(b) If a service must be conducted on a Sunday or holiday or at any other time outside the normal tour of duty of the employee, then reimbursable overtime, as provided for in part 97 of this chapter, must be paid for each service, in addition to the user fee listed in this section.

§ 130.8 [Amended]

10. In § 130.8, paragraph (a), the first sentence is amended by adding the words ''for any service rendered by an APHIS representative'' after the word ''fees''.

§ 130.11 [Amended]

11. In § 130.11, paragraph (a) is amended by adding the sentence ''These user fees do not apply to inspection activities covered in § 130.30(a)(2).'' after the last sentence.

12. In § 130.20, paragraph (b)(1) is amended by adding footnote 1 in the table heading and by revising in the table the entry for ''Nonslaughter horses to Canada'' to read as follows:

§ 130.20 User fees for endorsing export certificates.

* * * * *

(b)(1) * * *

Number [1] of tests or vaccinations and number of animals or birds on the certificate	User fee beginning Oct. 1, 2003
* * * * * * *	
Nonslaughter horses to Canada:	
First horse	$38.00
Each additional horse	4.25
* * * * * * *	

[1] Rabies vaccinations are not included in this number.

* * * * *

13. Section 130.30 is amended as follows:

a. In the introductory text of paragraph (a), by removing the words ''through (a)(13)'' and adding the words ''through (a)(18)'' in their place.

b. Paragraph (a)(2) is revised.

c. In paragraph (a)(4), by adding the words '', such as monitoring birds-including but not limited to pet birds-between flights'' after the word ''quarantine''.

d. Paragraph (a)(13) is redesignated as paragraph (a)(18), and new paragraphs (a)(13), (a)(14), (a)(15), (a)(16), and (a)(17) are added to read as set forth below.

§ 130.30 Hourly rate and minimum user fees.

(a) * * *

* * * * *

(2) Conducting inspections, including inspections of laboratories and facilities (such as biosecurity level two facilities), required either to obtain import permits for animal products, aquaculture products, or organisms or vectors, or to maintain compliance with import permits. This hourly rate does not apply to inspection activities covered in § 130.11.

* * * * *

(13) Import or entry services for feeder animals including, but not limited to, feeder goats and feeder bison not covered by a flat rate user fee in § 130.7.

(14) Export-related bird banding for identification.

(15) Export-related inspection and approval of pet food facilities, including laboratories that perform pet food testing.

(16) Export-related services provided at animal auctions.

(17) Various export-related facility inspections, including, but not limited to, fertilizer plants that utilize poultry waste, rendering plants, and potential embarkation facilities.

* * * * *

PART 156—VOLUNTARY INSPECTION AND CERTIFICATION SERVICE

14. The authority citation for part 156 continues to read as follows:

Authority: 7 U.S.C. 1622 and 1624; 21 U.S.C. 136a; 7 CFR 2.22, 2.80, and 371.4.

§ 156.2 [Amended]

15. Section 156.2 is amended as follows:

a. By removing the definition of *cooperative agreement.*

b. In the definition of *inspector,* by removing the words ''under a cooperative agreement''.

§ 156.4 [Amended]

16. Section 156.4 is amended by removing the words ''under a cooperative agreement''.

§ 156.5 [Amended]

17. Section 156.5 is amended by removing the words ''service is to be furnished under a cooperative agreement;'' and adding the words ''the requirements of part 130 of this title are met;'' in their place.

18. Section 156.7 is revised to read as follows:

§ 156.7 User fees under 9 CFR part 130.

User fees under part 130 of this chapter for service (including travel and other expenses incurred in connection with the furnishing of service) under this part shall be paid by the applicant. If required by the Administrator, the user fees under part 130 of this chapter shall be paid in advance. Since the user fees under part 130 of this chapter are for the purpose of reimbursing the Department for all costs incurred in connection with the furnishing of service under this part, the appropriate user fees under part 130 of this chapter to cover any such costs shall be paid even if service is withheld pursuant to § 156.8.

Done in Washington, DC, this 11th day of July 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–13775 Filed 7–16–07; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1755

Telecommunications Policies on Specifications, Acceptable Materials, and Standard Contract Forms

AGENCY: Rural Utilities Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Rural Utilities Service, an agency delivering the United States Department of Agriculture's (USDA) Rural Development Programs, hereinafter referred to as Rural Development and/or Agency, proposes to revise the fiber optic cable specification used by borrowers, their consulting engineers, and cable manufacturers. This revision will bring the specification to meet current industries standards. Additional requirements have been included in the specification to meet the construction requirement of fiber-to-the-home construction.

DATES: Comments must be submitted on or by September 17, 2007.

ADDRESSES: Submit comments by either of the following methods:

Federal eRulemaking Portal: Go to *http://www.regulations.gov* and, in the lower ''Search Regulations and Federal Actions'' box, select ''Rural Utilities Service'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select RUS–07–Telecom–0005 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after

the close of the comment period, is available through the site's ''User Tips'' link.

Postal Mail/Commercial Delivery: Please send your comment addressed to Michele Brooks, Acting Deputy Director, Program Development and Regulatory Analysis, USDA Rural Development, 1400 Independence Avenue, STOP 1522, Room 5159, Washington, DC 20250–1522. Please state that your comment refers to Docket No. RUS–07–Telecom–0005.

Other Information: Additional information about Rural Development and its programs is available on the Internet at *http://www.rurdev.usda.gov/index.html*.

FOR FURTHER INFORMATION CONTACT: Norberto Esteves, Chair, Technical Standards Committee ''A'' (Telecommunications), Advanced Services Division, USDA Rural Development Telecommunications Program, STOP 1550, Washington, DC 20250–1550, telephone number 202–720–0699, fax number 202–205–2924, e-mail *norberto.esteves@wdc.usda.gov*.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule is exempted from the Office of Management and Budget (OMB) review for purposes of Executive Order 12866 and, therefore, has not been reviewed by OMB.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. USDA Rural Development has determined that this proposed rule meets the applicable standards provided in section 3 of the Executive Order. In addition, all state and local laws and regulations that are in conflict with this proposed rule will be preempted; no retroactive effect will be given to the rule, and, in accordance with section 212(e) of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6912(e)), administrative appeals procedures, if any are required, must be exhausted before an action against the Department or its agencies may be initiated.

Regulatory Flexibility Act Certification

USDA Rural Development has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The standard USDA Rural Development telecommunications loan documents contain provisions on procurement of products and construction of telecommunications facilities purchased with loan funds. This ensures that the telecommunications systems financed with loan funds are adequate to serve the purposes for which they are to be constructed and that loan funds are adequately secured. USDA Rural Development borrowers, as a result of obtaining Federal financing, receive economic benefits that exceed any direct cost associated with complying with USDA Rural Development regulations and requirements.

Information Collection and Recordkeeping Requirements

The information collection and recordkeeping requirements contained in this proposed rule are cleared under control numbers 0572–0059 and 0572–0132 pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Under Executive Order 13132, this proposed rule does not have sufficient federalism implications requiring the preparation the preparation of a Federalism Assessment.

Catalog of Federal Domestic Assistance

The program described by this proposed rule is listed in the Catalog of Federal Domestic Assistance Program under No. 10.851, Rural Telephone Loans and Loan Guarantees and No. 10.857, Rural Broadband Access Loans and Loan Guarantees. This catalog is available on a subscription basis from the Superintendent of Documents, the United States Government Printing Office, Washington, DC 20402. Telephone: (202) 512–1800.

Executive Order 12372

This proposed rule is excluded from the scope of Executive Order 12372, Intergovernmental Consultation, which may require consultation with State and local officials. See the final rule related notice titled ''Department Programs and Activities Excluded from Executive Order 12372'' (50 FR 47034), advising that USDA Rural Development Utilities Programs loans and loan guarantees are excluded from the scope of Executive Order 12372.

Unfunded Mandates

This proposed rule contains no Federal Mandates (under the regulatory provisions of Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. Chapter 25)) for State, local, and tribal governments or the private sector. Thus, this proposed rule is not subject to the requirements of sections 202 and 205 of the Unfunded Mandates Reform Act of 1995.

National Environmental Policy Act Certification

The Agency has determined that this proposed rule will not significantly affect the quality of the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) Therefore, this action does not require an environmental impact statement or assessment.

Background

This proposed rule revises the current requirements for fiber optic cables of 7 CFR 1755.900 codified in 1995. The proposed rule sets the minimum performance requirements based on current industry standards. This revision was initiated to resolve problems the rural telecom industry is experiencing with cables manufactured under the existing specification and reported by rural carriers and their consulting engineers. It addresses the buffer tube shrinkage caused by storage at low temperatures, which impairs fiber-to-the-home system performance. The proposed specification also sets new requirements for drop cables (cables with 12 or fewer fibers operating up to 100 meters (300 feet)).

Cables manufactured to this revised specification will have lower average bi-directional loss at fusion splices, about 0.1 decibels (dB) instead of the 0.2 dB currently required. For fiber-to-the-home applications the specification requires a maximum mid-span length of 4.9 meters (16 feet) or 3 meters (10 feet), as specified by the buyer, for cables used on mid-span applications with buffer tube storage. From a polarization mode dispersion standpoint, the maximum Statistical Parameter of Polarization Mode Dispersion (PMD_Q) of 0.20 Picosecond per nanometer times kilometer (ps/√km) specified will allow the deployment of higher-speed transmission systems at longer distances: 3,000 kilometers (km) (1,864 miles) for digital systems operating at 10 Gigabit per second (Gbps) and 80 km (50 miles) operating at 40 Gbps. These performance refinements are necessary because purchasers deploying cable meeting this level of performance expect it to deliver high bitrate services during the useful economic life of these cables.

List of Subjects in 7 CFR Part 1755

Broadband, Fiber optic cables, Loan programs—communications, Reporting and recordkeeping requirements, Rural areas, Telecommunications, Telephone.

For the reasons set out in the preamble, the Agency proposes to amend part 1755, chapter XVII of title 7 of the Code of Federal Regulations, as follows:

PART 1755—TELECOMMUNICATIONS POLICIES ON SPECIFICATIONS, ACCEPTABLE MATERIALS, AND STANDARD CONTRACT FORMS

1. The authority citation for part 1755 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.*, 1921 *et seq.*, 6941 *et seq.*

2. The heading of part 1755 is revised to read as set out above.

3. Section 1755.900 is revised, an undesignated center heading is added, appendixes A and B to § 1755.900 are removed, and a new appendix to § 1755.900 is added, to read as follows:

Minimum Performance Specification for Fiber Optic Cables

§ 1755.900 Agency specification for fiber optic cables.

(a) *Abbreviations.* The following abbreviations apply to this section:

(1) ASTM Amercian Society for Testing and Materials;

(2) °C Centigrade temperature scale;

(3) dB Decibel;

(4) dB/km Decibels per 1 kilometer;

(5) ECCS Electrolytic chrome coated steel;

(6) EIA Electronic Industries Alliance;

(7) EIA/TIA Electronic Industries Alliance Telecommunications Industry Association;

(8) FTTH Fiber-to-the-Home;

(9) Gbps Gigabit per second or Gbit/s;

(10) GE General Electric;

(11) HDPE High density polyethylene;

(12) ICEA Insulated Cable Engineers Association, Inc.;

(13) Km kilometers(s)

(14) LDPE Low density polyethylene;

(15) m meter(s)

(16) Max. Maximum;

(17) MDPE Medium density polyethylene;

(18) MHz-km Megahertz-kilometer;

(19) Min. Minimum;

(20) MFD Mode-Field Diameter

(21) nm Nanometer(s);

(22) N Newton(s);

(23) NA Numerical aperture;

(24) NESC National Electrical Safety Code;

(25) OC Optical cable;

(26) O.D. Outside Diameter;

(2) OF Optical fiber;

(28) OSHA Occupational Safety and Health Administration;

(29) OTDR Optical Time Domain Reflectometer

(30) % Percent;

(31) ps/(nm·km) Picosecond per nanometer times kilometer;

(32) ps/(nm^2·km) Picosecond per nanometer squared times kilometer;

(33) SI International System (of Units) (From the French Système international d'unités); and

(34) µm Micrometer.

(b) *Definitions.* The following definitions apply to this section:

(1) *Agency:* The Rural Utilities Service, an agency which delivers the United States Department of Agriculture's (USDA) Rural Development Utilities Programs;

(2) *Armor:* A metal tape intended to provide mechanical and environmental protection against rodents, termites, etc.

(3) *Bandwidth:* The range of signal frequencies that can be transmitted by a communications channel with defined maximum loss or distortion. Bandwidth indicates the information-carrying capacity of a channel. For an optic fiber system bandwidth is usually given as its capacity to transmit information in a specific time period for a specific length, *e.g.*, 10 Mbit/sec/km.

(4) *Chromatic Dispersion:* The spreading out of light pulses as they travel in an optical fiber, proportional to length.

(5) *Cladding:* A layer of glass or other transparent material fused to and concentrically surrounding the core. The cladding has a lower refractive index than the core, so light is internally reflected along the core.

(6) *Core:* The central region of an optical waveguide or fiber through which light is transmitted.

(7) *Cutoff Wavelength:* The shortest wavelength at which only the fundamental mode of an optical wavelength can propagate.

(8) *Dielectric Cables:* Cable with no metallic members or other electrically conductive materials.

(9) *Graded Refractive Index Profile:* Any index profile that varies smoothly with radius.

(10) *Loose Tube Buffer:* A protective tube loosely surrounding a cabled fiber, often filled with suitable water blocking material.

(11) *Matched Cable:* Cable manufactured to this specification for which the calculated loss due to Mode Field Diameter (MFD) mismatch between two fibers to be spliced is ≤ 0.06 dB when using the following formula:

$$\text{LOSS (dB)} = -10\ \text{LOG}_{10}\left[4/(\text{MFD}_1/\text{MFD}_2 + \text{MFD}_2/\text{MFD}_1)^2\right],$$

where subscripts 1 and 2 refer to the two fibers to be spliced.

(12) *Mil:* A measurement unit of length indicating one thousandth of an inch.

(13) *Minimum Bending Diameter:* A smallest diameter that must be maintained to avoid degrading cable performance (Bending Diameter/Cable Diameter.)

(14) *Mode-Field Diameter:* The diameter of the one mode of light propagating in a single mode fiber.

(15) *Multimode Fiber:* An optical fiber which will allow more than one bound mode to propagate. It may be either a graded index or step index optical fiber.

(16) *Numerical Aperture (NA):* An optical fiber parameter that indicates the angle of acceptance of light into a fiber.

(17) *Optical Fiber:* Any fiber made of dielectric material that guides light.

(18) *Optical Point Discontinuities:* Localized deviation of the optical fiber loss characteristic which location and magnitude may be determined by appropriate OTDR measurements.

(19) *Optical Waveguide:* Any structure capable of guiding optical power. In optical communications, the term generally refers to a fiber designed to transmit optical signals.

(20) *Polarization Mode Dispersion:* A form of modal dispersion where different polarizations of the light caused by asymmetric distortions of the fiber form the ideal perfect shape of a cylinder that travel at different speeds due to random imperfections in the fiber waveguide causing random spreading of optical pulses.

(21) *Ribbon:* A planar array of parallel optical fibers.

(22) *Shield:* Conductive metal tape for lightning protection, bonding, grounding and electrical shielding.

(23) *Single Mode Fiber:* An optical fiber in which only one bound mode can propagate at the wavelength of interest.

(24) *Step Refractive Index Profile:* An index profile characterized by a uniform refractive index within the core and a sharp decrease in refractive index at the core-cladding interface. It corresponds to a power-law profile with profile parameter, g, approaching infinity.

(25) *Tight Tube Buffer:* One or more layers of buffer material tightly surrounding a fiber in contact with the coating of the fiber.

(c) *Scope.* This section is intended for cable manufacturers, Agency borrowers, and consulting engineers. It covers the requirements for fiber optic cables intended for aerial installation either by

attachment to a support strand or by an integrated self-supporting arrangement, for underground application by placement in a duct, or for buried installations by trenching, direct plowing, and directional or pneumatic boring.

(1) *Requirements.* Specification requirements are given in SI units which are the controlling units in this part. Approximate English equivalent of units are given for information purposes only.

(i) The optical waveguides are glass fibers having directly-applied protective coatings, and are called ''fibers'', herein. These fibers may be assembled in either loose fiber bundles with a protective core tube, encased in several protective buffer tubes, in tight buffer tubes, or ribbon bundles with a protective core tube.

(ii) Fillers, strength members, core wraps, and bedding tapes may complete the cable core.

(iii) The core or buffer tubes containing the fibers and the interstices between the buffer tubes, fillers, and strength members in the core structure are filled with a suitable material or water swellable elements to exclude water.

(iv) The cable structure is completed by an extruded overall plastic jacket. A shield or armor or combination thereof may be included under the jacket. The jacket may have strength members embedded in it.

(v) Buried installation requires armor under the outer jacket.

(vi) For self-supporting cable, the outer jacket may be extruded over the support messenger and cable core.

(vii) Cables for mid-span applications for network access shall be designed for easy mid-span access to the fibers. The manufacturer may use reversing oscillating stranding (SZ) described in section 6.4 of ITU–T Recommendation L.58 or any other manufacturer's method that is acceptable to the Agency.

(2) The normal temperature ranges for cable under this specification must meet paragraph 1.1.3 of ANSI/ICEA S–87–640.

(3) *Tensile Rating.* The standard installation tensile rating for cable under this specification is 2670 N (600 lbf.), unless, installation involves micro type cables that utilize less stress related methods of installation, i.e. blown micro-fiber cable or All-Dielectric Self-Supporting (ADSS) cables (see paragraph (c)(4) of this section.)

(4) *ADSS cables.* Based on the storm loading districts referenced in Section 25, Loading of Grades B and C, of the latest edition of NESC and the maximum span and location of cable installation provided by the purchaser, the manufacturer shall provide a cable design with sag and tension tables showing the maximum span and sag information for that particular installation. The information included shall be for Rule B, Ice and Wind Loading, and when applicable, information on Rule 250C, Extreme Wind Loading. Additionally, to ensure the proper ground clearance, typically 4.3 m (14 feet) the end user should factor in the maximum sag under loaded conditions as well as height of attachment for each application.

(5) *Minimum Bend Diameter.* For cable under loaded and unloaded conditions, the cable shall have the minimum bend diameters indicated in paragraph 1.1.5, Minimum Bend Diameter of the ANSI/ICEA S–87–640. For very small cables, manufacturers may specify fixed cable minimum bend diameters that are independent of the outside diameter. For a bend diameter of cables having a non-circular cross-section is to be determined using the thickness as the cable diameter and bending in the direction of the preferential bend.

(6) The cable is fully color coded so that each fiber is distinguishable from every other fiber. A basic color scheme of twelve colors allows individual fiber identification. Colored tubes, binders, threads, strippings, or markings provide fiber group identification.

(7) Cable manufactured to this specification must demonstrate compliance with the qualification testing requirements to ensure satisfactory end-use performance characteristics for the intended applications.

(8) Optical cable designs not specifically addressed by this specification may be allowed if accepted by the Agency. Justification for acceptance of a modified design must be provided to substantiate product utility and long term stability and endurance.

(9) All cables sold to Agency borrowers for projects involving Agency loan funds under this specification must be accepted by the Agency's Technical Standards Committee ''A'' (Telecommunications.) For cables manufactured to this specification, all design changes to an accepted design must be submitted for acceptance. The Agency will be the sole authority on what constitutes a design change.

(10) The Agency intends that the optical fibers contained in the cables manufactured under this specification have characteristics that will allow signals, having a range of wavelengths, to be carried simultaneously.

(d) *Optical Fibers.* (1) The solid glass optical fibers must consist of a cylindrical core and cladding covered by either an ultraviolet-cured acrylate or other suitable coating. Each fiber shall be continuous throughout its length.

(2) *Zero-dispersion.* Optical fibers shall meet the fiber attributes of Table 2/G.652, *G.652.B attributes*, of ITU–T Recommendation G.652. However, when the purchaser stipulates a low water peak fiber the optical fibers shall meet the fiber attributes of Table 4/G.652, *G.652.D attributes*, of ITU–T Recommendation G.652.

(3) *Non-zero dispersion.* Optical fibers shall meet the fiber attributes of ITU–T Recommendation G.656. However, when the buyer specified ITU–T Recommendation G.655 A, B, C, D, or E, the optical fibers shall meet the fiber attributes of such ITU–T Recommendation.

(4) *Multimode fibers.* Optical fibers shall meet the requirements of paragraphs 2.1 and 2.3.1 of ANSI/ICEA S–87–640.

(5) *Matched cables.* Unless otherwise specified by the buyer, all single mode fiber cables delivered to an Agency-financed project must be manufactured to the same MFD specification. However, notwithstanding the requirements indicated in paragraphs (d)(2) and (d)(3) of this section, the maximum MDF tolerance allowed for cable made under this specification shall be of a magnitude so the cable meets the definition of ''matched cables,'' as defined in this specification. With the use of cable manufactured to this specification the user can reasonably expect that the average bi-directional loss of a fusion splice to be ≤ 0.1 dB.

(6) Buyers will normally specify the MFD for the fibers in the cable. When a buyer does not specify the MFD for fiber compliant with ITU–T Recommendation G.652.B or 652.D, the fibers shall be manufactured to an MFD of 9.2 ± 0.5 μm (362 ± 20 microinch), unless the buyer agrees to accept cable with fibers specified to a different MD. When the buyer does specify an MFD with a MDF tolerance conflicting with the MFD maximum tolerance allowed by paragraph (d)(5) of this section, the requirements of paragraph (d)(5) shall prevail.

(7) Factory splices are not allowed.

(8) *Coating.* The optical fiber must be coated with a suitable material to preserve the intrinsic strength of the glass having an outside diameter of 250 ± 15 micrometers (10 ± 0.6 mils) when measured per EIA/TIA–455–55C. The protective coverings must be free from holes, splits, blisters, and other

imperfections and must be as smooth and concentric as is consistent with the best commercial practice. The diameter of the fiber as the fiber is used in the cable includes any coloring thickness or the uncolored coating, as the case may be. The strip force required to remove 30 ± 3 millimeters (1.2 ± 0.1 inch) of protective fiber coating shall be between 1.0 N (0.2 pound-force) and 9.0 N (2 pound-force).

(9) All optical fibers in any single length of cable must be of the same type unless otherwise specified by purchaser.

(10) Optical fiber dimensions and data reporting shall be as required by paragraph 7.13.1.1 of ANSI/ICEA S–87–640.

(e) *Buffers*. (1) The optical fibers contained in a tube buffer (loose tube), an inner jacket (unit core), a channel, or otherwise loosely packaged must have a clearance between the fibers and the inside of the container sufficient to allow for thermal expansions without constraining the fibers. The protective container must be manufactured from a material having a coefficient of friction sufficiently low to allow the fibers free movement. The loose tube shall contain a suitable water blocking material. Loose buffer tubes must be removable without damage to the fiber when following the manufacture's recommended procedures.

(2) The tubes for single mode loose tube cables shall be designed to allow a maximum mid-span buffer tube exposure of 3 meters (10 feet) or 4.9 meters (16 feet). The buyer should be aware that certain housing hardware may require cable designed for 4.9 meter buffer tube storage.

(3) Optical fibers covered in near contact with an extrusion (tight tube) must have an intermediate soft buffer to allow for thermal expansions and minor pressures. The buffer tube dimension shall be established by the manufacturer to meet the requirement of this specification. Tight buffer tubes must be removable without damage to the fiber when following the manufacture's recommended procedures. The tight buffered fiber shall be strippable per paragraph 7.20 of ANSI/ICEA S–87–640.

(4) Both loose tube and tight tube coverings of each color and other fiber package types removed from the finished cable must meet the following shrinkback and cold bend performance requirements. The fibers may be left in the tube.

(i) *Shrinkback*: Testing must be conducted per ASTM D 4565, Paragraph 14.1, using a talc bed at a temperature of 95 °C (203 °F). Shrinkback must not exceed 5 percent of the original 150 millimeter (6 inches) length of the specimen. The total shrinkage of the specimen must be measured. (Buffer tube material meeting this test may not meet the midspan test in paragraph (t)(18) of this section.)

(ii) *Cold Bend*: Testing must be conducted on at least one tube from each color in the cable. Stabilize the specimen to −30 ± 1 °C (−22 ± 2 °F) for a minimum of four hours. While holding the specimen and mandrel at the test temperature, wrap the tube in a tight helix ten times around a mandrel with a diameter to be the greater of five times the tube diameter or 50mm (2 inches.) The tube must show no evidence of cracking when observed with normal or corrected-to-normal vision.

Note to paragraph (E)(4)(II): Channel cores and similar slotted single component core designs need not be tested for cold bend.

(f) *Fiber Identification*. (1) Each fiber with a unit and each unit within the cable shall be identifiable per paragraph 4.2.1 and 4.3.1 of ANSI/ICEA S–87–640.

(2) The colors designated for identification of loose buffer tubes, tight tube buffer fibers, individual fibers in multi-fiber tubes, slots, bundles or units of fibers, and the units in cables with more than one unit shall be per TIA–598–C, *Optical Fiber Cable Color Coding*.

(3) *Standards of Colors*: The colors of fibers and tubes supplied shall be per the terms of the Munsell Color System (ASTM D 1535) and must comply with the color limits as defined in TIA–598–C.

(g) *Optical Fiber Ribbon*. (1) Each ribbon shall be identified per paragraphs 3.4.1 and 3.4.2 of ANSI/ICEA S–87–640.

(2) Ribbon fiber count shall be specified by the purchaser, *i.e.* 2, 4, 6, 12, etc.

(3) Ribbon dimensions shall be as agreed by the purchaser and manufactures per Paragraphs 3.4.4.1 of ANSI/ICEA S–87–640.

(4) Ribbons shall meet each of the following tests. These tests are included in the paragraphs of ANSI/ICEA S–87–640 that are indicated in parentheses below.

(i) Ribbon Dimensions (7.14 through 7.14.2)—Measures ribbon dimension using FOTP–123.

(ii) Ribbon Twist Test (7.15 through 7.15.2)—evaluates the ability of the ribbon to resist splitting or other damage while undergoing dynamic cyclically twisting the ribbon under load.

(iii) Ribbon Residual Twist Test (7.16 through 7.16.2)—evaluates the degree of permanent twist in a cabled optical ribbon.

(iv) Ribbon Separability Test (7.17 through 7.17.2)—evaluates the ability to separate fibers.

(5) Ribbons shall meet paragraph 3.4.4.6 of ANSI/ICEA S–87–640, Ribbon Strippability.

(h) *Strength Members*. (1) Strength members may be an integral part of the cable construction, but are not considered part of the support messenger for self-supporting optical cable.

(2) The strength members may be metallic or nonmetallic.

(3) The combined strength of all the strength members must be sufficient to support the stress of installation and to protect the cable in service.

(4) Strength members may be incorporated into the core as a central support member or filler, as fillers between the fiber packages, as an annular serving over the core, as an annular serving over the intermediate jacket, embedded in the outer jacket or as a combination of any of these methods.

(5) The central support member or filler must contain no more than one splice per kilometer of cable. Individual fillers placed between the fiber packages and placed as annular servings over the core must contain no more than one splice per kilometer of cable. Cable sections having central member or filler splices must meet the same physical requirements as un-spliced cable sections.

(6) In each length of completed cable having a metallic central member, the dielectric strength between the shield or armor, when present, and the metallic center member must withstand at least 15 kilovolts when tested per ASTM D 4566. The voltage shall be applied for 3 seconds minimum; no failures are allowed.

(i) *Cable Core*. (1) Protected fibers may be assembled with the optional central support member, fillers and strength members in such a way as to form a cylindrical group.

(2) The standard cylindrical group or core designs commonly consist of 4, 6, 12, 18, or 24 fibers. Cylindrical groups or core designs larger than the sizes shown above must meet all the applicable requirements of this section.

(3) When threads or tapes are used in cables using water blocking elements as core binders, they must be a non-hygroscopic and non-wicking dielectric material or be rendered such by the gel or water blocking material produced by the ingress of water.

(4) When threads or tapes are used as unit binders to define optical fiber units in loose tube, tight tube, slotted, or bundled cored designs, they must be a

non-hygroscopic and non-wicking dielectric material or be rendered such by the filling compound. The colors of the binders must be per paragraphs (f)(2) and (f)(3) of this section.

(j) *Core Water Blocking.* (1) To prevent the ingress of water into the core and water migration, a suitable filling compound or water blocking elements must be applied into the interior of the loose fiber tubes and into the interstices of the core. When a core wrap is used, the filling compound water or blocking elements, as the case may be, must also be applied to the core wrap, over the core wrap and between the core wrap and inner jacket when required.

(2) The materials or elements must be homogeneous and uniformly mixed; free from dirt, metallic particles and other foreign matter; easily removed; nontoxic and present no dermal hazards. The filling compound and water blocking elements shall contain a suitable antioxidant or be of such composition as to provide long term stability.

(3) The individual cable manufacturer must satisfy the Agency that the filling compound or water blocking elements selected for use is suitable for its intended application by submitting test data showing compliance with ASTM D 4568. The filling compound and water blocking elements must be compatible with the cable components when tested per ASTM D 4568 at a temperature of 80 °C (176 °F). The jacket shall retain a minimum of 85% of its un-aged tensile and elongation values.

(k) *Water Blocking Material.* (1) Sufficient flooding compound or water blocking elements must be applied between the inner jacket and armor and between the armor and outer jacket so that voids and air spaces in these areas are minimized. The use of flooding compound or water blocking elements between the armor and outer jacket is not required when uniform bonding, paragraph (o)(10) of this section, is achieved between the plastic-clad armor and the outer jacket.

(2) The flooding compound or water blocking elements must be compatible with the jacket when tested per ASTM D 4568 at a temperature of 80 °C ± 1 °C (176 ± 2 °F). The aged jacket shall retain a minimum of 85% of its unaged tensile strength and elongation values. The flooding compound must exhibit adhesive properties sufficient to prevent jacket slip when tested per paragraph 7.30.1 of ANSI/ICEA S–87–640 and meets paragraph 7.30.2 for minimum sheath adherence of 14 N/mm for armored cables.

(3) The individual cable manufacturer must satisfy the Agency by submitting test data showing compliance with the appropriate cable performance testing requirements of this section that the flooding compound or water blocking elements selected for use is acceptable for the application.

(l) *Core Wrap.* (1) At the option of the manufacturer, one or more layers of dielectric material may be applied over the core.

(2) The core wrap(s) can be used to provide a heat barrier to prevent deformation or adhesion between the fiber tubes or can be used to contain the core.

(m) *Inner Jackets.* (1) For designs with more than one jacket, the inner jackets shall be applied directly over the core or over the strength members when required by the purchaser. The jacket must be free from holes, splits, blisters, or other imperfections and shall be as smooth and concentric as is consistent with the best commercial practice. The inner jacket shall not adhere to other cable components such as fibers, buffer tubes, etc.

(2) For armored and unarmored cable an inner jacket is optional. The inner jacket may absorb stresses in the cable core that may be introduced by armor application or by armored cable installation.

(3) The inner jacket material and test requirements must be as for the outer jacket material of this specification, except that either black or natural polyethylene may be used and the thickness requirements are included in paragraph (m)(4) of this section. In the case of natural polyethylene, the requirements for absorption coefficient and the inclusion of furnace black are waived.

(4) The inner jacket thickness shall be determined by the manufacturer, but shall be no less than a nominal jacket thickness of 0.5mm (0.02 inch) with a minimum jacket thickness of 0.35mm (0.01 inch.)

(n) *Outer Jacket.* (1) The outer jacket must provide the cable with a tough, flexible, protective covering which can withstand exposure to sunlight, to atmosphere temperatures and to stresses reasonably expected in normal installation and service.

(2) The jacket must be free from holes, splits, blisters, or other imperfections and shall be as smooth and concentric as is consistent with the best commercial practice.

(3) The raw material used for the outer jacket must be one of the types listed below. The raw material must contain an antioxidant to provide long term stabilization and the materials must contain a minimum of 2.35 percent concentration of furnace black to provide ultraviolet shielding.

(i) Type L1. Low density, polyethylene (LDPE) must conform to the requirements of ASTM D 1248, Type I, Class C, Category 4 or 5, Grade J3.

(ii) Type L2. Linear low density, polyethylene (LLDPE) must conform to the requirements of ASTM D 1248, Type I, Class C, Category 4 or 5, Grade J3.

(iii) Type M. Medium density polyethylene (MDPE) must conform to the requirements of ASTM D 1248, Type II, Class C, Category 4 or 5, Grade J4.

(iv) Type H. High density polyethylene (HDPE) must conform to the requirements of ASTM D 1248, Type III, Class C, Category 4 or 5, Grade J4.

(4) Particle size of the carbon selected for use must not average greater than 20 nm.

(5) Absorption coefficient must be a minimum of 400 per the procedures of ASTM D 3349.

(6) The outer jacketing material removed from or tested on the cable shall be capable of meeting the performance requirements of Table 5.1 found in ANSI/ICEA S–87–640.

(7) *Testing Procedures.* The procedures for testing the jacket specimens for compliance with paragraph (n)(6) of this section must be as follows:

(i) *Jacket Material Density Measurement.* Test per paragraphs 7.7.1 and 7.7.2 of ANSI/ICEA S–87–640.

(ii) *Tensile Strength, Yield Strength, and Ultimate Elongation.* Test per paragraphs 7.8.1 and 7.8.2 of ANSI/ICEA S–87–640.

(iii) *Jacket Material Absorption Coefficient Test.* Test per paragraphs 7.9.1 and 7.9.2 of ANSI/ICEA S–87–640.

(iv) *Environmental Stress Crack Resistance Test.* For large cables (outside diameter ≥ 30 mm (1.2 inch)), test according with 7.10.1 through 7.10.1.2 of ANSI/ICEA S–87–640. For small cables (Diameter < 30 mm (1.2 inch)), test per paragraphs 7.10.2 through and 7.10.2.2 of ANSI/ICEA S–87–640. A crack or split in the jacket constitutes failure.

(v) *Jacket Shrinkage Test.* Test per paragraphs 7.11.1 and 7.11.2 of ANSI/ICEA S–87–640.

(8) *Jacket Thickness.* The outer jacket must meet the requirements of Paragraph 5.4.5.1 and 5.4.5.2 of ANSI/ICEA S–87–640.

(9) *Jacket Repairs.* Repairs are allowed per Paragraph 5.5 of ANSI/ICEA S–87–640.

(o) *Armor.* (1) A steel armor, plastic coated on both sides, is required for direct buried cable manufactured under this section. Armor is optional for duct and aerial cable, as required by the purchaser. The plastic coated steel armor must be applied longitudinally

directly over the core wrap or the intermediate jacket and have a minimum overlap of 3.0 millimeters (118 mills), except for small diameter cables with diameters of less than 10 mm (394 mills) for which the minimum overlap shall be 2mm (79 mills). When a cable has a shield, the armor should normally be applied over the shielding tape.

(2) The uncoated steel tape must be electrolytic chrome coated steel (ECCS) and shall meet the requirements of paragraph B.2.4 of ANSI/ICEA S–87–640.

(3) The reduction in thickness of the armoring material due to the corrugating or application process must be kept to a minimum and must not exceed 10 percent at any spot.

(4) The armor of each length of cable must be electrically continuous with no more than one joint or splice allowed in any length of one kilometer of cable. This requirement does not apply to a joint or splice made in the raw material by the raw material manufacturer.

(5) The breaking strength of any section of an armor tape, containing a factory splice joint, must not be less than 80 percent of the breaking strength of an adjacent section of the armor of equal length without a joint.

(6) For cables containing no flooding compound over the armor, the overlap portions of the armor tape must be bonded in cables having a flat, non-corrugated armor to meet the mechanical requirements of paragraphs (t)(1) through (t)(16)(ii) of this section. If the tape is corrugated, the overlap portions of the armor must be sufficiently bonded and the corrugations must be sufficiently in register to meet the requirements of paragraphs (t)(1) through (t)(16)(ii) of this section.

(7) The armor tape must be so applied as to enable the cable to pass the Cable Low (− 30 °C (− 22 °F)) and High (60 C (140 F)) Temperatures Bend Test, as required by paragraph (t)(3) of this section.

(8) The protective coating on the steel armor must meet the Bonding-to-Metal, Heat Sealability, Lap-Shear and Moisture Resistance requirements of Type I, Class 2 coated metals per ASTM B 736–92a.

(9) The ability of the plastic-clad metal to resist the flooding compound must be determined as required by ASTM D 4568 using a one meter (3.3 feet) length of coated steel which must be aged for 7 days at 68 ± 1 °C (154 ± 2 °F). There must be no delamination of the coating from the steel at the conclusion of the test.

(10) When the jacket is bonded to the plastic coated armor, the bond between the plastic coated armor and the outer jacket must not be less than 525 Newtons per meter (36 pound-force) over at least 90 percent of the cable circumference when tested per ASTM D 4565–90a. For cables with strength members embedded in the jacket, and residing directly over the armor, the area of the armor directly under the strength member is excluded from the 90 percent calculation.

(p) *Figure 8 Aerial Cables.* (1) When self-supporting aerial cable containing an integrated support messenger is supplied, the support messenger must comply with the requirements specified in paragraphs D.2.1 through D.2.4 of ANSI/ICEA S–87–640 with exceptions and additional provisions as follows:

(i) Any section of a completed strand containing a joint must have minimum tensile strength and elongation of 29,500 Newtons (6,632 pound-force) and 3.5 percent, respectively, when tested per the procedures specified in ASTM A 640.

(ii) The individual wires from a completed strand which contain joints must not fracture when tested according to the ''Ductility of Steel'' procedures specified in ASTM A 640 except that the mandrel diameter must be equal to 5 times the nominal diameter of the individual wires.

(iii) The support strand must be completely covered with a flooding compound that offers corrosion protection. The flooding compound must be homogeneous and uniformly mixed.

(iv) The flooding compound must be nontoxic and present no dermal hazard.

(v) The flooding compound must be free from dirt, metallic particles, and other foreign matter that may interfere with the performance of the cable.

(2) Other methods of providing self-supporting cable specifically not addressed in this section may be allowed if accepted by the Agency. Justification for acceptance of a modified design must be provided to substantiate product utility and long term stability and endurance.

(3) *Jacket Thickness Requirements.* Jackets applied over an integral messenger must meet the following requirements:

(i) The minimum jacket thickness at any point over the support messenger must meet the requirements of paragraph D.3 of ANSI/ICEA S–87–640.

(ii) The web dimension for self-supporting aerial cable must meet the requirements of paragraph D.3 of ANSI/ICEA S–87–640.

(q) *Sheath Slitting Cord.* (1) A sheath slitting cord or ripcord is optional.

(2) When a sheath slitting cord is used it must be capable of slitting the jacket or jacket and armor, at least a 1 meter (3.3 feet) length without breaking the cord at a temperature of 23 ± 5 °C (73 ± 9 °F).

(3) The sheath slitting cord must meet the sheath slitting cord test depicted in paragraph (t)(1) of this section.

(r) *Identification Markers.* (1) Each length of cable shall be permanently identified. The method of marking must be by means of suitable surface markings producing a clear distinguishable contrasting marking meeting paragraph 6.1.1 of ANSI/ICEA S–87–640 and shall meet the durability requirements of paragraphs 7.5.2 through 7.5.2.2 of ANSI/ICEA S–87–640.

(2) The color of the initial marking must be white or silver. If the initial marking fails to meet the requirements of the preceding paragraphs, it will be permissible to either remove the defective marking and re-mark with the white or silver color or leave the defective marking on the cable and re-mark with yellow. No further re-marking is permitted. Any re-marking must be on a different portion of the cables circumference than any existing marking when possible and have a numbering sequence differing from any other marking by at least 3,000. Any reel of cable that contains more than one set of sequential markings must be labeled to indicate the color and sequence of marking to be used. The labeling must be applied to the reel and also to the cable.

(3) Each length of cable must be permanently labeled either OPTICAL CABLE, OC, OPTICAL FIBER CABLE, or OF on the outer jacket and identified as to manufacturer and year of manufacture.

(4) Each length of cable intended for direct burial installation shall be marked with a telephone handset in compliance with Rule 350G of the National Electrical Safety Code (NESC).

(5) Each length of cable shall be identified as to the manufacturer and year of manufacturing. The manufacturer and year of manufacturing may also be indicated by other means as indicated in paragraphs 6.1.2 through 6.1.4 of ANSI/ICEA S–87–640.

(6) The number of fibers on the jacket shall be marked on the jacket.

(7) An alternative method of marking may be used if acceptable to the Agency.

(8) The completed cable must have sequentially numbered length markers in METERS or FEET at regular intervals of not more than 2 feet or not more than 1 meter along the outside of the jacket. Continuous sequential numbering must

be employed in a single length of cable. The numbers must be dimensioned and spaced to produce good legibility and must be approximately 3 millimeters (118 mills) in height. An occasional illegible marking is permissible if form the illegible mark a legible marking is located within 2 meters cable marked in meters or 4 feet for cable marked in feet.

(9) Agreement between the actual length of the cable and the length marking on the cable jacket must be within the limits of +1 percent and −0 percent.

(10) *Jacket Print test.* Cables manufactured under this specification must meet the Jacket Print Test depicted in paragraphs 7.5.2.1 and 7.5.2.2 of ANSI/ICEA S–87–640.

(s) *Performance of a Finished Cable.*—(1) *Zero Dispersion Optical Fiber Cable.* Unless otherwise specified by the purchaser, the optical performance of the fibers in a finished cable must comply, as appropriate, with the cable attributes of Table 2G/G.652.B Attributes or Table 2G/G.652D found in ITU Recommendations G.652.B and G.652.D.

(2) *Nonzero Dispersion Optical Fiber Cable.* Unless otherwise specified by the purchaser, the optical performance of the fibers in a finished cable must comply with the cable attributes of Table 1 of ITU–T Recommendation G.656. When the buyer specifies ITU–T G.655 Recommendation A, B, C, D or E, the optical performance of the fibers in a finished cable must comply with the cable attributes of such Recommendation.

(3) *Multimode Optical Fiber Cable.* Unless otherwise specified by the purchaser, the optical performance of the fibers in a finished cable must comply with Table 8.1 through 8.3, of ANSI/ICEA S–87–640.

(4) Measurement of the attenuation must be conducted at the wavelength specified for application and must be expressed in decibels per kilometer.

(5) Because the accuracy of attenuation measurements for single mode fibers becomes questionable when measured on short cable lengths, attenuation measurements are to be made utilizing characterization cable lengths. Master Cable reels shall be tested and the attenuation values measured will be used for shorter ship lengths of cable.

(6) Because the accuracy of attenuation measurements for multimode fibers becomes questionable when measured on short cable lengths, attenuation measurements are to be made utilizing characterization cable lengths. If the ship length of cable is less than one kilometer, the attenuation values measured on longer lengths of cable (characterization length of cable) before cutting to the ship lengths of cable may be applied to the ship lengths.

(7) Attenuation must be measured per FOTP–78.

(8) The bandwidth of multimode fibers in a finished cable shall be no less than the values specified in ANSI/ICEA S–87–640, Table 8.2 according to paragraph 8.3.1

(t) *Mechanical Requirements.* Fiber optic cables manufactured under the requirements of this section shall be tested by the manufacturer to determine compliance with such requirements. Unless otherwise specified, testing shall be performed at the standard conditions defined in TIA/EIA–455 (Temperature of 23 ± 5 °C (73 ± 9 °), Relative Humidity of 20 to 70%, and Atmospheric Pressure of the Site Ambient.) The standard optical test wavelengths to be used are 1550 nm single mode and 1300 nm multi-mode, unless otherwise specified in the individual test.

(1) *Sheath Slitting Cord Test.* All cables manufactured under the requirements of this section must meet the Ripcord Functional Test depicted in paragraphs 7.18.1 and 7.18.2 of ANSI/ICEA S–87–640.

(2) *Material Compatibility and Cable Aging Test.* All cables manufactured under the requirements of this section must meet the Material Compatibility and Cable Aging Test depicted in paragraphs 7.19 through paragraph 7.19.2.4 of ANSI/ICEA S–87–640.

(3) *Cable Low and High Bend Test.* Cables manufactured under the requirements of this section must meet the Cable Low (−30 °C (−22 °F)) and High (60 C (140 F)) Temperatures Bend Test per paragraphs 7.21 and 7.21.2 of ANSI/ICEA S–87–640.

(4) *Compound Flow Test.* All cables manufactured under the requirements of this section must meet the test depicted in paragraphs 7.23, 7.23.1 and 7.23.2 of ANSI/ICEA S–87–640.

(5) *Cyclic Flexing Test.* All cables manufactured under the requirements of this section must meet the Flex Test depicted in paragraphs 7.27 through 7.27.2 of the ICEA S–87–640.

(6) *Water Penetration Test.* All cables manufactured under the requirements of this section must meet paragraphs 7.28 through 7.28.2 of ANSI/ICEA S–87–640.

(7) *Cable Impact Test.* All cables manufactured under the requirements of this section must meet the Cable Impact Test depicted in paragraphs 7.29.1 and 7.29.2 of ANSI/ICEA S–87–640.

(8) *Cable Tensile Loading and Fiber Strain Test.* Cables manufactured under the requirements of this section must meet the Cable Loading and Fiber Strain Test depicted in paragraphs 7.30 through 7.30.2 of ANSI/ICEA S–87–640. This test does not apply to aerial self-supporting cables.

(9) *Cable Compression Test.* All cables manufactured under requirements of this section must meet the Cable Compressive Loading Test depicted in paragraphs 7.31 through 7.31.2 of ICEA S–87–640.

(10) *Cable Twist Test.* All cables manufactured under the requirements of this section must meet the Cable Twist Test depicted in paragraph 7.32 through 7.32.2 of ANSI/ICEA S–87–640.

(11) *Cable Lighting Damage Susceptibility Test.* Cables manufactured under the requirements of this section must meet the Cable Lighting Damage Susceptibility Test depicted in paragraphs 7.33 and 7.33.1 of ANSI/ICEA S–87–640.

(12) *Cable External Freezing Test.* All cables manufactured under the requirements of this section must meet the Cable External Freezing Test depicted in paragraphs 7.22 and 7.22.1 of ANSI/ICEA S–87–640.

(13) *Cable Temperature Cycling Test.* All cables manufactured under the requirements of this section must meet the Cable Temperature Cycling Test depicted in paragraph 7.24.1 of ANSI/ICEA S–87–640.

(14) *Cable Sheath Adherence Test.* All cables manufactured under the requirements of this section must meet the Cable Sheath Adherence Test depicted in paragraph 7.26.1 and 7.26.2 of ANSI/ICEA S–87–640.

(15) *Mid-Span Test.* This test is applicable only to cables of a loose tube design specified for mid-span applications with tube storage. Cable of specialty design may be exempted of this requirement when such exception is accepted by the Agency. All buried and underground loose tube single mode cables manufactured per the requirements in this section and intended for mid-span applications with tube storage must meet the following mid-span test without exhibiting an increase in fiber attenuation greater than 0.1 dB.

(i) The specimen shall be installed in a commercially available pedestal or closure, or in a device that mimics their performance, as follows: A length of cable sheath, equal to the mid-span length, shall be removed from the middle of the test specimen so as to allow access the buffer tubes. All binders, tapes, strength members, etc. shall be removed. The buffer tubes shall be left intact. The cable ends defining the ends of the mid-span length shall be properly secured in the closure, to the

more stringent of the cable or hardware manufacturer's recommendations. Strength members shall be secured with an end stop type clamp and the outer jacket shall be clamped to prevent slippage. A minimum of 20 feet of cable shall extend from the entry and exit ports of the closure, for the purpose of making optical measurements.

(ii) The expressed buffer tubes shall be loosely constrained during the test.

(iii) The enclosure, with installed cable, shall be placed in an environmental chamber for temperature cycling. It is acceptable for some or all of the two 20 ft. cable segments to extend outside the environmental chamber.

(iv) Lids, pedestal enclosures, or closure covers shall be removed if possible to allow for temperature equilibrium of the buffer tubes. If this is not possible, the manufacture must demonstrate that the buffer tubes are at temperature equilibrium prior to beginning the soak time.

(v) Measure the attenuation of dispersion-unshifted single mode fibers at 1310 ± 10 and 1550 ± 10 nm, dispersion-shifted single mode fibers at 1550 ± 10 nm.

(vi) After measuring the attenuation of the optical fibers, test the cable sample per EIA/TIA–455–3A. The following detailed test conditions shall apply:

(A) Section 4.1—Loose tube single mode optical cable sample shall be tested.

(B) Section 4.2—An Agency accepted 8 to 12 inch diameter optical buried distribution pedestal or equivalent sample shall be tested.

(C) Mid-span opening for installation of loose tube single mode optical cable in pedestal shall be 3 meters (10 feet) or 4.9 meters (16 feet) depending on the cable listing.

(D) Section 5.1—3 hours soak time.

(E) Section 5.2—Test Condition C–2, minimum −40 °C (−40 °F) and maximum 70° Celsius (158 °F).

(F) Section 5.7.2—A statistically representative amount of transmitting fibers in all express buffer tubes passing through the pedestal and stored shall be measured.

(vii) The cable may be allowed to warm to room temperature before visual inspection. The cable mid-span opening must not show visible evidence of fracture of the buffer tubes nor any degradation of all exposed cable assemblies. Fiber cable attenuation measured through the express buffer tubes during the last cycle at −40 °C C (−40 °F) and +70C (158 °F) and after the test shall not exceed 0.1 dB from the initial baseline measurements made per EIA/TIA–455–3A, Section 5.7.1 and Section 5.7.2 specified in paragraph (t)(15)(vi) of this section.

(16) *Aerial Self-Supporting Cables.* The following tests apply to aerial cables only:

(i) *Static Tensile Testing of Aerial Self-Supporting Cables.* Aerial self-supporting cable made to this specification must meet the test depicted in paragraphs D.4.1.1 through D.4.1.5 of ANSI/ICEA S–87–640 when using FOTP–33.

(ii) *Cable Galloping Test.* Aerial self-supporting cable made to the requirements of this section must meet the test depicted in paragraphs D.4.2 through D.4.2.3 of ANSI/ICEA S–87–640.

(u) *Pre-connectorized Cable.* (1) At the option of the manufacturer and upon request by the purchaser, the cable may be factory terminated with connectors acceptable to the Agency.

(2) All connectors must be accepted by the Agency prior to their use.

(v) *Acceptance Testing.* (1) The tests described in the Appendix to this section are intended for acceptance of cable designs and major modifications of accepted designs. What constitutes a major modification is at the discretion of the Agency. These tests are intended to show the inherent capability of the manufacturer to produce cable products that have satisfactory performance characteristics, long life and long-term optical stability but are not intended as field tests. After initial Agency acceptance is granted, the manufacturer will need to apply for continued product acceptance on January of the third year after the year of initial acceptance.

(2) *Acceptance.* For initial acceptance, the manufacturer must submit:

(i) An original signature certification that the product fully complies with each section of this specification;

(ii) Qualification Test Data, per the Appendix to this section;

(iii) A set of instructions for handling the cable;

(iv) OSHA Material Safety Data Sheets for all components;

(v) Agree to periodic plant inspections;

(vi) A certification stating whether the cable, as sold to the Agency Telecommunications program borrowers, complies with the following two provisions:

(A) Final assembly or manufacture of the product, as the product would be used by an Agency Telecommunications program borrower, is completed in the United States or eligible countries (currently, Mexico, Canada and Israel); and

(B) The cost of United States and eligible countries' components (in any combination) within the product is more than 50 percent of the total cost of all components utilized in the product. The cost of non-domestic components (components not manufactured within the United States or eligible countries) which are included in the finished product must include all duties, taxes, and delivery charges to the point of assembly or manufacture;

(vii) Written user testimonials concerning performance of the product; and

(viii) Other nonproprietary data deemed necessary by the Agency.

(3) *Re-qualification acceptance.* For submission of a request for continued product acceptance after the initial acceptance, follow paragraph (v)(1) of this section and then, on January every three years, the manufacturer shall submit an original signature certification stating that the product fully complies with each section of the specification, excluding the Qualification Section, and a certification that the products sold to Agency Telecommunications Program borrowers comply with paragraphs (v)(2)(vi) through (v)(2)(vi)(B) of this section. The tests of the Appendix to this section shall be conducted and records kept for at least three years and the data shall be made available to the Agency on request. The required data must have been gathered within 90 days of the submission. A certification shall be submitted to the Agency stating that the cable manufactured to the requirements of this section has been tested per the Appendix of this section and that the cable met the test requirements.

(4) Initial and re-qualification acceptance requests should be addressed to: Chairman, Technical Standards Committee ''A'' (Telecommunications), STOP 1550, Advanced Services Division, Rural Development Telecommunications Program, Washington, DC 20250–1500.

(5) *Tests on 100 Percent of Completed Cable.* (i) The armor for each length of cable must be tested for continuity using the procedures of ASTM D 4566.

(ii) Attenuation for each optical fiber in the cable must be measured.

(iii) Optical discontinuities greater than 0.1dB must be isolated and their location and amplitude recorded.

(6) *Capability Tests.* The manufacturer shall establish a quality assurance system consistent with nationally or internationally recognized standards such as ANSI/ASQC Q9000, ISO 9001, or TL 9000®. Tests on a quality assurance basis must be made as frequently as is required for each

manufacturer to determine and maintain compliance with all the mechanical requirements and the fiber and cable attributes required by this section, such as:

(i) Numerical aperture and bandwidth of multimode fibers;

(ii) Cut off wavelength of single mode fibers;

(iii) Dispersion of single mode fibers;

(iv) Shrinkback and cold testing of loose tube and tight tube buffers;

(v) Adhesion properties of the protective fiber coating;

(vi) Dielectric strength between the armor and the metallic central member;

(vii) Performance requirements for the fibers.

(viii) Performance requirements for the inner and outer jacketing materials;

(ix) Performance requirements for the filling and flooding compounds;

(x) Bonding properties of the coated armoring material;

(xi) Sequential marking and lettering;

(xii) Mechanical tests depicted in paragraphs (t)(1) through (t)(16)(ii) of this section.

(w) *Records Tests.* (1) Each manufacturer must maintain suitable summary records for a period of at least 3 years of all optical and physical tests required on completed cable by this specification as set forth in paragraphs (v)(5) and (v)(6) of this section. The test data for a particular reel must be in a form that it may be readily available to the Agency upon request. The optical data must be furnished to the purchaser on a suitable and easily readable form.

(2) Measurements and computed values must be rounded off to the number of places or figures specified for the requirement according to ASTM E 29.

(x) *Manufacturing Irregularities.* (1) Repairs to the armor, when present, are not permitted in cable supplied to the end user under this section.

(2) Minor defects in the inner and outer jacket (defects having a dimension of 3 millimeters or less in any direction) may be repaired by means of heat fusing per good commercial practices utilizing sheath grade compounds.

(y) *Packaging and Preparation for Shipment.* (1) The cable must be shipped on reels containing one continues length of cable. The diameter of the drum must be large enough to prevent damage to the cable from reeling and unreeling. The diameter must be at least equal to the minimum bending diameter of the cable. The reels must be substantial and so constructed as to prevent damage during shipment and handling.

(2) A circumferential thermal wrap or other means of protection must be secured between the outer edges of the reel flange to protect the cable against damage during storage and shipment. The thermal wrap must comply with the requirements included in the following test:

(i) *Thermal Reel Wrap Test.* This test procedure is for qualification of initial and subsequent changes in thermal reel wraps.

(A) *Sample Selection.* All testing must be performed on two 450 millimeter (18 inches) lengths of cable removed sequentially from the same fiber jacketed cable. This cable must not have been exposed to temperatures in excess of 38 °C (100 °F) since its initial cool down after sheathing.

(B) *Test Procedure. (1)* Place the two samples on an insulating material such as wood.

(2) Tape thermocouples to the jackets of each sample to measure the jacket temperature.

(3) Cover one sample with the thermal reel wrap.

(4) Expose the samples to a radiant heat source capable of heating the uncovered sample to a minimum of 71°C (160 °F). A GE 600 watt photoflood lamp or an equivalent lamp having the light spectrum approximately that of the sun shall be used.

(5) The height of the lamp above the jacket shall be 380 millimeters (15 inches) or an equivalent height that produces the 71 °C (160 °F) jacket temperature on the unwrapped sample shall be used.

(6) After the samples have stabilized at the temperature, the jacket temperatures of the samples shall be recorded after one hour of exposure to the heat source.

(7) Compute the temperature difference between jackets.

(8) For the thermal reel wrap to be acceptable to the Agency, the temperature difference between the jacket with the thermal reel wrap and the jacket without the reel wrap shall be greater than or equal to 17 °C (63 °F).

(3) Cable manufactured to the requirements of this specification must be sealed at the ends to prevent entrance of moisture.

(4) The end-of-pull (outer end) of the cable must be securely fastened to prevent the cable from coming loose during transit. The start-of-pull (inner end) of the cable must project through a slot in the flange of the reel, around an inner riser, or into a recess on the flange near the drum and fastened in such a way to prevent the cable from becoming loose during installation.

(5) Spikes, staples or other fastening devices must be used in a manner which will not result in penetration of the cable.

(6) The arbor hole must admit a spindle 63.5 millimeters (2.5 inches) in diameter without binding. Steel arbor hole liners may be used but must be accepted by the Agency prior to their use.

(7) Each reel must be plainly marked to indicate the direction in which it should be rolled to prevent loosening of the cable on the reel.

(8) Each reel must be stenciled or lettered with the name of the manufacturer.

(9) The following information must be either stenciled on the reel or on a tag firmly attached to the reel:

OPTICAL CABLE
Number of Fibers
Armored or Non-armored
Year of Manufacture
Name of Cable Manufacturer
Length of Cable
Reel Number 7 CFR 1755.900
Minimum Bending Diameter for both Residual and Loaded Condition during installation

Example:

OPTICAL CABLE
4 fibers
Armored
XYZ Company
1050 meters
Reel Number 3
7 CFR 1755.900
Minimum Bending Diameter:
Residual (Installed): 20 times Cable O.D
Loaded Condition: 40 times Cable O.D

APPENDIX TO § 1755.900

FIBER OPTIC CABLES

Bulletin 1753F–601(PE–90) Qualifications Test Data; Initial qualification and three year re-qualification test data required for TELECOMMUNICATIONS PROGRAM product acceptance. Please note that some tests may apply only to a particular cable design.

Paragraph	Test	Initial qualification	3 year re-qualification
(e)(4)(i)	Shrinkback	X	
(e)(4)(ii)	Cold Bend	X	

FIBER OPTIC CABLES—Continued

Bulletin 1753F–601(PE–90) Qualifications Test Data; Initial qualification and three year re-qualification test data required for TELECOMMUNICATIONS PROGRAM product acceptance. Please note that some tests may apply only to a particular cable design.

Paragraph	Test	Initial qualification	3 year re-qualification
(t)(1)	Sheath Slitting Cord	X	
(t)(2)	Material Compatibility	X	
(t)(3)	Cable Low & High Bend	X	X
(t)(4)	Compound Flow	X	
(t)(5)	Cyclic Flexing	X	X
(t)(6)	Water Penetration	X	X
(t)(7)	Cable Impact	X	X
(t)(8)	Cable Tensile Loading & Fiber Strain	X	X
(t)(9)	Cable Compression	X	
(t)(10)	Cable Twist	X	X
(t)(11)	Cable Lighting Damage Susceptibility	X	
(t)(12)	Cable External Freezing	X	
(t)(13)	Cable Temperature Cycling	X	X
(t)(14)	Cable Sheath Adherence	X	
(t)(15)	Mid-Span	X	
(t)(16)(i)	Static Tensile Testing of Aerial Self-Supporting Cables	X	X
(t)(16)(ii)	Cable Galloping	X	
(y)(2)(i)	Thermal Reel Wrap test	X	

4. Section 1755.901 is added to read as follows:

§ 1755.901 Incorporation by reference.

(a) The specifications in the table following paragraph (b) of this section are incorporated by reference by the Telecommunications Program and apply to §§ 1755.900 and 1755.902. This incorporation by reference was approved by the Director of the Federal Register per 5 U.S.C. 552(a) and 1 CFR part 51. Copies of these documents are available for inspection at the National Archives and Records Administration (NARA). For more information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.htm.*

(b) ANSI/IEEE C–2 can be obtained from IEEE at *http://standards.ieee.org/nesc/index.html.* ANSI ICEA S–87–640 and S–110–717 can be obtained from HIS at *http://global.ihs.com*; ASTM Standards A 370, A 640, A657/A657M, B 736, D 1248, D 1535, D 1693, D 3349, D 4565, D 4566, D 4568, and E 29 can be obtained from ANSI at *http://webstore.ansi.org/ansidocstore/default.asp;* EIA/TIA Standards 455–3 and 455–55C can be obtained at HIS at *http://global.ihs.com;* TIA/EIA 455–78A and EIA/TIA–455–78B can be obtained at *http://www.tiaonline.org/standards/catalog;* and ITU Recommendations G.652, G.655 and L.58 can be obtained at *http://www.itu.int/ITU-T/publications/recs.html.*

Specification and issue date	Title
ANSI/IEEE C–2 (2007)	National Electrical Safety Code (NESC).
ANSI/ICEA S–87–640 (2006)	Optical Fiber Outside Plant Communications Cable.
ANSI/ICEA S–110–717 (2003)	Optical Drop Cables.
ASTM A 370 (2005)	Standard Test Methods and Definitions for Mechanical Testing of Steel Products.
ASTM A 640 (1997)	Standard Specification for Zinc-Coated Steel Strand for Messenger Support of Figure 8 Cable.
ASTM A657/A657M (2003)	Standard Specification for Tin Mill Products, Black Plate Electrolytic Chromium-Coated, Single and Double Reduced.
ASTM B 736 (2000)	Standard Specification for Aluminum, Aluminum Alloy and Aluminum-Clad Steel Cable Shielding Stock.
ASTM D 1248 (2004)	Standard Specification for Polyethylene Plastics Molding and Extrusion Materials.
ASTM D 1535 (2006)	Standard Practice for Specifying Color by the MUNSELL System.
ASTM D 1693—01	Standard Test Method for Environmental Stress-Cracking of Ethylene Plastics.
ASTM D 3349—(1999)	Standard Test Method for Absorption Coefficient of Ethylene Polymer Material Pigmented with Carbon Black.
ASTM D 4565 (1999)	Standard Test Methods for Physical and Environmental Performance Properties of Insulations and Jackets for Telecommunications Wire and Cable.
ASTM D 4566—98	Standard Test Methods for Electrical Performance Properties of Insulations and Jackets for Telecommunications Wire and Cable.
ASTM D 4568—(1999)	Standard Test Methods for Evaluating Compatibility Between Cable Filling and Flooding Compounds and Polyolefin Wire and Cable Materials.
ASTM E 29 (2006)	Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications.
EIA/TIA–455–3 (1989)	FOTP–3, Procedure to Measure Temperature Cycling on Optical Fibers, Optical Cable, and Other Passive Fiber Optic Components.
EIA/TIA–455–55C (1998)	FOTP–55 End-View Methods for Measuring Coating and Buffer Geometry of Optical Fibers.
EIA/TIA–455–78A	FOTP–78 Spectral-Attenuation Cutback Measurement for Single-Mode Optical Fibers.
TIA/EIA 455–78B (2002)	Optical Fibres—PART 1–40: Measurement Methods and Test Procedures—Attenuation; FOTP–178 IEC 60793–1–40.
ITU–T Recommendation G.652 (2005)	Characteristics of a single-mode optical fibre and cable.
ITU–T Recommendation G.655 (2006)	Characteristics of a non-zero dispersion-shifted single-mode optical fibre and cable.

Specification and issue date	Title
ITU–T Recommendation G.656 (2006)	Characteristics of a fibre and cable with non-zero dispersion for wideband optical transport.
ITU–T Recommendation L.58 (2004)	Construction, Installation and Protection of Cables and Other Elements of Outside Plant.
TIA–598–C (2005)	Optical Fiber Cable Color Coding.
TIA/EIA–455–B (1998)	Standard Test Procedure for Fiber Optic Fibers, Cables, Transducers, Sensors, Connecting and Terminating Devices, and Other Fiber Optic Components.
TIA/EIA–455–3	Procedure to Measure Temperature Cycling Effects on Optical Fibers Optical Cable, and Other Passive Fiber Optic Components.

5. Section 1755.902 and an undesignated center heading are added to read as follows:

Fiber Optic Service Entrance Cables

§ 1755.902 Fiber optic service entrance cables.

This section covers the requirements for fiber optic service entrance cables intended for aerial installation either by attachment to a support strand or by an integrated self-supporting arrangement, for underground application by placement in a duct, or for buried installations by trenching, direct plowing, directional or pneumatic boring. Cable meeting this specification is recommended for fiber optic service entrances having 12 or fewer fibers with distances less than 100 meters (300 feet.) Service entrance cables shall meet the requirements of § 1755.900, except for any conflicting requirements with this section, in which case the following stipulations supersede requirements of § 1755.900:

(a) *Cable Detection.* For detection purposes, the cable may have toning elements embedded or extruded with the outer jacket.

(b) *Tensile Rating.* The cable shall have ratings that are no less than the tensile ratings indicated in paragraph 1.1.4, Tensile Rating, of Part 1 of the ICEA S–110–717 (ANSI/TIA 472F000).

(c) *Single Mode Cables.* Unless otherwise specified by the purchaser, the single mode optical fibers used in service entrance cables shall meet the fiber attributes of Table 2/G.652, *G.652.B attributes,* of ITU–T Recommendation G.652. However, when the purchaser stipulates a low water peak fiber the optical fibers shall meet the fiber attributes of Table 4/G.652, *G.652.D attributes,* of ITU–T Recommendation G.652.

(d) *Fiber Count.* Unless otherwise specified by the purchaser, the service entrance cable shall contain 12 fibers or less.

(e) *Armor.* A steel armor required in § 1755.900 for direct buried cable manufactured is optional, as required by the purchaser, for service entrance cable under this specification.

Dated: June 20, 2007.

James M. Andrew,

Administrator, Rural Utilities Service.

[FR Doc. E7–13795 Filed 7–16–07; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–28319; Directorate Identifier 2007–NE–27–AD]

RIN 2120–AA64

Airworthiness Directives; General Electric Company (GE) CF6–80C2D1F Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for GE CF6–80C2D1F turbofan engines, installed on McDonnell Douglas Corporation MD–11 series airplanes. This proposed AD would require removing previous software versions from the engine electronic control unit (ECU). Engines with new version software will have increased margin to flameout. This proposed AD results from reports of engine flameout events during flight, including reports of events where all engines simultaneously experienced a flameout or other adverse operation. Although the root cause investigation is not yet complete, we believe that exposure to ice crystals during flight is associated with these flameout events. We are proposing this AD to minimize the potential of an all-engine flameout event caused by ice accretion and shedding during flight.

DATES: We must receive any comments on this proposed AD by September 17, 2007.

ADDRESSES: Use one of the following addresses to comment on this proposed AD.

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

You can get the service information identified in this proposed AD from General Electric Company via Lockheed Martin Technology Services, 10525 Chester Road, Suite C, Cincinnati, Ohio 45215, telephone (513) 672–8400, fax (513) 672–8422.

FOR FURTHER INFORMATION CONTACT: John Golinski, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; e-mail: *john.golinski@faa.gov;* telephone: (781) 238–7135, fax: (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send us any written relevant data, views, or arguments regarding this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2007–28319; Directorate Identifier 2007–NE–27–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of the DOT Web site, anyone can find and read the

comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://dms.dot.gov.*

Examining the AD Docket

You may examine the AD docket on the Internet at *http://dms.dot.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is the same as the Mail address provided in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

Discussion

GE CF6–80C2 and CF6–80E1 series turbofan engines continue to experience flameout events that are due to ice accretion and shedding into the engine during flight. Although the investigation is not yet complete, we believe that the ice accretion is caused by exposure to ice crystals during flight. Industry reports 35 airplane flameout events, including reports of multi-engine events where all engines on the airplane simultaneously experienced a flameout. Some of these events had high pressure compressor blade damage that may have been caused by impact with shedding ice. In all events, the engines restarted and continued to operate normally for the remainder of the flight.

This proposed AD addresses only the CF6–80C2D1F turbofan engines, installed on McDonnell Douglas Corporation MD–11 series airplanes. We believe this model of CF6–80C2 engine is susceptible to flameouts caused by ice accretion and shedding into the engine during flight. Similar AD actions for other CF–80C2 and CF6–80E1 series engines may be forthcoming.

We view an all-engine flameout event as an unsafe condition particularly for low-altitude events, or other factors that might result in the inability to restart the engines and regain control of the airplane. Since some aspects of this problem are not completely understood, this proposed AD is considered an interim action due to GE's on-going investigation. Future AD action might become necessary based on the results of the investigation and field experience. This condition of insufficient margin to engine flameout due to ice accretion and shedding during flight, if not addressed, could result in an all-engine flameout event during flight.

Relevant Service Information

We have reviewed and approved the technical contents of GE Service Bulletin (SB) No. CF6–80C2 S/B 73–0351, dated April 11, 2007. That SB describes procedures for removing certain software versions from the ECU, and installing a software version that is FAA-approved. The new FAA-approved software version described in the SB modifies the variable bleed valve schedule, which will provide an increased margin to flameout. This increased margin is expected to reduce the rate of flameout occurrences due to ice accretion and shedding during flight.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other products of this same type design. We are proposing this AD, which would require removing certain software versions from the engine ECU.

Interim Action

These actions are interim actions due to the on-going investigation. We may take further rulemaking actions in the future, based on the results of the investigation and field experience.

Costs of Compliance

We estimate that this proposed AD would affect 175 CF6–80C2D1F turbofan engines installed on McDonnell Douglas Corporation MD–11 series airplanes of U.S. registry. We estimate it would take about 3 work-hours per ECU to perform the proposed actions if done at ECU shop visit, and 6 work-hours per ECU if done at engine shop visit. We estimate that 50% of the ECUs would be worked at ECU shop visit and the remaining 50% worked at engine shop visit. The average labor rate is $80 per work-hour. Based on these figures, we estimate the cost to U.S. operators to be $63,120. Our cost estimate is exclusive of warranty coverage.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify that the proposed AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. You may get a copy of this summary at the address listed under **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive:

General Electric Company: Docket No. FAA–2007–28319; Directorate Identifier 2007–NE–27–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this airworthiness directive (AD) action by September 17, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to General Electric Company (GE) CF6–80C2D1F turbofan engines, installed on McDonnell Douglas Corporation MD–11 series airplanes.

Unsafe Condition

(d) This AD results from reports of engine flameout events during flight, including reports of events where all engines simultaneously experienced a flameout or other adverse operation. We are issuing this AD to minimize the potential of an all-engine flameout event, due to ice accretion and shedding during flight. Exposure to ice crystals during flight is believed to be associated with these flameout events.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified unless the actions have already been done.

Interim Action

(f) These actions are interim actions due to the on-going investigation, and we may take further rulemaking actions in the future based on the results of the investigation and field experience.

Engine Electronic Control Unit (ECU) Software Removal

(g) At the next shop visit of the engine or of the ECU, whichever occurs first, and not to exceed 60 months from the effective date of this AD, remove the following software versions from the ECUs:

TABLE 1.—REMOVAL OF ECU SOFTWARE VERSIONS

Software version	Installed in ECU part No.
(1) 8.5.A	1851M51P01, 1851M51P02, 1851M52P01, 1851M52P02, 1851M53P01, 1851M53P02
(2) 8.3.C	1471M69P01, 1471M69P02, 1519M91P01
(3) 8.3.D	1519M91P02
(4) 8.3.E	1519M91P03, 1519M91P04
(5) 8.3.F	1519M91P05
(6) 8.3.G	1519M91P06, 1820M34P01
(7) 8.3.H	1519M91P07, 1820M34P02
(8) 8.3.J	1519M91P09, 1519M91P10, 1820M34P04, 1820M34P05

Previous Software Versions of ECU Software

(h) For a period of 24 months after the effective date of this AD, once an ECU containing a software version not listed in Table 1 of this AD is installed on an engine, that ECU can be replaced with an ECU containing a previous version of software listed in Table 1.

(i) Once the software version listed in Table 1 of this AD has been removed and new FAA-approved software version is installed in an ECU, reverting to those older software versions in that ECU is prohibited.

(j) After 60 months from the effective date of this AD, use of an ECU with a software version listed in Table 1 of this AD is prohibited.

Definitions

(k) For the purposes of this AD:

(1) Next shop visit of the ECU is when the ECU is removed from the engine for overhaul or maintenance after the effective date of this AD.

(2) Next shop visit of the engine is when the engine is removed from the airplane for maintenance in which a major flange is disassembled after the effective date of this AD. The following engine maintenance actions, either separately or in combination with each other, are not considered a next shop visit of the engine:

(i) Removal of the upper high pressure compressor (HPC) stator case solely for airfoil maintenance.

(ii) Module-level inspection of the HPC rotor stages 3–9 spool.

(iii) Replacement of stage 5 HPC variable stator vane bushings or lever arms.

(iv) Removal of the accessory gearbox.

(v) Replacement of the inlet gearbox polytetrafluoroethylene seal.

Alternative Methods of Compliance

(l) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Special Flight Permits

(m) Special flight permits are not authorized.

Related Information

(n) Information on removing ECU software and installing new software, which provides increased margin to flameout, can be found in GE Service Bulletin No. CF6–80C2 S/B 73–0351, dated April 11, 2007.

(o) Contact John Golinski, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; e-mail: *john.golinski@faa.gov;* telephone: (781) 238–7135, fax: (781) 238–7199, for more information about this AD.

Issued in Burlington, Massachusetts, on July 11, 2007.

Francis A. Favara,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. E7–13835 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA–2007–0032 (Formerly Docket No. OSHA–S031–2006–0665 and OSHA Docket No. S–031)]

RIN 1218–AC09

Explosives

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Proposed rule; close of comment period.

SUMMARY: On April 13, 2007, the U.S. Department of Labor published a proposed rule entitled Explosives with a comment period that ended 7/12/2007. On July 9, 2007, the comment period was extended to 9/10/2007. At this time the U.S. Department of Labor is closing the comment period effective July 17, 2007. The Department intends to re-propose the Explosives NPRM at a later date in order to clarify the intent of the rulemaking.

DATES: The comment period for the proposed rule published on April 13, 2007 (72 FR 18792) is closed effective July 17, 2007.

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries, contact Mr. Kevin Ropp, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–1999. For technical inquiries, contact Donald Pittenger, Directorate of Standards and Guidance, Room N–3609, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2255 or fax (202) 693–1663.

Signed at Washington, DC, on July 13, 2007.

Edwin G. Foulke, Jr.,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. E7–13925 Filed 7–16–07; 8:45 am]

BILLING CODE 4510–26–P

Notices

Federal Register
Vol. 72, No. 136
Tuesday, July 17, 2007

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Privacy Act of 1974; System of Records

AGENCY: United States Agency for International Development.

ACTION: Privacy Act System of Records Notice.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), the United States Agency for International Development (USAID) is giving notice that it proposes to establish a new system of records, the Partner Vetting System (PVS). The PVS will support the vetting of individuals, officers, or other officials of non-governmental organizations who apply for USAID contracts, grants, cooperative agreements, or other funding, or who apply for registration with USAID as Private and Voluntary Organizations (PVOs), ensuring that neither USAID funds nor USAID-funded activities inadvertently or otherwise provide support to entities or individuals associated with terrorism.

DATES: Written comments must be received on or before August 27, 2007. Unless there is a further notice in the **Federal Register**, this new system of records will become effective on August 27, 2007.

ADDRESSES: You may submit comments to:

E-mail: privacy@usaid.gov.

Fax: (703) 666–1466.

Mail: Chief Privacy Officer, United States Agency for International Development, 1300 Pennsylvania Avenue, NW., Office 2.12–003, Washington, DC 20523–2120.

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Coordinator for Counterterrorism, Office of Security, United States Agency for International Development, Ronald Reagan Building, 1300 Pennsylvania Avenue, NW., Washington, DC 20523. For privacy issues please contact: Chief Privacy Officer, United States Agency for International Development, 1300 Pennsylvania Avenue, NW., Office 2.12–003, Washington, DC 20523–2120.

SUPPLEMENTARY INFORMATION: USAID is establishing a new system of records pursuant to the Privacy Act (5 U.S.C. 552a), entitled the Partner Vetting System (PVS). Since September 2001, in accordance with Executive Order 13224 which prohibits any transactions or dealings with entities or individuals designated as terrorists, USAID has taken several steps to ensure USAID funds are not provided to individuals or entities associated with terrorism. These efforts include: (1) Requiring that all solicitations, contracts, Annual Program Statements or Requests for Applications, grants or cooperative agreements, or other comparable documents contain language reminding USAID partners of the laws and Executive Orders prohibiting the provision of resources and support to individuals and organizations associated with terrorism; (2) requiring all non-governmental organization (NGO) applicants for grants and cooperative agreements to submit terrorist financing certifications; and (3) requiring USAID contracting officers and agreement officers to check applicable terrorist listings to ensure that potential contractors, grantees, sub-contractors, and sub-grantees are not on these listings.

In addition to the precautions described above, there is also a statutory requirement for vetting under USAID's West Bank and Gaza (WBG) program. Since Fiscal Year 2003, the annual foreign operations appropriations legislation has required that, ''the Secretary of State shall take all appropriate steps to ensure that such assistance is not provided to or through any individual, private or government entity, or education institution that the Secretary knows or has reason to believe advocates, plans, sponsors, engages in, or has engaged in, terrorist activity.'' Accordingly, USAID's mission for the WBG developed anti-terrorism procedures for all awards that it administers and has conducted vetting since 2003. A recent review of the WBG program by the Government Accountability Office (GAO) identified processes and procedures that could be improved and streamlined with the use of additional information technology. The PVS is being created, in part, as a result of these recommendations and will assist not only the mission for WBG in better tracking and managing the overall vetting process, but all locations in which USAID has or will have a program.

PVS will facilitate the management and collection of information from individuals, officers, employees, or other officials of NGOs who apply for USAID contracts, grants, cooperative agreements or other USAID funding, or who apply for registration with USAID as PVOs. The information will be used to conduct national security screening of such individuals and NGOs to ensure that USAID funds do not inadvertently or otherwise provide support to entities or individuals associated with terrorism. To thoroughly conduct this screening, it is necessary to collect information on the principal officers and other employees of applicant organizations or on individuals that are applying directly for awards on their own behalf. Principal officers may include directors, program managers, members of governing bodies, or other individuals with operational control of the organization or those individuals that administer funds.

The primary source of information in PVS will be collected directly from the individuals acting in their own capacity or from the appointed official for the NGO applying for USAID funding or registration as a PVO. An exemption will not be claimed for information collected directly from the individuals acting in their own capacity or from the appointed official for the NGO and this information will be treated as unclassified. USAID is currently devising a retention schedule for these records. However, some information may be obtained from other U.S. government agencies or another agency's system of records. Any information that is recompiled from another agency's system of records will follow the retention plan for that agency, will carry the appropriate classification level, and be considered exempt under the originating agency's exemptions.

Electronic Access Addresses

You may submit comments by sending e-mail to: *privacy@usaid.gov*. You may submit comments by

submitting a facsimile document to: (703) 666–1466.

Dated: February 28, 2007.

Philip M. Heneghan,

Chief Privacy Officer.

Editorial Note: This document was received at the Office of the Federal Register on July 5, 2007.

USAID–027

SYSTEM NAME:

Partner Vetting System (PVS).

SECURITY CLASSIFICATION:

Classified and Sensitive but Unclassified.

SYSTEM LOCATION:

The United States Agency for International Development (USAID), Office of Security, 1300 Pennsylvania Avenue, Washington, DC 20523, and any relevant location(s) where USAID has a program.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

a. Individuals who are directors, officers, or are otherwise employed by either for-profit or non-profit non-governmental organizations who apply for USAID contracts, grants, cooperative agreements or other types of instruments;

b. Individuals who apply for personal services contracts or for other contracts, grants, or cooperative agreements;

c. Individuals or organizations who attempt to obtain other USAID assistance or benefits; and

d. Individuals who are officers or other officials of non-profit, non-governmental organizations who apply for registration with USAID as Private and Voluntary Organizations (PVOs).

CATEGORIES OF RECORDS IN THE SYSTEM:

Sensitive but Unclassified and non-exempt identifying information in this system includes, but is not limited to:

a. Full name (including any aliases or variations of spelling),

b. Date and place of birth,

c. Government-issued identification information (including, but not limited to, social security number, passport number, or other numbers originated by a government that specifically identifies an individual),

d. Current mailing address,

e. Telephone and fax numbers,

f. Email addresses,

g. Country of origin and/or nationality,

h. Citizenship,

i. Gender, and

j. Profession or other employment data.

Classified and exempt information in this system includes, but is not limited to:

a. Results generated from the screening of individuals covered by this notice;

b. Intelligence and law enforcement information related to national security; and

c. National security vetting and terrorism screening information, provided to USAID by other agencies.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

18 U.S.C. 2339A, 2339B and 2339C; 22 U.S.C. 2151 et seq.; Section 559 of the FY06 Foreign Operations Appropriations Act; Executive Orders 13224, 13099 and 12947; and HSPD–6.

PURPOSE(S):

To support the vetting of directors, officers, or other employees of non-governmental organizations who apply for USAID contracts, grants, cooperative agreements or other funding or who apply for registration with USAID as Private and Voluntary Organizations. The information collected from these individuals is specifically used to conduct screening to ensure that USAID funds and USAID-funded activities are not purposefully or inadvertently used to provide support to entities or individuals deemed to be a risk to national security.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

USAID may disclose relevant system records in accordance with any current and future blanket routine uses established for its record systems. See the Statement of General Routine Uses (and amendments), 42 FR 47371 (September 20, 1977); 59 FR 52954 (October 20, 1994); 59 FR 62747 (December 6, 1994). Routine uses are not meant to be mutually exclusive and may overlap in some cases.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, PROTECTING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored in both paper and electronic format. Paper records are maintained by the USAID regional offices when the information cannot be collected electronically. Electronic storage is on servers (hard disk media) and magnetic tapes (or other backup media), stored within a secure location within the USAID Washington headquarters.

RETRIEVABILITY:

Records in this system are retrieved by individual name, date of birth, place of birth, social security numbers, passport numbers or other identifying data specified under Categories of Records in the System.

SAFEGUARDS:

USAID maintains all classified records in an authorized security container with access limited to authorized government personnel and authorized contractors. Physical security protections include guards and locked facilities requiring badges. Only authorized government personnel and authorized contractors can access records within the system. USAID mandates and certifies that physical and technological safeguards appropriate for classified and Sensitive but Unclassified systems are used to protect the records against unauthorized access. All authorized government personnel and authorized contractors with access to the system must hold appropriate security clearance, sign a non-disclosure agreement, and undergo both privacy and security training.

For paper records: Classified and Sensitive but Unclassified records are kept in an approved security container at the USAID Washington headquarters, and at the relevant location(s) where USAID has a program. Access to these records is limited to those authorized government personnel and authorized contractors who have a need for the records in the performance of their official duties.

For electronic records: Records are kept in a secure database in the USAID Washington headquarters. Access to the records is restricted to those authorized government personnel and authorized contractors with a specific role in the vetting process as part of the performance of their official duties. The PVS database is housed on and accessed from a Sensitive but Unclassified computer network. Vetting requests, analyses, and results will be stored separately on a classified computer network. Both computer networks and the PVS database require a user identification name and password and approval from the Office of Security. An audit trail is maintained and periodically reviewed to monitor access to the system. Authorized government personnel and authorized contractors assigned roles in the vetting process are provided role-specific training to ensure that they are knowledgeable in how to protect personally identifiable information.

RETENTION AND DISPOSAL:

Records in this system will be retained and disposed of in accordance with a records schedule to be approved by the National Archives and Records Administration.

SYSTEM MANAGER(S) AND ADDRESS:

Coordinator for Counterterrorism, Office of Security, United States Agency for International Development, Ronald Reagan Building, 1300 Pennsylvania Avenue, NW., Washington, DC 20523.

NOTIFICATION PROCEDURE:

To the extent applicable, because this system contains classified information related to the government's national security programs, records in this system may be exempt from notification, access, and amendment as permitted by subsection (j) and (k) of the Privacy Act.

RECORD ACCESS PROCEDURES:

United States citizens or legal permanent residents can request access to a non-exempt record pertaining to him/her by sending a request in writing, signed, to the Chief Privacy Officer at the following address: Chief Privacy Officer, United States Agency for International Development, 1300 Pennsylvania Avenue, NW., Office 2.12–003, Washington, DC 20523–2120.

When requesting access to records covered by this Notice, an individual should provide his/her full name, date of birth, and complete address. An individual requesting access to records in person must provide identity documents, such as a government-issued photo ID, sufficient to satisfy the custodian of the records that the requester is entitled to access.

Requesters should also reasonably specify the record contents being sought. Rules regarding access to Privacy Act records appear in 22 CFR Part 215. If additional information or assistance is required, contact: Chief Privacy Officer, United States Agency for International Development, 1300 Pennsylvania Avenue, NW., Office 2.12–003, Washington, DC 20523–2120.

CONTESTING RECORD PROCEDURES:

Requests for correction or amendment must identify the information to be changed and the corrective action sought. Requests must be submitted to the Chief Privacy Officer as provided in the record access procedures above.

RECORD SOURCE CATEGORIES:

Information in this system is obtained from the non-governmental organization's official who is responsible for completing the application package required to compete for USAID funds or who apply for registration with USAID as a Private and Voluntary Organization. In the case of applications by an individual in his/her own capacity, the information will be collected directly from the individual applicant. Information in this system may also be obtained from public sources, agencies conducting national security screening, law enforcement and intelligence agency record systems, and other government databases.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

To the extent applicable, records in this system may be exempt from any part of 5 U.S.C. 552a except subsections (b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11) if the records in the system are subject to the exemption found in 5 U.S.C. 552a(j). To the extent applicable, records in this system may be exempt from subsections (c)(3), (d), (e)(1), (e)(4)(G), (H), (I), and (f) of 5 U.S.C. 552a if the records in the system are subject to the exemption found in 5 U.S.C. 552a(k). Any other exempt records from other systems of records that are recompiled into this system are also considered exempt to the extent they are claimed as such in the original systems. Rules have been promulgated in accordance with the requirements of 5 U.S.C. 553(b), (c), and (e).

[FR Doc. 07–3330 Filed 7–16–07; 8:45 am]

BILLING CODE 6116–01–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

Request for Proposals (RFP): Demonstration Program for Agriculture, Aquaculture, and Seafood Processing and/or Fishery Worker Housing Grants

AGENCY: Rural Housing Service, USDA.

ACTION: Notice.

SUMMARY: The Rural Housing Service (RHS) announces the availability of agriculture, aquaculture, and seafood processing and/or fishery worker housing grants in the States of Alaska, Mississippi, Utah, and Wisconsin. This Notice was published on April 6, 2004, in the **Federal Register**, vol. 69, page 18040, to award $4,970,500 in grant funds for a housing demonstration program for agriculture, aquaculture, and seafood processing and/or fishery workers in the above states.

Public Law 108–199 (Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2004) authorized RHS to establish a demonstration program to provide financial assistance (grants) for processing and/or fishery worker housing in the States of Alaska, Mississippi, Utah, and Wisconsin. This RFP requests proposals from qualified private and public nonprofit agencies, non-profit cooperatives, state and local governments, and tribal organizations in Alaska, Mississippi, Utah, and Wisconsin to construct housing for agriculture, aquaculture, and seafood processing and/or fishery workers. Any one project may not receive grant funds of more than $1,370,595 from this program. Applications will only be accepted from applicants who will use the funds awarded in the following states: Alaska, Mississippi, Utah, or Wisconsin. Housing facilities constructed under this RFP are expected to increase the supply of housing for agriculture, aquaculture, and seafood processing and/or fishery workers in markets where adequate housing is not available. The Agency has remaining funds in the amount of $1,370,595 which will be awarded in this Notice.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

Under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, OMB must approve all ''collections of information'' by RHS. The Act defines ''collection of information'' as a requirement for ''answers to * * * identical reporting or recordkeeping requirements imposed on ten or more persons * * *.'' (44 U.S.C. 3502(3)(A)) Because this RFP will receive less than 10 applicants, the Paperwork Reduction Act does not apply.

General Information

The agriculture, aquaculture, and seafood processing and/or fishery worker housing grants authorized by Public Law 108–199 are for the purpose of developing a housing demonstration program for agriculture, aquaculture, and seafood processing and/or fishery worker housing in markets that have a demonstrated need for housing for such workers. Under Public Law 108–199, RHS had the authority to award $4,970,500 in grant funds for a housing demonstration program for agriculture, aquaculture, and seafood processing and/or fishery workers in Alaska, Mississippi, Utah, and Wisconsin. This Notice is awarding the remaining $1,370,595 for the aforementioned purposes.

As part of the application, all applicants must also provide a Dun and Bradstreet Data Universal Numbering System (DUNS) number. As required by the Office of Management and Budget

(OMB), all grant applicants must provide a DUNS number when applying for Federal grants, on or after October 1, 2003. Organizations can receive a DUNS number at no cost by calling the dedicated toll-free DUNS number request line at 1–866–705–5711. Additional information concerning this requirement is provided in a policy directive issued by OMB and published in the **Federal Register** on June 27, 2003 (68 FR 38402–38405).

To comply with the President's Management Agenda, the Department of Agriculture is participating as a partner in the new government-wide site in FY 2007 grants.gov. The Web site can be found at *http://www.grants.gov.* The Agriculture, Aquaculture and Seafood Processing and/or Fishery Worker Housing Grant [Catalog of Federal Domestic Assistance #10.433] is one of the programs included at this Web site. Please note that you must locate the downloadable application package for this program by the CFDA Number or FedGrants Funding Opportunity Number, which can be found at *http://www.fedgrants.gov.* If you are an applicant under the Agriculture, Aquaculture and Seafood Processing and/or Fishery Worker Housing Grant, you may submit your application to the Agency in either electronic or paper format. The deadline for electronic and paper format is based on the local time for each USDA Rural Development State Office.

Users of grants.gov will be able to download a copy of the application package, complete it off line, and then upload and submit the application via the grants.gov site. You may not e-mail an electronic copy of a grant application to RHS; however, the Agency encourages your participation in grants.gov. The following are useful tips and instructions on how to use the Web site:

- When you enter the grants.gov site, you will find information about submitting an application electronically through the site as well as the hours of operation. RHS strongly recommends that you do not wait until the application deadline date to begin the application process through grants.gov. To use grants.gov, applicants must have a DUNS number.
- You may submit all documents electronically through the Web site, including all information typically included on the Application for Rural Housing Preservation Grants, and all necessary assurances and certifications.
- Your application must comply with any page limit requirements described in this NOFA.
- After you electronically submit your application through the Web site, you will receive an automatic acknowledgement from grants.gov that contains a grants.gov tracking number.
- RHS may request that you provide original signatures on forms at a later date.
- You must meet the closing date and local time deadline. If you experience technical difficulties on the closing date and are unable to meet the 5 p.m. (Washington, DC time) deadline, print out your application and submit it to your State Office.

DATES: The deadline for receipt of all applications in response to this RFP is 5 p.m., eastern time, on _____ 2007. The application closing deadline is firm as to date and hour. RHS will not consider any application that is received after the closing deadline. Applicants intending to mail applications must provide sufficient time to permit delivery on or before the closing deadline. Acceptance by a post office or private mailer does not constitute delivery. Facsimile (FAX), Cash on Delivery (COD), and postage due applications will not be accepted.

ADDRESSES: Applications should be submitted to Henry Searcy, Jr., Senior Loan Specialist, USDA Rural Development, Rural Housing Service, Multi-Family Housing Processing Division, STOP 0781, Room 1263, 1400 Independence Ave., SW., Washington, DC 20250–0781. RHS will date and time certify incoming applications to evidence timely receipt and, upon request, will provide the applicant with a written acknowledgement of receipt.

FOR FURTHER INFORMATION CONTACT: For further information and an application package, including all required forms, contact Henry Searcy, Jr., Senior Loan Specialist, USDA, Rural Housing Service, Multi-Family Housing Processing Division, Stop 0781, Room 1263, 1400 Independence Avenue, SW., Washington, DC 20250–0781, telephone (202) 720–1753. (This is not a toll-free number.)

I. Purpose

Public Law 108–199 authorized funds to implement a demonstration grant program for the construction of housing for agriculture, aquaculture, and seafood processing and/or fishery workers in Alaska, Mississippi, Utah, and Wisconsin.

The demonstration program has been designed to increase the supply of rental housing for a growing segment of the population whose needs are not currently being met. The program is expected to provide housing opportunities for processing workers in markets that cannot support other forms of conventional and government housing models. Grantees may not require any occupant of the housing or related facilities, as a condition of occupancy, to work or be employed by any particular processor, fishery, or other place, or work for or be employed by any particular person, firm, or interest.

Developers of housing under this program will receive a grant of up to 80% of the Total Development Cost (TDC) of the project. TDC includes all hard costs, soft costs, initial operating reserves, administrative fees, furnishings and equipment, and related facilities.

Housing constructed under this program may not receive RHS Rental Assistance or Operating Subsidies authorized under 42 U.S.C. 1490a for payment of tenant rents. Project financial models should be structured to work without rental subsidies while keeping rents affordable for the target population.

Projects should be located close to tenants' workplaces and services as much as feasible. Location of the project is not limited to rural areas as defined in 42 U.S.C. 1490.

II. Project Threshold Criteria

All applications must meet the minimum threshold requirements contained in this RFP. The threshold criteria are as follows:

A. Occupancy Requirements

Eligibility for residency in facilities constructed under this RFP is limited to individuals and families who earn at least 40% of their income from work as an agriculture, aquaculture, or seafood processing and/or fishery worker and earn less than or equal to 60% of the National Median Income for a family of four as reported by the U.S. Census Bureau. Residents must be United States citizens or be legally admitted for permanent residence.

B. Eligible Grantees

Eligibility for grants under this notice is limited to qualified private and public non-profit agencies, non-profit cooperatives, state and local governments, and tribal organizations in Alaska, Mississippi, Utah and Wisconsin to construct housing for agriculture, aquaculture, and seafood processing and/or fishery workers. Faith based applicants meeting these requirements are also eligible. Applicants must possess the experience, knowledge, and capacity to develop

affordable multi-family housing in rural areas.

C. Grant Limit

A grant under this RFP may fund up to 80% of a project's TDC. TDC includes all hard costs, soft costs, initial operating reserves, administrative fees, furnishings and equipment, and related facilities. Applications will only be accepted from the following states Alaska, Mississippi, Utah, or Wisconsin.

D. Equity Contributions and Leveraged Funds

As stated above, a grant may fund up to 80% of the TDC which leaves at least 20% of the TDC to be funded from other sources. The applicant is encouraged to seek funding from sources with favorable rates and terms in order to keep rents within the reach of the target population. For this reason, additional selection points will be given to proposals that have funding with favorable rates and terms. Examples of such funding sources may include the Federal Home Loan Bank, the U.S. Department of Housing and Urban Development, or a State, county, or local government. Conventional loans may also be used; however, the rates and terms may not be in excess of what is common in the housing industry. For this purpose, the interest rate of any such loan may not exceed 200 basis points above the 10-year Treasury bond rate as of the date of grant closing. The term of any loan must be a minimum of 10 years and it must be amortized over a 30 year period. Longer terms are preferred. The objective in setting these limits is to create affordable rents for the tenants. In each case, equity contributions and loans must be contributed and disbursed prior to the disbursement of any grant funds from the Agency.

E. Eligible Costs

Eligible costs for grants under this RFP include all project related costs including all hard costs, soft costs, initial operating reserves, administrative fees, furnishings and equipment, and related facilities. Eligible costs also include technical assistance received from a non-identity of interest nonprofit organization with housing and/or community development experience, to assist the applicant in the development and packaging of its grant docket and project. Eligible costs for technical assistance is permitted by 7 CFR 3560.53 and may not exceed 4 percent of the TDC.

F. Term of Use

The project will remain in use for the intended purpose as required under 7 CFR parts 3015, 3016, or 3019, as applicable. These provisions require the grant recipient to use the real property for the authorized purpose of the project. The type of security instrument will be determined, prior to grant closing, by the Agency's Regional Office of the General Counsel.

G. Site Control

The developer must own or demonstrate evidence of site control of the proposed site. At a minimum, site control must extend 180 days past the date of application submission and is preferred to be for one year. Proof of site control should be submitted with the application. This can be in the form of a contract of sale, option agreement, long-term lease agreement, or deed or other documentation of ownership by the applicant. The applicant must exercise care in site selection. Site approval is subject to completion of an environmental assessment by RHS and sites with environmental problems will increase the amount of time necessary to complete this assessment. Proposals which will directly or indirectly impact protected resources, such as floodplains or wetlands, can require consideration of alternative sites, changes in project design, or the implementation of other mitigation measures to lessen adverse effects on the environment.

H. Zoning

A zoning designation adequate to develop the type of housing and number of units proposed is required. Evidence of proper zoning must be included with the application. Where there is a clear plan to have a site rezoned, a narrative explaining the situation and detailing the process and timeline for rezoning may be accepted.

I. Utilities

Adequate capacity to connect the project to water, sewer, electricity, and telephone services must be demonstrated. Letters from utility providers must be included in the application. If on-site utilities are proposed, engineering reports indicating correct soil types, adequate land capacity, etc. must be included in the application.

J. Appraisals

As required by 7 CFR 3015.56, if land is being donated as part of the grantee's contribution, the market value must be set by an independent appraiser and certified by a responsible official of the grantee. An appraisal will also be required if project funds are used to purchase land.

K. Market Demand

Projects funded under this RFP shall be in markets with demonstrated need for agriculture, aquaculture, and seafood processing and/or fishery worker housing. All applications should include documentation of this need in the form of a market analysis, survey, or other documentation of need.

L. Design Characteristics

Housing constructed under this demonstration may be of any architectural style as long as it is permitted by local zoning laws, meets all applicable building codes, and fits with the character of the surrounding community. However, the facilities should not be of extravagant design and their size must be commensurate with the needs of the workers who will occupy the housing facility. When planning units for families, lower density building design and layout is normally desirable. Housing should be designed in such a manner that it will be decent, safe, sanitary, and modest in size and cost. Actual plans, specifications, and contract documents must be prepared in accordance with 7 CFR part 1924, subpart A.

Building design is subject to the requirements of section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act, the Fair Housing Amendments Act of 1988, and any state or local accessibility requirements. For these reasons, buildings must be designed and constructed in accordance with the Uniform Federal Accessibility Standards, the Americans with Disabilities Act Accessibility Guidelines, the Fair Housing Act Accessibility Guidelines, and any state or local standards.

Particular attention should be given to 7 CFR 1924.13 which gives supplemental requirements for complex construction. All construction contracts must be awarded on the basis of competitive bidding unless an exception is granted in accordance with 7 CFR 1924.13. In either case, the Contractor must be reliable and experienced in the construction of projects of similar size, design, scope, and complexity. The construction contracts must contain the nondiscrimination language, in its entirety, that is required by E.O. 11246 (refer to 41 CFR 60–1.4(b) subparagraphs 1–7 for the specific language). The plans and specifications, including the construction contract, must be reviewed and accepted by RHS prior to the start of construction.

Until the plans and specifications have been approved and the grant is closed, construction work should not be started. When there are construction changes that affect design, costs, or time, the change must be documented as a contract change order and must be signed by the borrower, borrower's architect, contractor, and Agency representative before the work involved in the change is started or the costs are included in a payment request. Changes that do not affect design, costs, or time, may be handled as field orders and do not require Agency approval.

RHS will conduct periodic inspections during construction to protect the interest of the Government.

M. Civil Rights

Title VI of the Civil Rights Act of 1964 prohibits recipients of Federal financial assistance from discriminating in their programs and activities on the basis of race, color, or national origin. It also requires recipients (1) to sign a civil rights assurance agreement (i.e., Form RD 400–4), (2) to collect statistical data on race and national origin, (3) submit to the Agency timely, complete, and accurate compliance reports so that the Agency can determine compliance with program regulations and applicable civil rights laws, and (4) to disseminate information to the public stating that the recipient operates a program that is subject to the non-discrimination requirements of Title VI and briefly explain the procedures for filing complaints.

Borrowers and grantees must take reasonable steps to ensure that Limited English Proficiency (LEP) persons receive the language assistance necessary to afford them meaningful access to USDA programs and activities, free of charge. Failure to ensure that LEP persons can effectively participate in or benefit from federally-assisted programs and activities may violate the prohibition under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d and Title VI regulations against national origin discrimination.

Section 504 of the Rehabilitation Act of 1973 prohibits recipients of Federal financial assistance from discriminating against persons with disabilities and requires recipients to make their programs and activities accessible to, and usable by, persons with disabilities.

The Fair Housing Act (Title VIII of the Civil Rights Act of 1968, as amended by the Fair Housing Amendments Act of 1988) prohibits discrimination because of race, color, religion, sex, handicap, familial status, and national origin in the sale, rental, or advertising of dwellings in providing services or availability of residential real estate transactions.

The Age Discrimination Act of 1975 prohibits recipients of Federal financial assistance from discriminating in their programs and activities on the basis of age. Post award compliance reviews will be conducted in accordance with RD Instruction 1901–E, section 1901.204.

As part of the grant proposal, the applicant must provide (1) a notice of all civil rights law suits filed against it; (2) a description of assistance applications they have pending in other Agencies and of Federal assistance being provided; (3) a description of any civil rights compliance reviews of the applicant during the preceding two years; and (4) a statement as to whether the applicant has been found in noncompliance with any civil rights requirements.

Successful applicants have a duty to affirmatively further fair housing. Proposals will include specific steps that the applicant will take to promote, ensure, and affirmatively further fair housing.

In the event Federal financial assistance will be used to obtain or improve real property, instruments of conveyance shall contain a covenant running with the land assuring non-discrimination for the period the real property is used for the same or similar purpose the Federal financial assistance is extended or for another purpose involving the provisions of similar services or benefits. The covenant shall be as follows:

''The property described herein was obtained or improved with Federal financial assistance and is subject to the provisions of Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, and the regulations issued thereto. This covenant is in effect for as long as the property continues to be used for the same or similar purpose for which the financial assistance was extended, or for as long as the above recipient owns it, whichever is longer.''

Contractors must comply with the Equal Employment Opportunity Executive Order 11246, as amended, and construction contracts must contain the specific non-discrimination language, in its entirety, that is required by the Executive Order.

Before funds are disbursed, a pre-award civil rights compliance review will be conducted by the Agency to determine whether the applicant is, and will be, in compliance with Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, the Fair Housing Act, and the Age Discrimination Act of 1975. In addition, the Agency will conduct a Civil Rights Impact Analysis.

N. Environmental Requirements

All applications are subject to satisfactory completion of the appropriate level of environmental review by RHS in accordance with 7 CFR part 1940, subpart G. For the purposes of 7 CFR part 1940, subpart G, applications under this RFP will be considered as applications for the financing of multi-family housing. All applications are subject to the requirements of Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-income Populations.''

All applications are subject to the flood insurance requirements of 7 CFR part 1806, subpart B.

O. Applicable Regulations

All grants funded under this program must meet the requirements of 7 CFR part 3015 and parts 3016 or 3019, as applicable, Rural Development Instruction 1924–A (7 CFR part 1924, subpart A), and 1924–C (7 CFR part 1924, subpart C).

P. Dun and Bradstreet Data Universal Numbering System (DUNS) Number

As required by the Office of Management and Budget (OMB), all grant applicants must provide a DUNS number when applying for Federal grants, on or after October 1, 2003. Organizations can receive a DUNS number at no cost by calling the dedicated toll-free DUNS Number request line at 1–866–705–5711. Additional information concerning this requirement is provided in a policy directive issued by OMB and published in the **Federal Register** on June 27, 2003 (68 FR 38402–38405).

III. Proposal Format

A. Proposals must include the following:

1. Standard Form (SF)–424, ''Application for Federal Assistance.''

2. Applicant's DUNS number.

3. Documentation to evidence the applicant's status as a private or public nonprofit agency, nonprofit cooperative, state or local government, or tribal organization.

4. Applicant's Financial Statements.

5. Form HUD 935.2, ''Affirmative Fair Housing Marketing Plan.''

6. Form RD 3560–30, ''Identity of Interest (IOI) Disclosure Certification'' and, ''Identity of Interest (IOI) Qualification.''

7. Form HUD 2530, ''Previous Participation Certification.''

8. Form RD 1924–13, ''Estimate and Certificate of Actual Cost.''

9. Form RD 3560–7, ''Multiple Family Housing Project Budget'' including rent schedule and operating and maintenance budget.

10. Form RD 1940–20, ''Request for Environmental Information.''

11. A narrative statement that documents the applicant's experience, knowledge, and capacity to develop multifamily housing.

12. A Sources and Uses Statement showing all sources of funding included in the proposed project. The terms and schedules of all sources included in the project should be included in the Sources and Uses Statement.

13. Applicant organizational documents (articles of incorporation, by laws, etc.).

14. A narrative description of the proposed project, including a description of site, housing, amenities, etc.

15. A location map showing the site and surrounding services.

16. Evidence of site control.

17. Evidence of proper zoning or explanation of how proper zoning will be achieved.

18. Evidence of utilities availability or evidence that the site is suitable for on-site utilities.

19. A description of any related facilities including justification and cost of such facilities.

20. Schematic design drawings including a site plan, building elevations, and floor plans.

21. Outline specifications.

22. A statement agreeing to pay any cost overruns from the applicant's own sources.

23. Documentation of need in the form of a market study, survey, or other sources.

24. A list of all other funding sources and conditional commitments from those funding sources. The conditional commitments must provide the costs of those funds (i.e., rates, terms, fees, etc.).

25. If seeking points under Evaluation Criteria, Paragraph IV.B., a copy of the Tenant Services Plan and letters from the service provider which document that they will provide the service on-site and on a reoccurring basis.

26. Form RD 400–4, Assurance Agreement.

B. The above items are required for the RFP response. If a proposal is accepted for further processing, there will be additional submittals required.

IV. Evaluation Criteria

A. Leveraging (Up to 40 Points)

Points will be awarded based on the percent of non-RHS funds specifically identified and designated to supplement RHS funds. Leveraged funds may include donated land. In the case of donated land, the amount of leveraging will be determined by an opinion of value to be prepared by an independent, licensed appraiser. Points will be awarded as follows:

Percent of leveraging	Points
Over 50%	10
21% to 50%	5

Additional points will be awarded based on the cost of the leveraged funds. A maximum of 30 points will be awarded under this criteria. If a proposal has multiple funding sources, points will be awarded proportionately to the amount that each funding source provides, as a percentage of the applicant's contribution. Points will be awarded as follows:

Cost of leveraged funds	Points
Grant funds without any repayment costs	30
Loans with interest rates below the 10-year Fed bond rate	25
Loans with interest rates above the 10-year Fed bond rate (but less then 101 basis points above it)	15
Loans with interest rates more than 100 basis points above the Fed bond rate (but no more than 200 points above it)	5

B. Tenant Services (Up to 25 Points)

Points will be awarded based on the presence of and extent to which a tenant services plan exists that clearly outlines services that will be provided to residents of the proposed project.

These services include but are not limited to:

1. Day care or before and after school child care.

2. Computer learning centers.

3. Homeownership and budget counseling.

4. Parenting programs for young parents (such as family support centers), parenting skills sessions for all interested parents, and parent and child activities.

5. Literacy programs (such as book clubs, toddler reading programs, story groups), libraries and book sharing groups or centers.

6. Art activities or art centers for children that include painting, photography, ceramics, etc.

7. Health education and referral or health care outreach centers.

8. Job training and preparation centers.

9. Housing services and/or community coordinators.

10. Mentoring programs where young adults mentor adolescents or more established adults mentor other adults.

11. Community meeting centers.

12. Recreation centers located within housing complexes.

13. Nutritional services.

14. Transportation services.

A Tenant Services Plan must be submitted with the application to receive points under this criteria. In addition, letters from the service provider must be submitted. The letters from the service providers must document that they will provide the services at the project site and on a regular, reoccurring basis. In addition, the proposed design of the housing must include the necessary physical space for the services to be provided on-site. Unless each of the above requirements are met, points will not be awarded. Five points will be awarded for each resident service included in the tenant services plan up to a maximum of 25 points.

C. Energy Generation and Energy Conservation (Up to 5 Points)

In an effort to implement USDA's nationwide initiative to promote renewable energy and energy conservation, Rural Development (RD) has adopted incentives for energy generation and energy conservation. Participation in these nationwide initiatives is voluntary, but is strongly encouraged.

Energy Generation. Applicants will be awarded points if the proposal includes the installation of energy generation systems to be funded by a third party. The proposal must include an overview of the energy generation system being proposed. Evidence that an energy generation system has been funded by a third party and that it has a quantifiable positive impact on energy consumption will be required. (5 points)

Energy Conservation. Applicants will be awarded points to construct (or substantially rehabilitate) housing that earns the ENERGY STAR label for new residential construction. Units earning the ENERGY STAR label must be independently verified to meet guidelines for energy efficiency as set by the U.S. Environmental Protection Agency. All procedures used in verifying a unit for the ENERGY STAR label must comply with National Home Energy Ratings System (HERS) guidelines. ENERGY STAR guidelines for residential construction apply to homes that are three stories or less and single or low-rise multi-family residential buildings.

The Applicant will include in the narrative an explanation of how they

plan to incorporate ENERGY STAR. Construction plans pertaining to energy efficiency must be developed with, reviewed, and accepted by a HERS certified rater, the contractor, and the owner. Progress inspections must be made at appropriate times by a HERS certified rater to ensure that the housing is being constructed or rehabilitated according to ENERGY STAR specifications. In order to receive final payment, applicants will be required to submit the appropriate rating reports from the HERS rater to RD as evidence that the housing has been constructed to meet the standards of ENERGY STAR. For further information about ENERGY STAR, see *http://www.energystar.gov* or call the following toll-free numbers: (888) 782–7939 or (888) 588–9920 (TTY). (5 points)

V. Review Process

All proposals will be evaluated by a RHS grant committee. The grant committee will make recommendations to the RHS Administrator concerning preliminary eligibility determinations and for the selection of proposal for further processing, based on the selection criteria contained in this RFP and the availability of funds. The Administrator will inform applicants of the status of their proposals within 30 days of the closing date of the RFP.

If the proposal is accepted for further processing, the applicant will be expected to submit additional information prior to grant obligation. In addition, RHS must complete the appropriate level of environmental review prior to grant obligation. The applicant is expected to assist RHS, as necessary, in the development of this environmental review. In the event that an application is selected for further processing and the applicant either declines or reduces the size of their grant request, the RHS National Office will, at its discretion, either select the next highest ranked unfunded proposal or not utilize the funds for this demonstration project.

Prior to grant obligation, grant recipients shall enter into the grant agreement provided as Appendix A to this RFP.

The applicant will have one year from the date of the obligation of grant funds to begin construction.

VI. RHS Monitoring

During construction, RHS will take part in periodic progress meetings at the project site and shall inspect completed work. RHS approval of work completed must be given before grant funds can be disbursed for that work.

RHS monitoring shall continue throughout the useful life of the project or until the grant is terminated under provisions established in 7 CFR part 3015 and parts 3016 or 3019, as applicable. Monitoring shall consist of initial and annual tenant certifications, civil rights compliance reviews, triennial physical inspections, annual proposed and actual operating budgets, and annual audits. If other funding sources involved in the project require reporting, those formats may be used in place of RHS methods as long as those formats meet RHS requirements.

Tenants and grantees must execute an Agency-approved tenant certification form establishing the tenant's eligibility prior to occupancy. In addition, tenant households must be recertified and must execute a tenant certification form at least annually.

Grantees will submit to a triennial (once every three years) physical inspection of the project. RHS will inspect for health and safety issues, deferred maintenance, and other physical problems that can endanger the provision of decent, affordable housing to the target population on a long-term basis.

Annual proposed and actual operating and maintenance budgets will be required to insure that all project needs are being met and all RHS guidelines are being followed. The form of operating and maintenance budgets will be designated by RHS.

The grantee must submit annual audits of the project finances to RHS in accordance with the requirements established by OMB, in accordance with in 7 CFR part 3052.

Nondiscrimination Statement

''The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

To file a complaint of discrimination write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, SW., Washington, DC. 20250–9410 or call (800) 795–3272 (voice) or (202) 720–6382 (TDD). USDA is an equal opportunity provider, employer, and lender.''

Dated: July 9, 2007.

Russell T. Davis,

Administrator, Rural Housing Service.

Appendix A—Processing and/or Fishery Worker Housing Grant Agreement

United States Department of Agriculture
Rural Housing Service

Processing and/or Fishery Worker Housing Grant Agreement

This Grant Agreement (Agreement) dated _____, ____, is a contract for receipt of grant funds under the Processing and/or Fishery Worker Housing Grant Demonstration Program authorized in the Consolidated Appropriations Act, 2004 (Pub. L. 108–199). This grant will be administered under the Request for Proposals (RFP): Demonstration Program for Agriculture, Aquaculture, and Seafood Processing and/or Fishery Worker Housing Grants published in the **Federal Register** on _____, 2007, and the regulations governing the Farm Labor Housing Grant program (7 CFR part 3560 subpart L and 7 CFR 3560 subpart E). These requirements do not supersede the applicable requirements for receipt of Federal funds stated in 7 CFR parts 3015, ''Uniform Federal Assistance Regulations,'' 3016 ''Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments,'' or 3019, ''Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Non-profit Organizations.'' Further, all relevant regulatory requirements, including 7 CFR parts 3015, 3016 and 3019, apply to applicants whether contained in here or not.

Between _____, a private or public nonprofit agency, nonprofit cooperative, state or local government, or tribal organization (Grantee) and the United States of America acting through the Rural Housing Service (RHS), Department of Agriculture, (Grantor)

Witnesseth:

All references herein to ''Project'' refer to a Processing and/or Fishery Worker Housing facility to serve a rural community generally known as _____. The principal amount of the grant is $_____ (Grant Funds) which is _____ percent of Project costs.

Whereas

Grantee has determined to undertake the acquisition, construction, enlargement, capital improvement, or purchase of equipment for a project with a total estimated cost of $_____. Grantee is able to finance and has committed $_____ of Project costs.

The Grantor has agreed to give the Grantee the Grant Funds, subject to the terms and conditions established by the Grantor. Provided, however, that any Grant Funds actually advanced and not needed for grant purposes shall be returned immediately to the Grantor. The Grantor may terminate the grant in whole, or in part, at any time before the date of completion, whenever it is determined that the Grantee has failed to

comply with the conditions of this Agreement or the applicable regulations.

As a condition of this Agreement, the Grantee assures and certifies that it is in compliance with and will comply in the course of the Agreement with all applicable laws, regulations, Executive Orders, and other generally applicable requirements, including those contained in 7 CFR 3015.205(b), which are incorporated into this Agreement by reference, and such other statutory provisions as are specifically contained herein.

Now, therefore, in consideration of said grant, and completing and reviewing the collection of information, Grantee agrees that Grantee will:

A. Cause said Project to be constructed within the total sums available to it, including Grant Funds, in accordance with any architectural or engineering reports, and any necessary modifications, prepared by Grantee and approved by Grantor.

B. Provide periodic reports as required by Grantor and permit periodic inspection of the Project by a representative of the Grantor. For grant-only Projects, Form SF–269, ''Financial Status Report,'' and a project performance report will be required on a quarterly basis (due 15 working days after each calendar quarter). A final project performance report will be required with the last ''Financial Status Report.'' The final report may serve as the last quarterly report. Grantees shall constantly monitor performance to ensure that time schedules are being met, projected work by time periods is being accomplished, and other performance objectives are being achieved. The project performance reports shall include, but are not limited to, the following:

1. A comparison of actual accomplishments to the objectives established for that period;

2. Reasons why established objectives were not met;

3. Problems, delays, or adverse conditions which will affect attainment of overall project objectives, prevent meeting time schedules or objectives, or preclude the attainment of particular project work elements during established time periods. This disclosure shall be accomplished by a statement of the action taken or planned to resolve the situation; and

4. Objectives and timetables established for the next reporting period.

C. Manage, operate, and maintain the facility, including this Project if less than the whole of said facility, continuously in an efficient and economical manner.

D. Not use grant funds to replace any financial support previously provided or assured from any other source. The Grantee agrees that the Grantee's level of expenditure for the Project shall be maintained and not reduced as a result of Grant Funds.

E. Make the public facility or services available to all persons in Grantee's service area without discrimination as to race, color, religion, sex, national origin, age, marital status, sexual orientation or physical or mental disability at reasonable rates, including assessments, taxes, or fees. Grantee may make modifications as long as they are reasonable and nondiscriminatory. The Grantee agrees to comply with Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, Title XI of the Education Act of 1973, the Age Discrimination Act of 1975, Title XI of the Education Act of 1972, Title VIII of the Fair Housing Act of 1968 as amended in 1988, and Executive Order 11246. The Grantee will make the public facility or service available to all persons in the Grantee's service area without regard to discrimination on the grounds of race, color, religion, sex national origin, age, martial status and disability. Grantee will make known to tenants and applicants the reasonable accommodation requirements under the Fair Housing Amendments Act, Section 504 of the Rehabilitation Act of 1973 and Departmental Regulations. Grantee is required to make modification at the complex's expense, unless to so, would cause an undue financial or administrative burden.

F. Execute any agreements required by Grantor which Grantee is legally authorized to execute. If any such agreement has been executed by Grantee as a result of a loan being made to Grantee by Grantor contemporaneously with the making of this grant, that agreement applies equally to the grant and another identical agreement need not be executed in connection with this grant.

G. Repay to Grantor the Grant Funds with any legally permitted interest from the date of any default under its representations or agreements contained in this instrument. The provisions of this Agreement may be enforced by Grantor, at its option and without regard to prior waivers of previous defaults by Grantee, by judicial proceedings to require specific performance of the terms of this Agreement or by such other proceedings in law or equity, in either Federal or State courts, as may be deemed necessary by Grantor to assure compliance with the provisions of this Agreement and the laws and regulations under which this grant is made.

H. Use the real property including land, improvements, structures, and appurtenances thereto, for authorized purposes of the grant as long as needed.

1. Title to real property shall vest in the Grantee subject to the condition that the Grantee shall use the real property for the authorized purpose of the original grant as long as needed.

2. The Grantee shall obtain Grantor's approval to use the real property in other projects when the Grantee determines that the property is no longer needed for the original grant purposes. Use in other projects shall be limited to those under other Federal grant programs or programs that have purposes consistent with those authorized for support by the Grantor.

3. When the real property is no longer needed, as provided in Paragraphs H.1 and H.2 above, the Grantee shall request disposition instructions from the Grantor.

This Grant Agreement covers the following described real property (use continuation sheets as necessary).

I. Abide by the following conditions pertaining to equipment which is furnished by the Grantor or acquired wholly or in part with Grant Funds. Equipment means tangible, non-expendable personal property having a useful life of more than one year.

1. Use of equipment.

(a) The Grantee shall use the equipment in the Project for which it was acquired as long as needed. When no longer needed for the original project, the Grantee shall dispose or use the equipment in accordance with 7 CFR parts 3015, 3016 or 3019 whichever is applicable.

3. The Grantee's property management standards for equipment shall include:

(a) Property records which accurately provide for: A description of the equipment; manufacturer's serial number or other identification number; acquisition date and cost; source of the equipment; percentage (at the end of budget year) of Federal participation in the cost of the Project for which the equipment was acquired; location, use, and condition of the equipment and the date the information was reported; and ultimate disposition data including sales price or the method used to determine current fair market value if the Grantee reimburses the Grantor for its share.

(b) A physical inventory of equipment shall be taken and the results reconciled with the equipment records at least once every two years to verify the existence, current utilization, and continued need for the equipment.

(c) A control system shall be in effect to ensure adequate safeguards to prevent loss, damage, or theft of the equipment. Any loss, damage, or theft of equipment shall be investigated and fully documented.

(d) Adequate maintenance procedures shall be implemented to keep the equipment in good condition.

(e) Proper sales procedures shall be established for unneeded equipment which would provide for competition to the extent practicable and result in the highest possible return.

This Grant Agreement covers the following described equipment (use continuation sheets as necessary).

J. Provide Financial Management Systems which will include:

1. Accurate, current, and complete disclosure of the financial results of each grant. Financial reporting will be on an accrual basis.

2. Records which identify adequately the source and application of funds for grant-supported activities. Those records shall contain information pertaining to grant awards and authorizations, obligations, unobligated balances, assets, liabilities, outlays, and income.

3. Effective control over and accountability for all funds, property, and other assets. Grantees shall adequately safeguard all such assets and shall ensure that they are used solely for authorized purposes.

4. Accounting records supported by source documentation.

K. Retain financial records, supporting documents, statistical records, and all other records pertinent to the grant for a period of at least three years after grant closing except that the records shall be retained beyond the three-year period if audit findings have not

been resolved. Microfilm or photocopies or similar methods may be substituted in lieu of original records. The Grantor and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the Grantee's which are pertinent to the specific grant program for the purpose of making audits, examinations, excerpts, and transcripts.

L. Provide either an audit report, annual financial statements, or other documentation prepared in accordance with Grantor regulations to allow the Grantor to determine that funds have been used in compliance with the proposal, any applicable laws and regulations, and this Agreement.

M. Agree to account for and to return to Grantor interest earned on grant funds pending their disbursement for program purposes when the Grantee is a unit of local government. States and agencies or an instrumentality of a State shall not be held accountable for interest earned on Grant Funds pending their disbursement.

N. Not encumber, transfer or dispose of the property or any part thereof, furnished by the Grantor or acquired wholly or in part with Grantor funds without the written consent of the Grantor except as provided in Paragraphs H and I.

O. Not duplicate other Project purposes for which monies have been received, are committed, or are applied to from other sources (public or private).

P. From construction completion throughout the term of the grant, the grantee shall submit on an annual basis, or as needed, the following:

1. Project Operating Budget to be completed on Form RD 1930–7 ''Multiple Family Housing Project Budget.'' All sections of the budget are to be completed including, but not limited to, proposed and actual income and expense estimates, operating and maintenance expenses, special account statements (reserve, tax and insurance, and security deposit accounts) and capital improvement budgets.

2. Annual Tenant Certification to be completed on Form RD 1944–8, ''Tenant Certification.'' This document shall be the official means by which tenant eligibility is established. This document must be completed by each tenant and the Grantee at the time of initial move-in, following a fluctuation in tenant income or change in employment sector (processing to non-processing), and on each annual lease anniversary. The Grantee shall verify tenant income and employment sector with pay stubs, employer letters, or other documents which can verify the tenant's employment in agriculture, aquaculture, and seafood processing and/or fishery work and the tenants household income.

3. Other forms and reports as required by Federal, State, or local statute.

Q. Use of Real Property. The facility shall remain in use for its initially designated purpose of providing housing for agriculture, aquaculture, and seafood processing and/or fishery workers. Grantee will not require any occupant of the housing or related facilities, as a condition of occupancy, to work or be employed by any particular processor, fishery, or other place, or work for or be employed by any particular person, firm, or interest. When no longer needed, RHS may approve the use of the property for other uses in accordance with 7 CFR parts 3015, 3016 and 3019, whichever is applicable.

Grantor Agrees That It:

A. Will make available to Grantee for the purpose of this Agreement not to exceed $_____ which it will advance to Grantee to meet but not to exceed ____ percent of the Project development costs in accordance with the actual needs of Grantee as determined by Grantor.

B. Will assist Grantee, within available appropriations, with such technical assistance as Grantor deems appropriate in planning the Project and coordinating the plan with local official comprehensive plans for essential community facilities and with any State or area plans for the area in which the project is located.

C. At its sole discretion and at any time, may give any consent, deferment, subordination, release, satisfaction, or termination of any or all of Grantee's grant obligations, with or without valuable consideration, upon such terms and conditions as Grantor may determine to be (1) advisable to further the purpose of the grant or to protect Grantor's financial interest therein and (2) consistent with both the statutory purposes of the grant and the limitations of the statutory authority under which it is made.

Termination of This Agreement

This Agreement may be terminated for cause in the event of default on the part of the Grantee or for convenience of the Grantor and Grantee prior to the date of completion of the grant purpose. Termination for convenience will occur when both the Grantee and Grantor agree that the continuation of the Project will not produce beneficial results commensurate with the further expenditure of funds.

In witness whereof, Grantee has this day authorized and caused this Agreement to be executed by

_____

and attested with its corporate seal affixed (if applicable) by

_____

Attest:

_____

By _____

(Title) _____

United States of America Rural Housing Service

By _____

(Name) _____

(Title) _____

[FR Doc. E7–13763 Filed 7–16–07; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Docket 39–2006]

Foreign–Trade Zone 29 – Louisville, Kentucky, Application for Subzone Status, NACCO Materials Handling Group, Inc., Plant, (Forklift Trucks), Amendment of Application: Additional Site

Notice is hereby given that the application submitted by the Louisville and Jefferson County Riverport Authority, grantee of FTZ 29, requesting special–purpose subzone status for the forklift truck manufacturing facility of NACCO Materials Handling Group, Inc. (NMHG), located in Berea, Kentucky (71 FR 54611, 9–18–2006) has been amended to include an additional site (1 warehouse/195,000 sq.ft./22 acres) comprised of Building 105 located at 145 Hi Lane Drive in Richmond (Madison County), Kentucky.

Public comment is invited from interested parties. The comment period is hereby reopened until [30 days from date of publication]. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below.

A copy of the application and the amendment is available for public inspection at each of the following locations: U.S. Department of Commerce Export Assistance Center, 1600 World Trade Center, 333 W. Vine Street, Lexington, Kentucky 40507; and, Office of the Executive Secretary, Foreign–Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Washington, District of Columbia 20230–0002. For further information, contact Pierre Duy, examiner, at pierre__duy@ita.doc.gov, or (202) 482–1378.

Dated: July 10, 2007.

Andrew McGilvray,

Executive Secretary.

[FR Doc. E7–13823 Filed 7–16–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Docket 22–2007]

Foreign–Trade Zone 86 – Tacoma, Washington, Expansion of Manufacturing Authority – Subzone 86D; Tesoro Refining and Marketing Company, Anacortes, Washington

An application has been submitted to the Foreign–Trade Zones (FTZ) Board

(the Board) by the Port of Tacoma, grantee of FTZ 86, requesting authority on behalf of Tesoro Refining and Marketing Company (Tesoro), to expand the scope of manufacturing activity conducted under zone procedures within Subzone 86D at the Tesoro oil refinery complex in Anacortes, Washington. The application was submitted pursuant to the Foreign–Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on July 10, 2007.

Subzone 86D (108,200 BPD capacity, 350 employees) was approved by the Board in 2001 for the manufacture of fuel products and certain petrochemical feedstocks and refinery by–products (Board Order 1140, 66 FR 6583–6585, 1–22–2001).

The subzone is located on West March Point Road in Anacortes, Washington (Skagit County). The request anticipates expansion of Tesoro's crude unit and modifications and upgrades to existing units within the refinery complex that may increase the overall crude distillation capacity of the refinery up to 150,000 BPD. No additional feedstocks or products have been requested.

Zone procedures would exempt the increased production from customs duty payments on the foreign products used in its exports. On domestic sales of the increased production, the company would be able to choose the finished product duty rate on certain petrochemical feedstocks and refinery by–products (duty–free) by admitting foreign crude oil in non–privileged foreign status. The duty rates on crude oil range from 5.25 cents/barrel to 10.5 cents/barrel. The application indicates that the savings from zone procedures help improve the refinery's international competitiveness.

In accordance with the Board's regulations, a member of the FTZ staff has been designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is September 17, 2007. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to October 1, 2007).

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce Export Assistance Center, 2601 Fourth Avenue, Suite 310, Seattle, WA 98121.

Office of the Executive Secretary, Foreign–Trade Zones Board, U.S. Department of Commerce, Room 2111, 1401 Constitution Ave., NW, Washington, DC 20230.

For further information, contact Diane Finver at *Diane_Finver@ita.doc.gov* or (202) 482–1367.

Dated: July 10, 2007.

Andrew McGilvray,

Executive Secretary.

[FR Doc. E7–13824 Filed 7–16–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 070619210–7211–01]

Request for Public Comments on a Systematic Review of the Commerce Control List

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of inquiry.

SUMMARY: The Bureau of Industry and Security (BIS) is soliciting comments from the public regarding the Commerce Control List (CCL) in the Export Administration Regulations (EAR). BIS has already requested that its Technical Advisory Committees (TACs) review the CCL and recommend potential changes to BIS. BIS believes that it would also be beneficial to allow interested members of the public to submit comments regarding the CCL.

DATES: Comments must be received by September 17, 2007.

ADDRESSES: Written comments on this notice of inquiry may be sent by e-mail to *publiccomments@bis.doc.gov*. Include ''Notice of Inquiry—CCL'' in the subject line of the message. Comments may also be submitted by mail or hand delivery to Timothy Mooney, Office of Exporter Services, Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, 14th St. & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230, ATTN: Notice of Inquiry—CCL; or by fax to (202) 482–3355.

FOR FURTHER INFORMATION CONTACT: Timothy Mooney, Regulatory Policy Division, Bureau of Industry and Security, telephone: (202) 482–2440, e-mail: *tmooney@bis.doc.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Commerce Control List (CCL) is found in Supplement No. 1 to part 774 of the EAR. The CCL is a list of items subject to the Export Administration Regulations (EAR). Items subject to the EAR are under the export control jurisdiction of the Bureau of Industry and Security (BIS), U.S. Department of Commerce. The CCL covers items (i.e., commodities, software, and technology) enumerated in Export Control Classification Numbers (ECCNs). There are 10 general categories (0–9) of ECCNs and each category has five parts (Systems, Equipment and Components; Test, Inspection and Production Equipment; Materials; Software; and Technology). The CCL covers a broad range of commodities, software and technologies and plays an important role in the U.S. system for controlling the export of dual-use items. Items not listed on the CCL, but subject to the EAR, are designated as EAR99.

Changes are made regularly to the CCL to reflect revisions in the control lists of the multilateral export control regimes (Wassenaar Arrangement; Missile Technology Control Regime; Australia Group; Nuclear Suppliers' Group). To conduct a more systematic review of the CCL, BIS has requested that its TACs review the CCL and recommend potential changes to BIS.

In addition to seeking recommendations from its TACs, BIS is also inviting the interested public to submit comments regarding:

(1) The overall structure of the CCL, including suggestions for how the structure of the CCL may be changed to better advance U.S. national security, foreign policy, and economic interests;

(2) Types of items that should be listed on the CCL and the appropriate levels of controls to be placed on those items, taking into account technology levels, markets, and foreign availability;

(3) Any updates to the CCL item descriptions that would enable the descriptions to better reflect the intent of the multinational controls and to eliminate any overly broad descriptions that inadvertently capture non-critical items that are not controlled by other countries; and

(4) Coordination and harmonization of controls on items covered by the multilateral regimes, such as the Wassenaar Arrangement.

Comments should be submitted to BIS as described in the **ADDRESSES** section of this notice by September 17, 2007.

Dated: July 11, 2007.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. E7–13843 Filed 7–16–07; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

A–570–898

Chlorinated Isocyanurates from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') is conducting an administrative review of the antidumping duty order on chlorinated isocyanurates (''chlorinated isos'') from the People's Republic of China (''PRC'') covering the period December 16, 2004, through May 31, 2006. We have preliminarily determined that sales have been made below normal value (''NV'') by Hebei Jiheng Chemical Company Ltd. (''Jiheng Chemical''). If these preliminary results are adopted in our final results of this review, we will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries of subject merchandise during the period of review (''POR'').

Interested parties are invited to comment on these preliminary results. We intend to issue the final results no later than 120 days from the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act'').

EFFECTIVE DATE: July 17, 2007.

FOR FURTHER INFORMATION CONTACT: Katharine Huang or Charles Riggle, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–1271 or (202) 482–0650, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 24, 2005, the Department published the antidumping duty order on chlorinated isos from the PRC.[1] On June 2, 2006, the Department published a notice of opportunity to request an administrative review of this order.[2] On June 30, 2006, in accordance with 19 CFR 351. 213(b)(1), the following requests were made: Clearon Corporation (''Clearon'') and Occidental Chemical Corporation (''OxyChem''), petitioners in the underlying investigation, and BioLab, Inc. (''BioLab''), a domestic producer of the like product, requested that the Department conduct an administrative review of Jiheng Chemical's sales and entries during the POR; On the same date, in accordance with 19 CFR 351.213(b)(2), Jiheng Chemical, a foreign producer/exporter of subject merchandise, requested that the Department review its sales of subject merchandise.

On July 27, 2006, the Department initiated this administrative review with respect to Jiheng Chemical.[3] The Department issued an antidumping duty questionnaire to Jiheng Chemical on August 15, 2006.

On August 16, 2006, the Department requested that the Office of Policy provide a list of surrogate countries for this review.[4] On August 23, 2006, the Office of Policy issued its list of surrogate countries.[5]

On August 24, 2006, the Department requested that interested parties submit surrogate value information. On September 12, 2006, the Department requested that interested parties provide surrogate country selection comments. On September 15, 2006, Clearon and OxyChem (''Petitioners'') and BioLab requested an extension of time for all interested parties to submit surrogate value information, provide surrogate country selection comments, and submit factual information. On September 19, 2006, the Department granted the Petitioners' and BioLab's extension requests. On October 25, 2006, BioLab requested a further extension of time to submit surrogate value information and provide surrogate country selection comments. On October 31, 2006, the Department granted the requested extension to all parties.

On November 17, 2006, Petitioners, BioLab and Jiheng Chemical provided comments on publicly available information to value the factors of production (''FOP'') and the selection of a surrogate country. All interested parties recommended India as the surrogate country. On November 27, 2006, Jiheng Chemical submitted rebuttal comments on Petitioners' November 17, 2006 surrogate value submission. On November 27, 2006, Petitioners and BioLab requested an extension of time for all parties to submit rebuttal information concerning surrogate values. On November 28, 2006, the Department granted Petitioners' and BioLab's extension requests. On November 30, 2006, BioLab requested an extension of time for all parties to submit factual information. On December 4, 2006, the Department granted BioLab's extension request. On December 6, 2006, Petitioners and BioLab submitted rebuttal comments on Jiheng Chemical's November 17, 2006 surrogate value submission. On December 15, 2006, Jiheng Chemical submitted rebuttal information on Petitioners' and BioLab's December 6, 2006 submissions.

On December 15, 2006, Petitioners and BioLab submitted factual information on surrogate value selection. On December 26, 2006, Petitioners submitted comments on Jiheng Chemical's December 15, 2006 rebuttal information. On January 5, 2007, Jiheng Chemical submitted rebuttal information on Petitioners' December 26, 2006 comments. On January 16, 2007, Petitioners submitted rebuttal information on Jiheng Chemical's January 5, 2007 comments.

On October 11, 2006, Jiheng Chemical submitted its sections A, C, and D questionnaire responses (''AQR, CQR and DQR'', respectively). On November 6, 2006, the Department issued a section A supplemental questionnaire to Jiheng Chemical. On November 17, 2006, BioLab submitted comments on Jiheng Chemical's AQR, CQR and DQR. Petitioners submitted comments on Jiheng Chemical's AQR, CQR and DQR on November 20, 2006. On November 28, 2006, Jiheng Chemical submitted rebuttal comments on Petitioners' November 20, 2006, and BioLab's November 17, 2006, comments on its AQR, CQR and DQR. On December 5, 2006, Jiheng Chemical submitted its section A supplemental questionnaire response (''1st SQR''). On January 19, 2007, BioLab submitted comments on Jiheng Chemical's 1st SQR.

[1] *See Notice of Antidumping Duty Order: Chlorinated Isocyanurates From the People's Republic of China*, 70 FR 36561 (June 24, 2005).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review*, 71 FR 32032 (June 2, 2006).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 71 FR 42626 (July 17, 2006).

[4] *See* Memorandum to Ron Lorentzen, Director, Office of Policy, from Wendy Frankel, Director, AD/CVD Operations, Office 8, ''Surrogate-Country Selection: 2004-2006 Administrative Review of the Antidumping Duty Order on Chlorinated Isocyanurates from the People's Republic of China'' (August 16, 2006).

[5] *See* the Memorandum from Ron Lorentzen, Director, Office of Policy, to Wendy Frankel, Director, AD/CVD Operations, Office 8, ''Administrative Review of Chlorinated Isocyanurates from the People's Republic of China: Request for a List of Surrogate Countries'' (August 23, 2006) (''Surrogate Country Memorandum'').

On March 6, 2007, the Department issued a second supplemental questionnaire to Jiheng Chemical. On April 5, 2007, Jiheng Chemical submitted its second supplemental questionnaire response (''2nd SQR''). On April 20, 2007, the Department issued a supplemental questionnaire requesting that Jiheng Chemical provide more information on the desiccant it uses. On April 24 and 25, 2007, respectively, Petitioners and BioLab submitted comments on Jiheng Chemical's 2nd SQR, and requested that the Department conduct verification of Jiheng Chemical.

On April 30, 2007, Jiheng Chemical submitted its supplemental questionnaire response on desiccant. Jiheng Chemical submitted rebuttal comments on May 1, 2007, addressing Petitioners' April 24, 2007 and BioLab's April 25, 2007 comments on its 2nd SQR. On May 8, 2007, the Department issued a third supplemental questionnaire, and on May 17, 2007, the Department issued a fourth supplemental questionnaire. On May 21, 2007, Jiheng Chemical submitted its response to the Department's third supplemental questionnaire (''3rd SQR''), and on June 7, 2007, Jiheng Chemical submitted its response to the Department's fourth supplemental questionnaire (''4th SQR'').

On March 5, 2007, the Department published a notice in the **Federal Register** extending the time limit for the preliminary results of review until May 1, 2007.[6] On May 2, 2007, the Department published a notice in the **Federal Register** further extending the time limit for the preliminary results of review until July 2, 2007.[7]

Scope of the Order

The products covered by this order are chlorinated isocyanurates, as described below:

Chlorinated isocyanurates are derivatives of cyanuric acid, described as chlorinated s–triazine triones. There are three primary chemical compositions of chlorinated isocyanurates: (1) trichloroisocyanuric acid ($Cl_3(NCO)_3$), (2) sodium dichloroisocyanurate (dihydrate) ($NaCl_2(NCO)_3 \bullet 2H_2O$), and (3) sodium dichloroisocyanurate (anhydrous) ($NaCl_2(NCO)_3$). Chlorinated isocyanurates are available in powder, granular, and tableted forms. This order covers all chlorinated isocyanurates.

Chlorinated isocyanurates are currently classifiable under subheadings 2933.69.6015, 2933.69.6021, 2933.69.6050, 3808.40.50, 3808.50.40 and 3808.94.50.00 of the Harmonized Tariff Schedule of the United States (''HTSUS''). The tariff classification 2933.69.6015 covers sodium dichloroisocyanurates (anhydrous and dihydrate forms) and trichloroisocyanuric acid. The tariff classifications 2933.69.6021 and 2933.69.6050 represent basket categories that include chlorinated isocyanurates and other compounds including an unfused triazine ring. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Non–Market Economy Country Status

Jiheng Chemical did not contest the Department's treatment of the PRC as a non–market economy (''NME''), and the Department has treated the PRC as an NME country in all past antidumping duty investigations and administrative reviews and continues to do so in this case.[8] No interested party in this case has argued that we should do otherwise. Designation as an NME country remains in effect until it is revoked by the Department. See Section 771(18)(C)(i) of the Act.

Surrogate Country

Section 773(c)(1) of the Act directs the Department to base NV on the NME producer's FOPs, valued in a surrogate market–economy country or countries considered to be appropriate by the Department. In accordance with section 773(c)(4) of the Act, in valuing the FOPs, the Department shall use, to the extent possible, the prices or costs of the FOPs in one or more market–economy countries that are: (1) at a level of economic development comparable to that of the NME country; and (2) significant producers of comparable merchandise. The sources of the surrogate factor values are discussed under the ''Normal Value'' section below and in the Surrogate Value Memorandum.[9]

The Department has previously determined that India, Indonesia, Sri Lanka, the Philippines, and Egypt are countries comparable to the PRC in terms of economic development. *See* Surrogate Country Memorandum. Customarily, we select an appropriate surrogate country from the Surrogate Country Memorandum based on the availability and reliability of data from the countries that are significant producers of comparable merchandise. In this case, we have found that India is a significant producer of comparable merchandise.[10]

The Department used India as the primary surrogate country and accordingly, has calculated NV using Indian prices to value the PRC producers' FOPs, when available and appropriate. *See* Surrogate Country Selection Memorandum and Surrogate Value Memorandum. We have obtained and relied upon publicly available information wherever possible.

In accordance with 19 CFR 351.301(c)(3)(ii), for the final results in an antidumping administrative review, interested parties may submit publicly available information to value factors of production within 20 days after the date of publication of the preliminary results of review.

Separate Rates

In proceedings involving NME countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control, and thus, should be assigned a single antidumping duty deposit rate. It is the Department's policy to assign all exporters of subject merchandise subject to review in an NME country a single rate unless an exporter can demonstrate that it is sufficiently independent of government control to be entitled to a separate rate.[11] We have considered

[6] *See Chlorinated Isocyanurates from the People's Republic of China: Extension of Time limit for Preliminary Results of Antidumping Duty Administration Review*, 72 FR 9729 (March 5, 2007).

[7] *See Chlorinated Isocyanurates from the People's Republic of China: Extension of Time limit for Preliminary Results of Antidumping Duty Administration Review*, 72 FR 24272 (May 2, 2007).

[8] *See, e.g., Certain Cased Pencils from the Peoples Republic of China: Final Results of Antidumping Duty Administrative Review*, 72 FR 27074 (May 14, 2007); and *Carbazole Violet Pigment 23 from the People's Republic of China: Final Results of Antidumping Duty Administrative Review*, 72 FR 26589 (May 10, 2007).

[9] *See* Memorandum from Katharine Huang, International Trade Compliance Analyst, through Charles Riggle, Program Manager, to Wendy Frankel, Director, AD/CVD Operations, Office 8, ''Preliminary Results of the 2004-2006 Administrative Review of Chlorinated Isocyanurates from the People's Republic of China: Surrogate Value Memorandum'' (July 2, 2007) (''Surrogate Value Memorandum'').

[10] *See* Memorandum from Katharine Huang, International Trade Compliance Analyst, through Charles Riggle, Program Manager, to Wendy Frankel, Director, AD/CVD Operations, Office 8, ''Antidumping Administrative Review of Chlorinated Isocyanurates: Selection of a Surrogate Country,'' (July 2, 2007) (''Surrogate Country Selection Memorandum'').

[11] *See, e.g., Certain Cased Pencils from the People's Republic of China; Preliminary Results of Antidumping Duty Administrative Review*, 71 FR 70949, 71 FR 70952 (December 7, 2006) (unchanged in the final results); *Carbazole Violet Pigment 23 From the People's Republic of China; Preliminary Results of Antidumping Duty Administrative Review and Rescission in Part*, 71 FR 65073, 65074 (November 7, 2006) (unchanged in the final results).

whether the reviewed company based in the PRC is eligible for a separate rate.

The Department's separate–rate test to determine whether the exporters are independent from government control does not consider, in general, macroeconomic/border–type controls, *e.g.*, export licenses, quotas, and minimum export prices, particularly if these controls are imposed to prevent dumping. The test focuses, rather, on controls over the investment, pricing, and output decision–making process at the individual firm level.[12]

To establish whether an exporter is sufficiently independent of government control to be entitled to a separate rate, the Department analyzes the exporter in light of select criteria, discussed below.[13] Under this test, exporters in NME countries are entitled to separate, company–specific margins when they can demonstrate an absence of government control over exports, both in law (''*de jure*'') and in fact (''*de facto*'').

Jiheng Chemical provided company–specific separate–rate information. Jiheng Chemical reported that it is owned by all the people of the PRC. *See* Jiheng Chemical's AQR at A–4. Therefore, a separate–rates analysis is necessary to determine whether its export activities are independent from government control.

A. Absence of De Jure Control

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (1) an absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; or (3) any other formal measures by the government decentralizing control of companies. *See Sparklers*, 56 FR 20588 at Comment 1.

Jiheng Chemical has placed documents on the record to demonstrate the absence of *de jure* control, including its list of shareholders, business license, and the Company Law of the People's Republic of China, as revised October 27, 2005 (''Company Law''). Other than limiting Jiheng Chemical to activities referenced in the business license, we found no restrictive stipulations associated with the license. In addition, in previous cases, the Department has analyzed the Company Law and found that it establishes an absence of *de jure* control.[14] We have no information in this segment of the proceeding that would cause us to reconsider this determination. Therefore, based on the foregoing, we have preliminarily found an absence of *de jure* control for Jiheng Chemical.

B. Absence of De Facto Control

As stated in previous cases, there is some evidence that certain enactments of the PRC central government have not been implemented uniformly among different sectors and/or jurisdictions in the PRC.[15] Therefore, the Department has preliminarily determined that an analysis of *de facto* control is critical in determining whether Jiheng Chemical is, in fact, subject to a degree of government control that would preclude the Department from assigning separate rates. The Department typically considers four factors in evaluating whether each respondent is subject to de facto government control of its export functions: (1) whether the exporter sets its own export prices independent of the government and without the approval of a government authority; (2) whether the respondent has authority to negotiate and sign contracts, and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of its management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses.[16]

With regard to *de facto* control, Jiheng Chemical reported that: (1) it independently set prices to the United States through direct arm's–length negotiations with its customers and these prices are not subject to review by any government organization; (2) Jiheng Chemical did not coordinate with other exporters or producers to set the price or to determine to which market the companies will sell subject merchandise; (3) Jiheng Chemical is a member of the China Chamber of Commerce of Metals Minerals & Chemicals Importers & Exporters, which is a non–governmental association, and does not interfere with the export activities of Jiheng Chemical; (4) Jiheng Chemical's authorized sales representatives have the authority to contractually bind it to sell subject merchandise; (5) in accordance with the Article of Association, its board of directors designated the general manager; (6) there is no restriction on its use of export revenues; (7) its shareholders ultimately determine the disposition of respective profits, and Jiheng Chemical has not had a loss in the last two years. Our analysis of Jiheng Chemical's questionnaire responses reveals no other information indicating government control of its export activities. Therefore, based on the information on the record, we preliminarily determine that there is an absence of *de facto* government control with respect to Jiheng Chemical's export functions and that Jiheng Chemical has met the criteria for the application of a separate rate.

Date of Sale

Section 351.401(i) of the Department's regulations states that:

> in identifying the date of sale of the subject merchandise or foreign like product, the Secretary normally will use the date of invoice, as recorded in the exporter or producer's records kept in the normal course of business. However, the Secretary may use a date other than the date of invoice if the Secretary is satisfied that a different date better reflects the date on which the exporter or producer establishes the material terms of sale.

Jiheng Chemical reported the shipment date as the date of sale because it claims that, for its U.S. sales of subject merchandise made during the POR, the material terms of sale were established on the shipment date and its shipment date was on or before the invoice date. We have preliminarily determined that the shipment date is the most appropriate date to use as Jiheng Chemical's date of sale in accordance with our long–standing practice of determining as the date of sale the date on which the final terms of sale are established.[17]

[12] *See Certain Cut-to-Length Carbon Steel Plate from Ukraine: Final Determination of Sales at Less than Fair Value*, 62 FR 61754, 61757 (November 19, 1997); and *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China: Final Results of Antidumping Duty Administrative Review*, 62 FR 61276, 61279 (November 17, 1997).

[13] *See Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China*, 56 FR 20585, 22587 (May 6, 1991) (''*Sparklers*''); and *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide From the People's Republic of China*, 59 FR 22585 (May 2, 1994).

[14] *See, e.g., Certain Non-Frozen Apple Juice Concentrate from the People's Republic of China: Final Results, Partial Recision and Termination of a Partial Deferral of the 2002-2003 Administrative Review*, 69 FR 65148, 65150 (November 10, 2004).

[15] *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Certain Preserved Mushrooms from the People's Republic of China*, 63 FR 72255, 72257 (December 31, 1998).

[16] *See, e.g., Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol From the People's Republic of China*, 60 FR 22544, 22545 (May 8, 1995).

[17] *Notice of Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances: Certain Frozen and*

Continued

Normal Value Comparisons

To determine whether sales of chlorinated isos to the United States by Jiheng Chemical were made at less than NV, we compared export price (''EP'') to NV, as described in the ''Export Price,'' and ''Normal Value'' sections of this notice, pursuant to section 771(35) of the Act.

Export Price

Petitioners and BioLab requested that the Department determine that Jiheng Chemical is affiliated with one of its U.S. customers and, accordingly, base U.S. price on constructed–export-price (''CEP'') rather than EP. Our analysis of Jiheng Chemical's questionnaire responses reveals no information to support a finding that Jiheng Chemical is affiliated with its U.S. customer.[18] Because Jiheng Chemical sold the subject merchandise to unaffiliated purchasers in the United States prior to importation into the United States and the use of the CEP methodology is not otherwise indicated, we have used EP in accordance with section 772(a) of the Act.

We calculated EP based on the delivered price to unaffiliated purchasers for Jiheng Chemical. From this price, we deducted amounts for foreign inland freight, brokerage and handling and marine insurance, where applicable, pursuant to section 772(c)(2)(A) of the Act.[19]

The Department used two sources to calculate a surrogate value for domestic brokerage expenses. The Department averaged the December 2003–November 2004 data contained in Essar Steel's February 28, 2005 public version response submitted in the antidumping duty administrative review of hot–rolled carbon steel flat products from India.[20] These data were averaged with the February 2004–January 2005 data contained in Agro Dutch Industries Limited's (''Agro Dutch'') May 24, 2005, public version response submitted in the administrative review of the antidumping duty order on certain preserved mushrooms from India.[21] The brokerage–expense data reported by Essar Steel and Agro Dutch in the public versions of their respective responses are ranged data. The Department first derived an average per–unit amount from each data source. We then separately adjusted each average rate for inflation. Finally, we averaged the two per–unit amounts to derive an overall average rate for the POR. *See* Surrogate Value Memorandum at 9 and Attachment XXII.

To value truck freight, we used the freight rates published by Indian Freight Exchange, available at http://www.infreight.com. The truck freight rates are contemporaneous with the POR; therefore, we made no adjustments for inflation.

Jiheng Chemical reported that its U.S. customer(s) provided it with certain raw materials and packing materials free of charge. For Jiheng Chemical's products that contained inputs provided free of charge by its customer,[22] consistent with the Department's practice, we added to the U.S. price paid by the Jiheng Chemical's customer the built–up cost (*i.e.*, the surrogate value for these raw materials and packing materials multiplied by the reported FOPs for these items).[23]

Normal Value

Section 773(c)(1) of the Act provides that, in the case of an NME, the Department shall determine NV using an FOP methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home–market prices, third–country prices, or constructed value under section 773(a) of the Act.

The Department will base NV on FOP because the presence of government controls on various aspects of these economies renders price comparisons and the calculation of production costs invalid under our normal methodologies. Therefore, we calculated NV based on FOP in accordance with sections 773(c)(3) and (4) of the Act and 19 CFR 351.408(c). The FOPs include: (1) hours of labor required; (2) quantities of raw materials employed; (3) amounts of energy and other utilities consumed; and (4) representative capital costs. We used the FOPs reported by respondents for materials, energy, labor, by–products, and packing.

In accordance with 19 CFR 351.408(c)(1), the Department will normally use publicly available information to value the FOPs, but when a producer sources an input from a market–economy country and pays for it in market–economy currency, the Department may value the factor using the actual price paid for the input.[24] Jiheng Chemical reported that it did not purchase any inputs from market economy suppliers for the production of the subject merchandise. *See* Jiheng Chemical's DQR at D–8.

With regard to both the Indian import–based surrogate values and the market–economy input values, we have disregarded prices that we have reason to believe or suspect may be subsidized. We have reason to believe or suspect that prices of inputs from India, Indonesia, South Korea, and Thailand may have been subsidized. We have found in other proceedings that these countries maintain broadly available, non–industry-specific export subsidies and, therefore, it is reasonable to infer that all exports to all markets from these countries may be subsidized.[25] We are also guided by the statute's legislative history that explains that it is not

Canned Warmwater Shrimp from Thailand, 69 FR 76918 (December 23, 2004), and accompanying Issues and Decision Memorandum at Comment 10; and *Notice of Final Determination of Sales at Less Than Fair Value: Structural Steel Beams from Germany*, 67 FR 35497 (May 20, 2002), and accompanying Issues and Decision Memorandum at Comment 2.

[18] *See* the Memorandum from Katharine Huang, International Trade Compliance Analyst, through Charles Riggle, Program Manager, to Wendy Frankel, Director, AD/CVD Operations, Office 8, ''Preliminary Results of the 2004-2006 Administrative Review of Chlorinated Isocyanurates from the People's Republic of China: Memorandum on Affiliation Issue between Jiheng Chemical and its US Customer'' (July 2, 2007).

[19] *See* Memorandum to the File from Katharine Huang, International Trade Compliance Analyst, through Charles Riggle, Program Manager, AD/CVD Operations, Office 8, ''Analysis for the Preliminary Results of the 2004-2006 Administrative Review of Chlorinated Isocyanurates from the People's Republic of China: Hebei Jiheng Chemical Company Ltd. (July 2, 2007).

[20] *See Certain Hot-Rolled Carbon Steel Flat Products From India: Notice of Preliminary Results of Antidumping Duty Administrative Review*, 71 FR 2018 (January 12, 2006).

[21] *See Certain Preserved Mushrooms From India: Final Results of Antidumping Duty Administrative Review*, 70 FR 37757 (June 30, 2005); and *Notice of Preliminary Determination of Sales at Less Than Fair Value, Affirmative Critical Circumstances, In Part, and Postponement of Final Determination: Certain Lined Paper Products from the People's Republic of China*, 71 FR 19695, 19704 (April 17, 2006) (which utilized these same data and was unchanged for the final determination).

[22] Jiheng Chemical stated that its customer sourced materials from both market-economy and non-market-economy suppliers. Jiheng Chemical further stated that it does not know the names of the market-economy suppliers. See Jiheng Chemical's October 11, 2006 section D response at D-6 - D-7.

[23] *See e.g., Notice of Final Determination of sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products from the People's Republic of China*, 71 FR 53079 (September 8, 2006), and the accompanying Issues and Decision Memorandum at Comment 17.

[24] *See* 19 CFR 351.408(c)(1); *see also, Lasko Metal Products v. United States*, 43 F.3d 1442, 1445-1446 (Fed. Cir. 1994) (affirming the Department's use of market-based prices to value certain FOPs).

[25] *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Notice of Preliminary Results and Preliminary Partial Rescission of Antidumping Duty Administrative Review*, 70 FR 54007, 54011 (September 13, 2005) (unchanged in the final results); *Automotive Replacement Glass Windshields From the People's Republic of China: Final Results of Administrative Review*, 69 FR 61790 (October 21, 2004) and accompanying Issues and Decision Memorandum at Comment 5; and *China National Machinery Import & Export Corporation v. United States*, 293 F. Supp. 2d 1334 (CIT 2003), as affirmed by the Federal Circuit, 104 Fed. Appx. 183 (Fed. Cir. 2004).

necessary to conduct a formal investigation to ensure that such prices are not subsidized. *See* H.R. Rep. 100–576 at 590 (1988). Rather, the Department was instructed by Congress to base its decision on information that is available to it at the time it is making its determination. Therefore, we have not used prices from these countries in calculating the Indian import–based surrogate values.

Factor Valuations

In accordance with section 773(c) of the Act, we calculated NV based on the FOPs reported by Jiheng Chemical for the POR. To calculate NV, we multiplied the reported per–unit factor quantities by publicly available Indian surrogate values (except as noted below). In selecting the surrogate values, we considered the quality, specificity, and contemporaneity of the data. As appropriate, we adjusted input prices by including freight costs to render them delivered prices. Specifically, we added to Indian import surrogate values a surrogate freight cost using the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory. This adjustment is in accordance with the decision of the Federal Circuit in *Sigma Corp. v. United States*, 117 F. 3d 1401, 1408 (Fed. Cir. 1997). For a detailed description of all surrogate values used for Jiheng Chemical, see the Surrogate Value Memorandum.

Except as noted below, we valued raw material inputs using the weighted–average unit import values derived from the Monthly Statistics of the Foreign Trade of India, as published by the Directorate General of Commercial Intelligence and Statistics of the Ministry of Commerce and Industry, Government of India in the World Trade Atlas, available at http://www.gtis.com/wta.htm (''WTA''). Where we could not obtain publicly available information contemporaneous with the POR with which to value FOPs, we adjusted the SVs using, where appropriate, the Indian Wholesale Price Index (''WPI'') as published in the International Financial Statistics of the International Monetary Fund. *See* Surrogate Value Memorandum at 2 and Attachments II and III. We further adjusted these prices to account for freight costs incurred between the supplier and respondent. We used the freight rates published by Indian Freight Exchange available at http://www.infreight.com, to value truck freight. *See* the Surrogate Value Memorandum at 9 and Attachment XX. The truck and rail freight rates are contemporaneous with the POR. Therefore, we made no adjustments for inflation. For a complete description of the factor values we used, see the Surrogate Value Memorandum.

We valued hydrochloric acid, barium chloride and sulfuric acid using *Chemical Weekly* because we did not have reliable Indian import statistics in the WTA for these factors. We adjusted these values for taxes and to account for freight costs incurred between the supplier and Jiheng Chemical.

Jiheng Chemical reported that its U.S. customer(s) provided certain raw materials and packing materials free of charge. For Jiheng Chemical's products that included raw materials and packing materials provided free of charge by its customer, consistent with the Department's practice, we used the built–up cost (*i.e.*, the surrogate value for these raw materials and packing materials multiplied by the reported FOPs for these items) in the NV calculation.[26] Where applicable, we also adjusted these values to account for freight costs incurred between the port of exit and Jiheng Chemical's plants. *See* Surrogate Value Memorandum at 9, and Jiheng Chemical Preliminary Analysis Memorandum.

To value electricity, we used the 2000 electricity price data from International Energy Agency, Energy Prices and Taxes - Quarterly Statistics (First Quarter 2003), adjusted for inflation. *See* Surrogate Value Memorandum at 7 and Attachment XVI.

To value water, we used the revised Maharashtra Industrial Development Corporation (''MIDC'') water rates for June 1, 2003 for the Mumbai region, available at http://www.midcindia.com/water–supply, adjusted for inflation. *See* Surrogate Value Memorandum at 4 - 5 and Attachment XI.

For direct labor, indirect labor and packing labor, consistent with 19 CFR 351.408(c)(3), we used the PRC regression–based wage rate as reported on Import Administration's web site.[27] Because this regression–based wage rate does not separate the labor rates into different skill levels or types of labor, we have applied the same wage rate to all skill levels and types of labor reported by each respondent. *See* Surrogate Value Memorandum at 8.

For factory overhead, selling, general, and administrative expenses (''SG&A''), and profit values, we used information from Kanoria Chemicals and Industries Limited, and DCM Sriram Consolidated Ltd. for the year ending March 31, 2006. From this information, we were able to determine factory overhead as a percentage of the total raw materials, labor and energy (''ML&E'') costs; SG&A as a percentage of ML&E plus overhead (*i.e.*, cost of manufacture); and the profit rate as a percentage of the cost of manufacture plus SG&A. *See* Surrogate Value Memorandum at 8–9 and Attachment XIX for a full discussion of the calculation of these ratios.

For packing materials, we used the per–kilogram values obtained from the WTA and made adjustments to account for freight costs incurred between the PRC supplier and Jiheng Chemical's plant. *See* Surrogate Value Memorandum at Attachment VI.

Currency Conversion

We made currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales, as certified by the Federal Reserve Bank.

Preliminary Results of Review

We preliminarily determine that the following weighted–average dumping margin exists:

Manufacturer/Exporter	Margin (Percent)
Jiheng Chemical	6.75

Disclosure

We will disclose the calculations used in our analysis to parties to this proceeding within five days of the publication date of this notice. *See* 19 CFR 351.224(b). Interested parties are invited to comment on the preliminary results and may submit case briefs and/or written comments within 30 days of the date of publication of this notice. *See* 19 CFR 351.309(c)(ii). Any interested party may request a hearing within 30 days of publication of this notice. See 19 CFR 351.310(c). Any hearing, if requested, will be held 42 days after the date of publication of this notice. *See* 19 CFR 351.310(d). Rebuttal briefs and rebuttals to written comments, limited to issues raised in such briefs or comments, may be filed no later than 35 days after the date of publication. *See* 19 CFR 351.309(d). The Department requests that parties

[26] *See e.g., Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products from the People's Republic of China*, 71 FR 53079 (September 8, 2006), and the accompanying Issues and Decision Memorandum at Comment 17.

[27] *See* Expected Wages of Selected NME Countries (revised November 2005) (available at http://ia.ita.doc.gov/wages). The source of these wage rate data on the Import Administration's web site is the *Yearbook of Labour Statistics 2003*, ILO, (Geneva: 2003), Chapter 5B: Wages in Manufacturing. The years of the reported wage rates range from 1998 to 2003.

submitting written comments also provide the Department with an additional copy of those comments on diskette. The Department will issue the final results of this administrative review, which will include the results of its analysis of issues raised in any such comments, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries. The Department intends to issue appropriate assessment instructions directly to CBP 15 days after the date of publication of the final results of this administrative review. If these preliminary results are adopted in our final results of review, we will direct CBP to assess the resulting per–unit value or *ad valorum* rate against the entered customs value for the subject merchandise on each importer's/customer's entries during the POR.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) for Jiheng Chemical, which has a separate rate, the cash deposit rate will be the company–specific rate established in the final results of review (except, if the rate is zero or *de minimis*, no cash deposit will be required); (2) for previously investigated or reviewed PRC and non–PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter–specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC–wide rate of 285.63 percent; and (4) for all non–PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non–PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 2, 2007.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E7–13801 Filed 7–16–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–805]

Notice of Rescission of Antidumping Duty New Shipper Review: Certain Circular Welded Non–Alloy Steel Pipe from Mexico

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On April 20, 2007, the Department of Commerce (''the Department'') published the preliminary intent to rescind the antidumping duty new shipper review of the antidumping duty order on certain circular welded non–alloy steel pipe from Mexico. *See Certain Circular Welded Non–Alloy Steel Pipe and Tube from Mexico: Preliminary Intent to Rescind Antidumping Duty New Shipper Review*, 72 FR 19880 (April 20, 2007) (*Intent to Rescind*). This new shipper review covers Conduit S.A. de C.V. (''Conduit''), a manufacturer and exporter of the subject merchandise. The period of review (''POR'') is November 1, 2005, through April 30, 2006. We did not receive any comments from parties, and are rescinding this new shipper review.

EFFECTIVE DATE: July 17, 2007.

FOR FURTHER INFORMATION CONTACT: John Drury or Patrick Edwards, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230, telephone (202) 482–0195 or (202) 482–8029, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 2, 1992, the Department published the antidumping duty order on circular welded non–alloy steel pipe from Mexico. *See Notice of Antidumping Duty Order: Certain Circular Welded non–Alloy Steel Pipe from Brazil, the Republic of Korea (Korea), Mexico, and Venezuela, and Amendment to Final Determination of Sales at Less Than Fair Value: Certain Circular Welded Non–Alloy Steel Pipe from Korea*, 57 FR 49453 (November 2, 1992). On May 26, 2006, we received a request for a new shipper review from Conduit for the period November 1, 2005, through April 30, 2006. We initiated the review on July 10, 2006. *See Circular Welded Non–Alloy Steel Pipe and Tube from Mexico: Initiation of New Shipper Antidumping Duty Review*, 71 FR 38851 (July 10, 2006).

On April 20, 2007, the Department published in the **Federal Register** its preliminary intent to rescind the antidumping duty new shipper review of certain circular welded non–alloy steel pipe from Mexico for the period November 1, 2005, through April 30, 2006. *See Intent to Rescind*. No party commented on our preliminary intent to rescind the new shipper review for Conduit.

Scope of the Order

The merchandise under review is circular welded non–alloy steel pipes and tubes, of circular cross-section, not more than 406.4 millimeters (16 inches) in outside diameter, regardless of wall thickness, surface finish (black, galvanized, or painted), or end finish (plain end, beveled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipes and tubes and are intended for the low–pressure conveyance of water, steam, natural gas, and other liquids and gases in plumbing and heating systems, air conditioning units, automatic sprinkler systems, and other related uses, and generally meet ASTM A–53 specifications. Standard pipe may also be used for light load–bearing applications, such as for fence tubing, and as structural pipe tubing used for framing and support members for reconstruction or load–bearing purposes in the construction, shipbuilding, trucking, farm equipment, and related industries. Unfinished conduit pipe is also included in these orders. All carbon steel pipes and tubes within the physical description outlined above are included within the scope of these orders, except line pipe, oil country tubular goods, boiler tubing, mechanical tubing, pipe and tube hollows for

redraws, finished scaffolding, and finished conduit. Standard pipe that is dual or triple certified/stenciled that enters the U.S. as line pipe of a kind used for oil or gas pipelines is also not included in these orders.

Imports of the products covered by these orders are currently classifiable under the following Harmonized Tariff Schedule (HTS) subheadings: 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, and 7306.30.50.90. Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of these proceedings is dispositive.

Rescission of Review

The Department may rescind a new shipper review with respect to an exporter or producer if the Department concludes that there were no entries, exports, or sales of the subject merchandise to the United States during the period of review. *See* 19 CFR § 351.214(f)(2). The Department has previously detailed its findings at verification with respect to the merchandise sold by Conduit subject to this new shipper review. *See Intent to Rescind* at 19881. As noted above, the Department received no comments from interested parties. Therefore, based on the findings at verification, the Department determines that the merchandise sold by Conduit, and subject to this new shipper review, is not within the scope of the order of certain circular welded non–alloy steel pipe from Mexico. As a result, the Department is rescinding this new shipper review.

Notification

The Department will notify U.S. Customs and Border Protection that bonding is no longer permitted to fulfill security requirements for shipments by Conduit of certain circular welded non–alloy steel pipe from Mexico entered, or withdrawn from warehouse, for consumption in the United States on or after the publication of this rescission notice in the **Federal Register**, and that a cash deposit of 32.62 percent *ad valorem* should be collected for any entries exported by Conduit.

This notice also serves as the only reminder to parties subject to administrative protective orders (''APO'') of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR § 351.305(a)(3). Timely written notification of the return/destruction of APO material or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation that is subject to sanctions.

This notice is issued and published in accordance with sections 751(a)(2) and 777(i)(1) of the Tariff Act of 1930, as amended.

Dated: July 10, 2007.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E7–13834 Filed 7–16–02; 8:45 am]

Billing Code: 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

A–428–830

Stainless Steel Bar from Germany: Final Results of New Shipper Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: This new shipper review covers stainless steel bar from Germany manufactured by Schmiedewerke Groditz GmbH (''SWG''). The Department of Commerce (''the Department'') published the preliminary results of this new shipper review on March 19, 2007. *See Stainless Steel Bar from Germany: Preliminary Results of New Shipper Review*, 72 FR 12765 (March 19, 2007) (''*Preliminary Results*''). Based on our analysis of the comments received, these final results do not differ from the *Preliminary Results*.

EFFECTIVE DATE: July 17, 2007.

FOR FURTHER INFORMATION CONTACT: Damian Felton, Audrey R. Twyman, or Brandon Farlander, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington DC 20230; telephone (202) 482–0133, (202) 482–3534, or (202) 482–0182, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 19, 2007, the Department published its *Preliminary Results* of this antidumping duty new shipper review of stainless steel bar from Germany. The Department conducted a verification of SWG's response from April 16 through 18, 2007, and issued the report on the verification findings for SWG on May 18, 2007. In response to the Department's invitation to comment on the *Preliminary Results*, petitioners[1] submitted their case brief on May 29, 2007, and SWG submitted its rebuttal brief on June 1, 2007.

Period of Review

The period of review (''POR'') covers March 1, 2005, through February 28, 2006.

Scope of the Order

For the purposes of this order, the term ''stainless steel bar'' includes articles of stainless steel in straight lengths that have been either hot–rolled, forged, turned, cold–drawn, cold–rolled or otherwise cold–finished, or ground, having a uniform solid cross section along their whole length in the shape of circles, segments of circles, ovals, rectangles (including squares), triangles, hexagons, octagons, or other convex polygons. Stainless steel bar (''SSB'') includes cold–finished stainless steel bars that are turned or ground in straight lengths, whether produced from hot–rolled bar or from straightened and cut rod or wire, and reinforcing bars that have indentations, ribs, grooves, or other deformations produced during the rolling process.

Except as specified above, the term does not include stainless steel semi–finished products, cut length flat–rolled products (*i.e.*, cut length rolled products which if less than 4.75 mm in thickness have a width measuring at least 10 times the thickness, or if 4.75 mm or more in thickness having a width which exceeds 150 mm and measures at least twice the thickness), products that have been cut from stainless steel sheet, strip or plate, wire (*i.e.*, cold–formed products in coils, of any uniform solid cross section along their whole length, which do not conform to the definition of flat–rolled products), and angles, shapes and sections.

The SSB subject to this order is currently classifiable under subheadings 7222.11.00.05, 7222.11.00.50, 7222.19.00.05, 7222.19.00.50, 7222.20.00.05, 7222.20.00.45, 7222.20.00.75, and 7222.30.00.00 of the *Harmonized Tariff Schedule of the United States* (''HTSUS''). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this new shipper review are addressed in the

[1] The petitioners are Carpenter Technology Corporation, Valbruna Slater Stainless, Inc., and Electralloy Corporation (collectively, ''petitioners'').

Issues and Decision Memorandum from Stephen J. Claeys, Deputy Assistant Secretary for Import Administration, to David M. Spooner, Assistant Secretary for Import Administration (''Decision Memorandum''). A list of issues addressed in the Decision Memorandum is appended to this notice. The Decision Memorandum is on file in the Central Records Unit in Room B–099 of the main Commerce building, and can also be accessed directly on the Web at *http://ia.ita.doc.gov/frn/index.html*. The paper copy and electronic version of the Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of comments received, we have made no changes to our *Preliminary Results*.

Final Results of Review

As a result of our review, we determine that the following weighted–average margin exists for SWG for the period of March 1, 2005, through February 28, 2006:

Producer	Weighted–Average Margin (Percentage)
Schmiedewerke Groditz GmbH ..	0.00

Assessment Rates

The Department shall determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries. Pursuant to 19 CFR 351.212(b)(1), for the U.S. sale made by the respondent for which it has reported the importer of record and entered value, we have calculated an importer–specific assessment rate based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the U.S. sale.

The Department clarified its ''automatic assessment'' regulation on May 6, 2003 (68 FR 23954). This clarification will apply to entries of subject merchandise during the period of review produced by reviewed companies for which these companies did not know their merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all–others rate if there is no rate for the intermediate company(ies) involved in the transaction. For a full discussion of this clarification, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

The Department will issue appropriate assessment instructions directly to CBP 15 days after the date of publication of these final results of the new shipper review.

Cash Deposit Requirements

The following cash deposit rate will be effective upon publication of the final results of this new shipper review for shipments of stainless steel bar from Germany entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Tariff Act of 1930, as amended (''the Act''). For subject merchandise produced and exported by SWG, the cash deposit rate will be the rate established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, de minimis, the cash deposit rate will be zero. This cash deposit requirement, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective orders (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation, which is subject to sanction.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 10, 2007.

David M. Spooner,

Assistant Secretary for Import Administration.

Appendix

I. *Bona Fide* Nature of U.S. Sale

Comment 1: Quantity, Pricing and Terms of Sale Differences

Comment 2: Principal/Agent Relationship

Comment 3: Mill Certificates

Comment 4: Communication with U.S. Customer

II. Home Market Date of Sale

Comment 5: Home Market Date of Sale

[FR Doc. E7–13803 Filed 7–16–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

Virginia Polytechnic Institute and State University, et al., Notice of Consolidated Decision on Applications, for Duty–Free Entry of Electron Microscopes

This is a decision consolidated pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651,as amended by Pub. L. 106–36, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 2104, U.S. Department of Commerce, 14th and Constitution Avenue.,NW, Washington, D.C.

Docket Number: 07–026. Applicant: Virginia Polytechnic Institute and State University, Blacksburg, VA. Instrument: Electron Microscope, Model Helios 600 Nanolab. Manufacturer: FEI Company, The Netherlands. Intended Use: See notice at 72 FR 31287, June 6, 2007.

Docket Number: 07–032. Applicant: University of Missouri–Columbia, Columbia, MO. Instrument: Electron Microscope, Model Quanta 600 FEG. Manufacturer: FEI Company, Czech Republic. Intended Use: See notice at 72 FR 31287, June 6, 2007.

Comments: None received. Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as these instruments are intended to be used, was being manufactured in the United States at the time the instruments were ordered. Reasons: Each foreign instrument is an electron microscope and is intended for research or scientific educational uses requiring an electron microscope. We know of no electron microscope, or any other instrument suited to these purposes, which was being manufactured in the United States at the time of order of each instrument.

Dated: July 11, 2007.

Faye Robinson,

Director, Statutory Import Programs Staff,Import Administration.

[FR Doc. E7–13806 Filed 7–16–07; 8:45 am]

Billing Code: 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

ENVIRONMENTAL PROTECTION AGENCY

Coastal Nonpoint Pollution Control Program: Approval Decision on Guan Coastal Nonpoint Pollution Control Program

AGENCY: National Oceanic and Atmospheric Administration, U.S. Department of Commerce, and the U.S. Environmental Protection Agency.

ACTION: Notice of Intent to Approve the Guam Coastal Nonpoint Program.

SUMMARY: Notice is hereby given of the intent to fully approve the Guam Coastal Nonpoint Pollution Control Program (coastal nonpoint program) and of the availability of the draft Approval Decisions on conditions for the Guam coastal nonpoint program. Section 6217 of the Coastal Zone Act Reauthorization Amendments (CZARA), 16 U.S.C. section 1455b, requires States and Territories with coastal zone management programs that have received approval under section 306 of the Coastal Zone Management Act to develop and implement coastal nonpoint programs. Coastal States and Territories were required to submit their coastal nonpoint programs to the National Oceanic and Atmospheric Administration (NOAA) and the U.S. Environmental Protection Agency (EPA) for approval in July 1995. NOAA and EPA conditionally approved the Guan coastal nonpoint program on October 3, 1997. NOAA and EPA have drafted approval decisions describing how Guam has satisfied the conditions placed on its program and therefore has a fully approved coastal nonpoint program.

NOAA and EPA are making the draft decisions for the Guam coastal nonpoint program available for a 30-day public comment period. If comments are received, NOAA and EPA will consider whether such comments are significant enough to affect the decision to fully approve the program.

Copies of the draft Approval Decisions can be found on the NOAA Web site at *http://coastalmanagement.noaa.gov/czm/6217/findings.html* or be obtained upon request from: Allison Castellan, Coastal Programs Division (N/ORM3), Office of Ocean and Coastal Resource Management, NOS, NOAA, 1305 East-West Highway, Silver Spring, Maryland 20910, phone (301) 713–3155, x125, e-mail *Allison.Castellan@noaa.gov.*

DATES: Individuals or organizations wishing to submit comments on the draft Approval Decisions should do so by August 16, 2007.

ADDRESSES: Comments should be made to: John King, Chief, Coastal Programs Division (N/ORM3), Office of Ocean and Coastal Resource Management, NOS, NOAA, 1305 East-West Highway, Silver Spring, Maryland 20910, phone (301) 713–3155, x188, e-mail *John.King@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Allison Castellan, Coastal Programs Division, (N/ORM3), Office of Ocean and Coastal Resource Management, NOS, NOAA, 1305 East-West Highway, Silver Spring, Maryland 20910, phone (301) 713–3155, x125, e-mail *Allison.Castellan@noaa.gov.*

(Federal Domestic Assistance Catalog 11.419 Coastal Zone Management Program Administration)

Dated: July 5, 2007.

John H. Dunnigan,

Assistant Administrator for Ocean Services and Coastal Zone Management, National Oceanic and Atmospheric Administration.

Benjamin H. Grumbles,

Assistant Administrator, Office of Water, Environmental Protection Agency.

[FR Doc. 07–3465 Filed 7–16–07; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[XRIN: 0648–XB44]

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council will hold a meeting of its Information and Education Advisory Panel, in North Charleston, SC.

DATES: The meeting will take place August 29–30, 2007. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meeting will be held at the Hilton Garden Inn Charleston Airport, 5265 International Boulevard, North Charleston, SC; telephone: (843) 308–9331 or toll free (800) 445–8667.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer; telephone: (843) 571–4366 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: Members of the Information and Education Advisory Panel will meet from 1:30 p.m. to 5 p.m. on August 29, 2007, and from 8:30 a.m. to 5 p.m. on August 30, 2007.

Agenda items for the meeting include, but are not limited to: (1) Review and update of current outreach efforts used by the South Atlantic Fishery Management Council, including web site, news releases, quarterly newsletters and other publications; (2) discussion and recommendations for outreach efforts, including partnerships, for deepwater marine protected areas proposed for the South Atlantic region; and (3) review and provide recommendations for NOAA Fisheries' FishWatch Seafood Consumer Education Program.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Dated: July 11, 2007.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E7–13733 Filed 7–16–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF DEFENSE

Department of the Army

Draft Legislative Environmental Impact Statement (LEIS) for the Limestone Hills Training Area Land Withdrawal, Montana Army National Guard (MTARNG)

AGENCY: National Guard Bureau (NGB), Department of the Army (DA), DoD.

ACTION: Notice of Availability.

SUMMARY: This LEIS has been prepared by NGB (lead agency) and the Department of the Interior's (DOIs) Bureau of Land Management (BLM) (cooperating agency). The LEIS analyzes the proposed withdrawal of 18,644 acres of federal land within the Limestone Hills Training Area (LHTA) from BLM administration. The LEIS proposes that the DOI and Congress transfer administrative responsibility of all federal land within the LHTA to the Army for military training use by the MTARNG. No new facilities are proposed in this LEIS.

DATES: The public comment period for the Draft LEIS will end 90 days after publication of an NOA in the **Federal Register** by the U.S. Environmental Protection Agency.

ADDRESSES: Written comments or questions should be forwarded by mail to Ms. Sundi West, MTARNG, Fort Harrison, P.O. Box 4789, Helena, Montana 59604–4789; via telephone at (406) 324–3088, or via e-mail at *Sundi.West@us.army.mil.*

FOR FURTHER INFORMATION CONTACT: Ms. Mary L. Figarelle, BLM, 106 North Parkmont, Butte, Montana 59701; via telephone at (406) 533-7671; or via e-mail at *Mary_Figarelle@blm.gov*.

SUPPLEMENTARY INFORMATION: The objective of the LEIS is to provide comprehensive analysis of the proposed action and alternatives to the Secretaries of Interior and Army so findings and recommendations can be forwarded to Congress regarding the proposed land withdrawal. The study area for the environmental analysis is resource dependent. It includes Lewis and Clark County and Broadwater County for socioeconomic resources, MTARNG facilities for military mission, and the LHTA for biological and mineral resources.

The LEIS analyzes potential environmental effects of four alternatives:

(1) *Alternative 1:* Under this alternative, management responsibility for all resources, except for mineral resources, would be shifted from the BLM to the MTARNG. The DA could exercise its authority to condemn private land, and/or terminate any mineral claim or grazing permits under this alternative.

(2) *Alternative 2:* Under this alternative, the MTARNG and BLM would share resource management responsibilities. Most resources in the LHTAs closure area would be managed by MTARNG. Most resources in the nonclosure area would be managed by the BLM. The closure area is the portion of the LHTA that restricts access without prior approval of the MTARNG. The nonclosure area is the portion of the LHTA that is open to public access for surface use only.

(3) *Alternative 3 (Preferred Alternative):* Under the preferred alternative, the LHTA would be withdrawn from BLM jurisdiction with modifications based on scoping comments and stakeholder recommendations. The proposed withdrawal area is approximately 18,644 acres of federal land that encloses 2,666 acres of state owned and private land. Land proposed for withdrawal is limited to BLM administrated land within the withdrawal boundary. If does not include private or state owned land.

(4) *Alternative 4 (No Action Alternative):* Under this alternative, the BLMs current right-of-way grant for military use of the LHTA by MTARNG would not be renewed and would expire in 2014.

Significant Issues: The LHTA is a 23,100-acre parcel of land with private and state owned in-holdings totaling approximately 2,666 acres. The BLM managed 20,460 acres of the total acreage and allows the MTARNG to conduct military training on its property through the right-of-way grant. The public land is also used for grazing, mining, recreation, transportation, utility right-of-ways, and wildlife management. A limestone mine is currently operating within the LHTA. Every federally managed acre of the LHTA falls within ne of seven grazing allotments. In addition, the MTARNG is currently engaged in clearing unexploded ordnance from an LHTA range that is no longer in use.

Issues in the LEIS include the following: (1) Continued ability of Graymont Western's Indian Creek Limestone Mine to extract and process ore within the LHTA; (2) allocation and management of grazing allotments; (3) public access to the LHTA; (4) noise and dust generated during training exercises and by vehicular traffic; (5) impacts to Broadwater County due to possible termination of FLM payments in lieu of taxes if the withdrawal is granted; (6) potential impacts to wildlife I the Elkhorn Management Area; (7) consistency of land management policies after transfer of administrative responsibilities; (8) potential impacts to range management and cleanup activities; (9) owner access to, and use of, in-holdings; and (10) impacts to the local economy and MTARNG training under the no action alternative.

Potential significant adverse impacts to socioeconomics are expected under Alternatives 1 and 4. There are no potentially significant adverse impacts expected under Alternative 2 or 3 (Preferred Alternative).

The DA, through MTARNG, is continuing its public comment process for this action. Public meetings will be held during the LEIS public review period.

Dated: July 3, 2007.

H.E. Wolfe,

Principal Deputy Assistant Secretary of the Army (Environment, Safety and Occupational Health).

[FR Doc. 07–3472 Filed 7–16–07; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before August 16, 2007.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, Washington, DC 20503. Commenters are encouraged to submit responses electronically by e-mail to: *oira_submission@omb.eop.gov* or via fax to (202) 395–6974. Commenters should include the following subject line in their response ''Comment: [insert OMB number], [insert abbreviated collection name, e.g., ''Upward Bound Evaluation'']. Persons submitting comments electronically should not submit paper copies.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and

Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: July 11, 2007.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Institute of Education Sciences

Type of Review: Extension.

Title: Impact Evaluation of Upward Bound's Increased Focus on Higher-Risk Students—Baseline Data Collection Protocols.

Frequency: One time.

Affected Public: Individuals or household.

Reporting and Recordkeeping Hour Burden:

Responses: 10,890.
Burden Hours: 3,900.

Abstract: This evaluation will focus on the impacts of Upward Bound on students applying to enter the program as early as the summer of 2007. This new study is designed to assess program impacts both for Upward Bound students overall, as well as for higher-risk students.

Requests for copies of the information collection submission for OMB review may be accessed from: *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 3345. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to: *ICDocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to: *ICDocketMgr@ed.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E7–13812 Filed 7–16–07; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before September 17, 2007.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) title; (3) summary of the collection; (4) description of the need for, and proposed use of, the information; (5) respondents and frequency of collection; and (6) reporting and/or recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: July 11, 2007.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Special Education and Rehabilitative Services

Type of Review: Revision.

Title: IDEA Part B State Performance Plan (SPP) and Annual Performance Report (APR).

Frequency: SPP—one time; APR—every year.

Affected Public: Federal Government.

Reporting and Recordkeeping Hour Burden:

Responses: 60.
Burden Hours: 19,500.

Abstract: The Individuals with Disabilities Education Improvement Act, signed on December 3, 2004, became Public Law 108–446. In accordance with 20 U.S.C. 1416(b)(1), not later than one year after the date of enactment of the Individuals with Disabilities Education Improvement Act of 2004, each State must have in place a performance plan that evaluates the State's efforts to implement the requirements and purposes of Part B and describe how the State will improve such implementation. This plan is called the Part B State Performance Plan (Part B—SPP). In accordance with 20 U.S.C. 1416(b)(2)(C)(ii) the State shall report annually to the public on the performance of each local educational agency located in the State on the targets in the State's performance plan. The State also shall report annually to the Secretary on the performance of the State under the State's performance plan. This report is called the Part B Annual Performance Report (Part B—APR). Information Collection 1820–0624 corresponds to 34 CFR 300.600–300.602.

Requests for copies of the proposed information collection request may be accessed from: *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 3406. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of

Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to: *ICDocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to: *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E7–13813 Filed 7–16–07; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

National Committee on Foreign Medical Education and Accreditation; Meeting

AGENCY: National Committee on Foreign Medical Education and Accreditation, Department of Education.

What Is the Purpose of This Notice?

The purpose of this notice is to announce the upcoming meeting of the National Committee on Foreign Medical Education and Accreditation. Parts of this meeting will be open to the public, and the public is invited to attend those portions.

When and Where Will the Meeting Take Place?

We will hold the public meeting on September 10, 2007 from 8 a.m. until approximately 5 p.m. in the Potomac Three Room at The Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037–6936. You may call the hotel at 202–955–6400 to inquire about room accommodations.

What Assistance Will be Provided to Individuals with Disabilities?

The meeting site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (e.g., interpreting service, assistive listening device, or materials in an alternate format) notify the contact person listed in this notice at least two weeks before the scheduled meeting date. Although we will attempt to meet a request received after that date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

Who Is the Contact Person for the Meeting?

Please contact Ms. Carol A. Griffiths, the Designated Federal Official for the National Committee on Foreign Medical Education and Accreditation, if you have questions about the meeting. You may contact her at the U.S. Department of Education, room 7128, MS 7563, 1990 K St., NW., Washington, DC 20006, telephone: (202) 219–7035, fax: (202) 219–7005, e-mail: *Carol.Griffiths@ed.gov.*

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service at 1–800–877–8339.

What Are the Functions of the National Committee?

The National Committee on Foreign Medical Education and Accreditation was established by the Secretary of Education under section 102 of the Higher Education Act of 1965, as amended.

The Committee's responsibilities are to:

- Evaluate the standards of accreditation applied to applicant foreign medical schools; and
- Determine the comparability of those standards to standards for accreditation applied to United States medical schools.

What Items Will Be on the Agenda for Discussion at the Meeting?

The National Committee on Foreign Medical Education and Accreditation will review the standards of accreditation applied to medical schools by several foreign countries to determine whether those standards are comparable to the standards of accreditation applied to medical schools in the United States. Discussions of the standards of accreditation will be held in sessions open to the public. Discussions that focus on specific determinations of comparability are closed to the public in order that each country may be properly notified of the decision.

The countries tentatively scheduled to be discussed at the meeting include: Australia/New Zealand, Dominican Republic, Hungary, India, Israel, The Netherlands, Pakistan, Philippines, Poland, Saba, Slovakia, and Taiwan. Beginning August 27, you may call the contact person listed above to obtain the final listing of the countries whose standards will be discussed during this meeting. The listing of countries will also be posted on the Department of Education's Web site at the following address: *http://www.ed.gov/about/bdscomm/list/ncfmea.html.*

How May I Obtain Electronic Access to This Document?

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/legislation/FedRegister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Authority: 5 U.S.C. Appendix 2.

Dated: July 9, 2007.

James F. Manning,

Acting Assistant Secretary, Office of Postsecondary Education.

[FR Doc. E7–13762 Filed 7–16–07; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Sunshine Act Notice

AGENCY: United States Election Assistance Commission.

ACTION: Notice of public meeting (amended agenda).

DATE AND TIME: Thursday, July 19, 2007, 1 p.m.–4 p.m.

PLACE: The Charlotte Convention Center, Room 207D, 501 South College Street, Charlotte, NC 28202, (704) 339–6000.

AGENDA: In addition to considering the adoption of a draft EAC manual on Poll Worker Recruitment, Training and Retention, and a draft EAC manual on Recruiting College Poll Workers, and other administrative matters (notice published in the **Federal Register** on July 2, 2007), Commissioners will also consider a report to Congress on the expenditure of funds distributed under the Help America Vote Act.

This meeting will be open to the public.

FOR FURTHER INFORMATION CONTACT: Bryan Whitener, Telephone: (202) 566–3100.

Thomas R. Wilkey,

Executive Director, U.S. Election Assistance Commission.

[FR Doc. 07–3482 Filed 7–13–07; 11:10 am]

BILLING CODE 6820–KF–M

ELECTION ASSISTANCE COMMISSION

Sunshine Act Notice

AGENCY: United States Election Assistance Commission.

ACTION: Notice of rescheduled plenary teleconference meeting for the Technical Guidelines Development Committee.

DATE AND TIME: Friday August 17, 2007, 11:30 a.m. to 5:30 p.m. EDT.

PLACE: National Institute of Standards and Technology, 100 Bureau Drive, Building 101, Gaithersburg, Maryland 20899–8900.

STATUS: This teleconference meeting will be Web cast to the public. Additional meeting information and URL Web link for the event will be available at: *http://vote.nist.gov* by July 30, 2007.

SUMMARY: The Technical Guidelines Development Committee (the ''Development Committee'') has rescheduled a plenary teleconference meeting for August 17, 2007. This meeting date serves as a rescheduling of the July 3, 2007 plenary teleconference that was cancelled. The Development Committee was established in 2004 to act in the public interest to assist the Executive Director of the U.S. Election Assistance Commission (EAC) in the development of voluntary voting system guidelines. The Development Committee has held nine previous plenary meetings. The proceedings of these plenary sessions are available at: *http://vote.nist.gov*. The purpose of the tenth meeting of the Development Committee will be to review and approve a final draft of recommendations for future voluntary voting system guidelines to the EAC. The draft recommendations respond to tasks defined in resolutions passed at the previous Development Committee meetings as well as a review of a complete draft of recommendations presented at the May 2007 plenary meeting.

SUPPLEMENTARY INFORMATION: The Technical Guidelines Development Committee (the ''Development Committee'') has scheduled a plenary teleconference meeting for July 3, 2007. The Committee was established pursuant to 42 U.S.C. 15361, to act in the public interest to assist the Executive Director of the Election Assistance Commission in the development of the voluntary voting system guidelines. The Technical Guidelines Development Committee held their first plenary meeting on July 9, 2004. At this meeting, the Development Committee agreed to a resolution forming three working groups: (1) Human Factors & Privacy; (2) Security & Transparency; and (3) Core Requirements & Testing to gather information and review preliminary reports on issues pertinent to voluntary voting standard recommendations. At subsequent plenary sessions, additional resolutions were debated and adopted by the TGDC. The resolutions define technical work tasks for NIST that assist the TGDC in developing recommendations for voluntary voting system guidelines. The Development Committee approved initial recommendations for voluntary voting system guidelines at the April 20th & 21st, 2005 meeting. The recommendations were formally delivered to the EAC in May 2005 for their review. In September of 2005, the Development Committee began review of preliminary technical reports for the next iteration of voluntary voting system guidelines. The Committee will review, debate and approve a final draft of recommendations for the next iteration of voluntary voting system guidelines at the August 17, 2007 teleconference meeting.

FOR FURTHER INFORMATION CONTACT: Allan Eustis 301–975–5099. If a member of the public would like to submit comments concerning the Committee's affairs at any time before or after the meeting, written comments should be addressed to the contact person indicated above, c/o NIST, 100 Bureau Drive, Mail Stop 8970, Gaithersburg, MD 20899 or to: *voting@nist.gov*.

Thomas R Wilkey,

Executive Director, U.S. Election Assistance Commission.

[FR Doc. 07–3483 Filed 7–13–07; 11:10 am]

BILLING CODE 6820–KF–M

DEPARTMENT OF ENERGY

Office of Science; Basic Energy Sciences Advisory Committee; Notice of Open Meeting

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Basic Energy Sciences Advisory Committee (BESAC). Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Tuesday, July 31, 2007, 9 a.m. to 5 p.m., and Wednesday, August 1, 2007, 8:30 a.m. to 12 p.m.

ADDRESSES: Hilton Washington DC/Rockville Executive Meeting Center 1750 Rockville Pike, Rockville, MD.

FOR FURTHER INFORMATION CONTACT: Karen Talamini; Office of Basic Energy Sciences; U.S. Department of Energy; Germantown Building, Independence Avenue, Washington, DC 20585; Telephone: (301) 903–4563.

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting: The purpose of this meeting is to provide advice and guidance with respect to the basic energy sciences research program.

Tentative Agenda: Agenda will include discussions of the following:

- News from the Office of Science.
- News from the Office of Basic Energy Sciences.
- Report of the COV of the Scientific Facilities Division.
- Reports of BES Basic Research Needs Workshops.
- Reports of the BESAC Grand Challenges Subcommittee.

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Karen Talamini at 301–903–6594 (fax) or *karen.talamini@science.doe.gov* (e-mail). You must make your request for an oral statement at least 5 business days prior to the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: The minutes of this meeting will be available for public review and copying at: *http://www.sc.doe.gov/production/bes/BESAC/Meetings.html.*

Issued in Washington, DC, on July 11, 2007.

Rachel M. Samuel,

Deputy Committee Management Officer.

[FR Doc. E7–13800 Filed 7–16–07; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Hydrogen and Fuel Cell Technical Advisory Committee (HTAC)

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: The Hydrogen and Fuel Cell Technical Advisory Committee (HTAC) was established under section 807 of the Energy Policy Act of 2005 (EPACT), Public Law 109–58; 119 Stat. 849. The Federal Advisory Committee Act, Public Law 92–463, 86 Stat. 770, requires that public notice of these meetings be announced in the **Federal Register**. To attend the meeting and/or to make oral statements during the public comment period, please e-mail: *HTAC.Committee@ee.doe.gov* at least 5 business days before the meeting.

DATES: Tuesday, July 31, 2007, from 9 a.m.–6 p.m. and Wednesday, August 1, 2007 from 9 a.m.–12 p.m.

ADDRESSES: Crystal City Marriott, 1999 Jefferson-Davis Highway, Arlington, Virginia 22202.

FOR FURTHER INFORMATION CONTACT: *HTAC.Committee@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting: To prepare biennial report to be completed in October 2007 focusing on the EPACT Section 804 Plan, also known as the Hydrogen Posture Plan.

Tentative Agenda (Subject to change; updates will be posted on: http://hydrogen.energy.gov and copies of the final agenda will be available the date of the meeting): The following items will be covered on the agenda:

- Input from HTAC on Suggested Focus Areas for the Interagency Task Force.
- Briefing on the Well-to-Wheels Analysis, Appendix B of Hydrogen Posture Plan.
- Update on Restructuring of HELP.
- Members' Preparation of the Posture Plan Review Report.
- Next Steps.

Public Participation: In keeping with procedures, members of the public are welcome to observe the business of the meeting of HTAC and to make oral statements during the specified period for public comment. The public comment period will take place between 11 a.m. and 12 noon on August 1, 2007. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, e-mail: *HTAC.Committee@ee.doe.gov* at least 5 business days before the meeting. (Please indicate if you will be attending the meeting both days or just one day.) Members of the public will be heard in the order in which they sign up for the Public Comment Period. Oral comments should be limited to two minutes in length. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chair of the Committee will make every effort to hear the views of all interested parties and to facilitate the orderly conduct of business. If you would like to file a written statement with the Committee, you may do so either two days before or after the meeting (electronic and hard copy).

Minutes: The minutes of the meeting will be available for public review at: *http://hydrogen.energy.gov.*

Issued at Washington, DC, on July 11, 2007.

Rachel Samuel,

Deputy Committee Management Officer.

[FR Doc. E7–13770 Filed 7–16–07; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Meeting; Notice of Vote; Explanation of Action Closing Meeting; and List of Persons to Attend

Date: July 12, 2007.

The following notice of meeting is published pursuant to section 3(a) of the Government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

Agency Holding Meeting: Federal Energy Regulatory Commission.

Date and Time: July 19, 2007, Following regular commission meeting.[1]

Place: Room 2C, Commission Meeting Room, 888 First Street, NE., Washington, DC 20426.

Status: Closed.

Matters To Be Considered: Non-public investigations and inquiries, enforcement related matters.

Contact Person For More Information: Kimberly D. Bose, Secretary, Telephone (202) 502–8400.

Chairman Kelliher and Commissioners Kelly, Spitzer, Moeller, and Wellinghoff voted to hold a closed meeting on July 19, 2007. The certification of the General Counsel explaining the action closing the meeting is available for public inspection in the Commission's Public Reference Room at 888 First Street, NE., Washington, DC 20426.

[1] The Commission's open meeting is scheduled to start at 10 a.m. in Room 2C.

The Chairman and the Commissioners, their assistants, the Commission's Secretary, the General Counsel and members of his staff, and a stenographer are expected to attend the meeting. Other staff members from the Commission's program offices who will advise the Commissioners in the matters discussed will also be present.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–13817 Filed 7–16–07; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[Regional Docket Nos. V–2005–1, –2, –3, and V–2006–2, FRL–8440–1]

Clean Air Act Operating Permit Program; Petitions for Objection to State Operating Permits for Midwest Generation, LCC

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final orders on petitions to object to State operating permits.

SUMMARY: This document announces that the EPA Administrator has responded to four petitions asking EPA to object to six Clean Air Act (CAA) operating permits proposed by the Illinois Environmental Protection Agency (IEPA). Specifically, the Administrator denied the petitions submitted by the Illinois Attorney General, the Chicago Legal Clinic and the Environmental Law and Policy Center to object to the proposed operating permits for all six of the Midwest Generation, LCC stations.

Pursuant to section 505(b)(2) of the CAA, a Petitioner may seek judicial review in the United States Court of Appeals for the appropriate circuit of those portions of the petitions which EPA denied. Any petition for review shall be filed within 60 days from the date this notice appears in the **Federal Register**, pursuant to section 307 of the CAA.

ADDRESSES: You may review copies of the final orders, the petitions, and other supporting information at the EPA Region 5 Office, 77 West Jackson Boulevard, Chicago, Illinois 60604. If you wish to examine these documents, you should make an appointment at least 24 hours before visiting day. Additionally, the final orders for the Midwest Generation petitions are available electronically at: *http://yosemite.epa.gov/r5/ardcorre.nsf/permits.*

FOR FURTHER INFORMATION CONTACT: Pamela Blakley, Chief, Air Permits Section, Air Programs Branch, Air and Radiation Division, EPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, telephone (312) 886–4447.

SUPPLEMENTARY INFORMATION: The Act affords EPA a 45-day period to review, and object to as appropriate, operating permits proposed by state permitting authorities. Section 505(b)(2) of the Act authorizes any person to petition the EPA Administrator within 60 days after the expiration of the EPA review period to object to state operating permits if EPA has not done so. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the state, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period, or the grounds for the issues arose after this period.

On November 28, 2005 and April 5, 2006, the EPA received four petitions from the Illinois Attorney General, the Chicago Legal Clinic and the Environmental Law and Policy Center requesting that EPA object to the proposed Title V operating permits for the Midwest Generation, LCC stations. The petitions raise issues regarding the lack of compliance schedules in the permits. The petitioners alleged that the proposed permits are legally inadequate because: (1) Self-reporting by Midwest Generation based on continuous opacity monitoring provides evidence that all of the Midwest Generation facilities are in violation of their opacity limitations, yet the permits lack the required compliance schedules; and (2) IEPA failed to require compliance schedules to bring Midwest Generation into compliance with New Source Review requirements.

On June 14, 2007 and June 18, 2007, the Administrator issued orders denying the petitions. The orders explain the reasons behind EPA's conclusion to deny the petitions.

Dated: July 5, 2007.

Bharat Mathur,

Deputy Regional Administrator, Region 5.

[FR Doc. E7–13790 Filed 7–16–07; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 9, 2007.

A. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. Heritage Management Company, Inc., Washington, Missouri; to become a bank holding company by acquiring 100 percent of the voting shares of United Bank of Chamois, Chamois, Missouri.

2. Lonoke Bancshares, Inc., Lonoke, Arkansas; to retain control of 6.88 percent of Pinnacle Bancshares, Inc., and Pinnacle Bank both of Bentonville, Arkansas.

3. Lonoke Bancshares, Inc., Lonoke, Arkansas; to acquire additional shares of Central Bank, Little Rock, Arkansas, for a total of 9.65 percent, of Central Bank, Little Rock, Arkansas.

Board of Governors of the Federal Reserve System, July 11, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E7–13720 Filed 7–16–07; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 10, 2007.

A. Federal Reserve Bank of Chicago (Burl Thornton, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. PrivateBancorp, Inc. Chicago, Illinois; to acquire 81 percent of the voting shares of The PrivateBank, Kansas City, Missouri (in organization), and thereby indirectly operate a federal savings bank pursuant to section 225.28 (b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, July 12, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc.E7–13765 Filed 7–16–07; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:30 a.m., Monday, July 23, 2007.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

FOR FURTHER INFORMATION CONTACT: Michelle Smith, Director, or Dave Skidmore, Assistant to the Board, Office of Board Members at 202–452–2955.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Board of Governors of the Federal Reserve System, July 13, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 07–3502 Filed 7–13–07; 3:15 pm]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nomination for Appointment to the Advisory Committee on Minority Health

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office of Minority Health.

ACTION: Notice.

Authority: 42 U.S.C. 300u–6, Section 1707 of the Public Health Service Act, as amended. The Advisory Committee is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The Department of Health and Human Service (HHS), Office of Public Health and Science (OPHS), is seeking nominations of qualified candidates to be considered for appointment as a member of the Advisory Committee on Minority Health (ACMH). In accordance with Public Law 105–392, the Committee provides advice to the Deputy Assistant Secretary for Minority Health, on the development of goals and specific program activities of the Office of Minority Health (OMH) designed to improve the health of racial and ethnic minority groups. Nominations of qualified candidates are being sought to fill vacant positions on the Committee.

DATES: Nominations for membership on the Committee must be received no later than 5 p.m. EST on September 17, 2007, at the address listed below.

ADDRESSES: All nominations should be mailed or delivered to Dr. Garth Graham, Deputy Assistant Secretary for Minority Health, Office of Minority Health, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootton Parkway, Suite 600, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ms. Monica Baltimore, Executive Director, Advisory Committee on Minority Health, Office of Minority Health, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootton Parkway, Suite 600, Rockville, MD 20852; Telephone: (240) 453–2882.

A copy of the Committee charter and list of the current membership can be obtained by contacting Ms. Baltimore or by accessing the Web site managed by OMH at *http://www.omhrc.gov/acmh.*

SUPPLEMENTARY INFORMATION: Pursuant to Public Law 105–392, the Secretary of Health and Human Services established the ACMH. The Committee provides advice to the Deputy Assistant Secretary for Minority Health in carrying out the duties stipulated under Public Law 105–392. This includes providing advice to improve the health of each racial and ethnic minority group and in the development of goals and specific activities of the OMH, which are:

(1) Establish short-range and long-range goals and objectives and coordinate all other activities within the Public Health Service that relate to disease prevention, health promotion, service delivery, and research concerning such individuals;

(2) Enter into interagency agreements with other agencies of the Public Health Service;

(3) Support research, demonstrations, and evaluations to test new and innovative models;

(4) Increase knowledge and understanding of health risk factors;

(5) Develop mechanisms that support better information dissemination, education, prevention, and service delivery to individuals from disadvantaged backgrounds, including individuals who are members of racial or ethnic minority groups;

(6) Ensure that the National Center for Health Statistics collects data on the health status of each minority group;

(7) With respect to individuals who lack proficiency in speaking the English language, enter into contracts with public and nonprofit private providers of primary health services for the purpose of increasing the access of these individuals to such services by developing and carrying out programs to provide bilingual or interpretive services;

(8) Support a national minority health resource center to carry out the following:

(a) Facilitate the exchange of information regarding matters relating to health information and health promotion, preventive health services, and education in appropriate use of health care;

(b) Facilitate access to such information;

(c) Assist in the analysis of issues and problems relating to such matters;

(d) Provide technical assistance with respect to the exchange of such information (including facilitating the development of materials for such technical assistance);

(9) Carry out programs to improve access to health care services for individuals with limited proficiency in speaking the English language. Activities under the preceding sentence shall include developing and evaluating model projects; and

(10) Advising in matters related to the development, implementation, and evaluation of health professions education in decreasing disparities in health care outcomes, including cultural competency as a method of eliminating health disparities.

Management and support services for the ACMH are provided by the OMH, which is a program office within the OPHS.

Nominations: The OPHS is requesting nominations for vacant positions on the ACMH. The Committee is composed of 12 voting members, in addition to non-voting *ex officio* members. This announcement is seeking nominations for voting members. Voting members of the Committee are appointed by the Secretary from individuals who are not officers or employees of the Federal Government and who have expertise regarding issues of minority health. To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and expertise working on issues/matters impacting the health of racial and ethnic minority populations. The charter

stipulates that the racial and ethnic minority groups shall be equally represented on the Committee membership. This means we are seeking candidates who can represent the health interest of Hispanics/Latino Americans; Blacks/African Americans; American Indians and Alaska Natives; and/or Asian Americans, Native Hawaiians, and other Pacific Islanders.

Mandatory Professional/Technical Qualifications: Nominees must meet all of the following mandatory qualifications to be eligible for consideration.

(1) Expertise in minority health and racial and ethnic health disparities.

(2) Expertise in developing or contributing to the development of health policies and/or programs. This may include experience in the analysis, evaluation, and interpretation of Federal health or regulatory policy.

(3) Involvement in national, regional, tribal, and/or community efforts to improve minority health.

(4) Educational achievement, professional certification(s) in health-related field (behavioral health, public health, nursing, environmental health, nutrition, pharmacy, epidemiology, health administration, etc.), and professional experience that will support ability to give expert advise on issues related to improving minority health and eliminating racial and ethnic health disparities.

Desirable Qualifications: It is desired that the nominee have:

(1) Knowledge of national health policies and programs managed by the HHS.

(2) Job-related training, self-development, and outside professional activities which provides evidence of initiative, resourcefulness, and potential for effective performance.

Requirements for Nomination Submission: Nominations should be typewritten (one nomination per nominator). The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (i.e., specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address, and daytime telephone number, and the home and/or work address, telephone number, and e-mail address of the individual being nominated; (3) a current copy of the nominee's curriculum vitae, and (4) provide narrative responses to the mandatory professional/technical qualifications listed above in regard to the nominee's expertise. Federal employees should not be nominated for consideration of appointment to this Committee.

Individuals selected for appointment to the Committee shall be invited to serve four year terms. Committee members who are not officers or employees of the United States Government will receive a stipend for attending Committee meetings and conducting other business in the interest of the Committee, including per diem and reimbursement for travel expenses incurred.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that a broad representation of geographic areas, females, ethnic and minority groups, and the disabled are given consideration for membership on HHS Federal advisory committees. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status. Nominations must state that the nominee is willing to serve as a member of ACMH and appears to have no conflict of interest that would preclude membership. An ethics review is conducted for each selected candidate. Therefore, individuals selected for nomination will be required to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

Dated: July 2, 2007.

Mirtha R. Beadle,

Deputy Director, OMH.

[FR Doc. E7–13739 Filed 7–16–07; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG 2007–28460]

Long Range Aids to Navigation (LORAN–C) Program; Preparation of Programmatic Environmental Impact Statement

AGENCY: Coast Guard, DHS.

ACTION: Notice of intent, notice of public meeting, and request for public comments.

SUMMARY: The U.S. Coast Guard (USCG) announces that it intends to prepare a Programmatic Environmental Impact Statement (PEIS) on the Future of the Long Range Aids to Navigation (LORAN) Program. The current system (LORAN–C) is a low frequency hyperbolic radionavigation system approved for use in the U.S. Coastal Confluence Zone (CCZ) and as a supplemental air navigation aid. LORAN–C provides navigation, location, and timing services for both civil and military air, land, and marine users in the CONUS and Alaska. The PEIS will evaluate the environmental effects of alternative futures for the LORAN–C Program, and aid the USCG in its decision on whether to terminate or continue to operate and invest in the LORAN–C system.

Publication of this notice begins a scoping process that will identify and determine the scope of environmental issues to be addressed in the PEIS. This notice requests public participation in the scoping process, establishes a public comment period, and provides information on how to participate.

DATES: Public meetings will be held August 15, 21 and 23, 2007, in Washington, DC, Juneau, AK, and Seattle, WA, respectively. Each meeting will consist of an informational open house from 4:30 p.m. to 6 p.m. and a public scoping meeting from 6 p.m. to 8 p.m. The public meetings may end later than the stated time, depending on the number of persons wishing to speak. Comments and related material must reach the docket on or before August 31, 2007.

ADDRESSES: The Washington, DC meeting will be held at:

Ronald Reagan Building and International Trade Center 1300 Pennsylvania Avenue, NW., Washington, DC 20004, 202–312–1426.

The Seattle meeting will be held at: Seattle Hilton, 1301 Sixth Avenue, Seattle, WA 98101, (206) 695–6060.

The Juneau meeting will be held at: Centennial Hall Convention Center, 101 Egan Drive, Juneau, AK 99801, (907) 586–5283.

All meeting spaces will be wheelchair-accessible. You do not need to attend the meetings in order to comment. You may submit comments, identified by docket number USCG 2007–28460, to the Docket Management Facility at the U.S. Department of Transportation (DOT). To avoid duplication, please use only one of the following methods:

(1) Electronically through the Web site for the Docket Management System, at: *http://dms.dot.gov.*

(2) By mail to the Docket Management Facility, U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

(3) By fax to the Docket Management Facility at (202) 493–2251.

(4) By delivery to Room W12–140, West Building, Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.

(5) By the Federal eRulemaking Portal at: *http://www.regulations.gov/.*

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public will become part of this docket and will be available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays. This docket may also be found on the Internet at: *http://dms.dot.gov.*

Comments and related material must reach the Docket Management Facility by August 31, 2007.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, please call or e-mail LT Michael Herring, LORAN–C Program Manager, at (202) 372–1561, or *Michael.L.Herring@uscg.mil,* respectively. If you have questions about viewing or submitting material to the docket, please call Renee V. Wright, Program Manager, Docket Operations, Office of Information Services, Office of the Assistant Secretary for Administration, Office of the Secretary, at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Request for Comments

The USCG requests public comments and other relevant information on environmental issues related to the future of the LORAN–C Program. The scheduled public meetings are not the only opportunity you have to comment. In addition to or instead of providing comments at the meeting, you can submit comments to the Docket Management Facility during the public comment period (see **DATES**). The USCG will consider all comments and materials received during the comment period.

On January 8, 2007, the USCG published a request for comments on the need to continue to operate or invest in the North American LORAN–C radionavigation system (72 **Federal Register** 796). To avoid duplication and resubmission of comments, all comments previously submitted under docket USCG 2006–24685 will be considered during the LORAN–C PEIS scoping process.

All comments received will be posted, without change, to: *http://dms.dot.gov* and will include any personal information you have provided. The USCG has an agreement with the DOT to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

Submitting comments: If you submit a comment, please include your name and address, and identify the docket number for this notice (USCG 2007–28460). You may submit your comments by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under ADDRESSES; but please submit your comments by only one means. If you submit comments by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to confirm that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope.

Viewing comments and documents: To view comments, go to: *http://dms.dot.gov* at any time, click on ''Simple Search,'' enter the last five digits of the docket number (28460), and click on ''Search.'' You may also visit the Docket Management Facility in the west building, Ground Floor, Room W12–140 located at 1200 New Jersey Avenue, SE., Washington, DC 20590. Docket contents are available for public inspection and copying, at this address, in room W12–140, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Facility's telephone is 202–366–9329, its fax is 202–493–2251, and its Web site for electronic submissions or for electronic access to docket contents is: *http://dms.dot.gov.*

Privacy Act: Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the DOT's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov.*

Public Meeting and Open House

The USCG invites you to learn about the PEIS on the Future of the LORAN–C Program at an informational open house, and to identify and comment on environmental issues related to the proposed action and alternatives at a public meeting. Your comments will help the USCG identify and refine the scope of the environmental issues to be addressed in the PEIS.

In order to allow everyone a chance to speak at the public meeting, the USCG may limit speaker time, or extend the meeting hours, or both. When you rise to speak, you must identify yourself, and any organization you represent, by name. Your remarks will be recorded or transcribed for inclusion in the public docket.

You may submit written material at the public meeting, either in place of or in addition to speaking. Written material must include your name and address, and will be included in the public docket. Comments given at a public meeting and written comments submitted to the docket will receive full and equal consideration.

The public meeting locations are wheelchair-accessible. If you plan to attend an open house or public meeting and need special assistance such as sign language interpretation or other reasonable accommodation, please notify the USCG (see **FOR FURTHER INFORMATION CONTACT**) at least 3 business days in advance. Include your contact information as well as information about your specific needs.

Background and Purpose

LORAN is a radionavigation system first developed during World War II and operated by the USCG. The current system (LORAN–C) is a low frequency hyperbolic radionavigation system approved for use in the CCZ and as a supplemental air navigation aid. LORAN–C provides navigation, location, and timing services for both civil and military air, land, and marine users in the Contiguous United States (CONUS) and Alaska. The USCG operates 18 CONUS LORAN Stations, 6 Alaska LORAN Stations, and 24 monitor sites. The system is controlled remotely from Alexandria, VA and Petaluma, CA. Nationwide system operation is based on links between ''chains'' of stations; therefore, decisions made on any one station may potentially impact multiple stations or chains, necessitating an overall LORAN system decision rather than a segmented approach.

The PEIS will evaluate the environmental effects of alternatives regarding the LORAN–C Program to aid the USCG in its decision of whether further investment in modernizing and improving LORAN–C is in the public interest.

The PEIS on the Future of the LORAN–C Program will be a program-level document that will provide USCG with high-level analysis of the potential impacts on the human environment from the alternatives for the future of the LORAN–C Program. The USCG is the lead agency for determining the scope of this review and has determined that a PEIS will best meet its needs. The PEIS will comply with the National Environmental Policy Act of 1969 (NEPA), the Council on Environmental Quality regulations in 40 CFR parts 1500–1508, Department of Homeland Security (DHS) Management Directive 5100.1 (*Environmental Planning Program*), and Coast Guard Commandant Instruction (COMDTINST) M16475.1D (*National Environmental Policy Act Implementing Procedures and Policy for Considering Environmental Impacts*). The geographic scope of the LORAN–C PEIS is those areas covered by the radionavigation system. Should the USCG decide to end its involvement with LORAN–C, the analysis provided in the PEIS will enable the USCG to prepare tiered documents on the disposition of each LORAN Station and monitoring station.

Proposed Action and Alternatives

The PEIS will address the following four alternatives to represent the range of possible management options for the future of the USCG LORAN–C Program:

(1) *Decommission the USCG LORAN–C Program and Terminate North American LORAN–C Signal*. Under this alternative, all USCG LORAN–C signals would be terminated at one time. All USCG LORAN Stations would be decommissioned; LORAN artifacts, documents and equipment (i.e., towers and related infrastructure) would be removed; and USCG personnel would be reassigned. LORAN Station property would be declared excess to the needs of the USCG following Federal guidelines on transfer of excess property. The disposition of each LORAN Station would range from transferring ownership of the property with such infrastructure as buildings, roads, piers, and airstrips intact, to returning the property to a natural state prior to its transfer.

(2) *Transfer Management of the LORAN–C Program to another government agency*. Under this alternative, the USCG would continue to operate the LORAN–C Program until the transfer to another Agency.

(3) *Automate, Secure, and Unstaff LORAN Stations*. Under this alternative, the USCG would continue to operate the LORAN–C Program. The LORAN–C signal would remain on the air but the USCG would reduce staffing. To the extent practical, the USCG would automate equipment; secure buildings and fencing to protect equipment, antenna, and antenna guides; and reassign personnel. The LORAN Stations would become LORAN Sites operating unstaffed with preventive and corrective maintenance performed by contractor personnel.

(4) *No Action Alternative*. The LORAN–C signal would remain on air, and LORAN–C operations would remain as they currently are with no change in staffing. Maintenance and modernization of equipment would continue to keep the signal operating.

The PEIS will serve as a top tier environmental analysis of program-level changes. This notice of intent is required by 40 CFR 1508.22, and briefly describes the proposed action and possible alternatives and our proposed scoping process. The PEIS will provide a general level of analysis of environmental impacts on the 24 LORAN Stations, 24 Monitoring Sites, and the LORAN Support Unit (LSU) since the disposition of each facility is not currently known. The PEIS will also discuss the No Action Alternative as required under NEPA. You can address any questions about the proposed action, the scoping process, or the PEIS to the USCG LORAN–C Program Office (see **FOR FURTHER INFORMATION CONTACT**).

Scoping Process

Public scoping is an early and open process for identifying and determining the scope of issues to be addressed in the PEIS. Scoping begins with this notice, continues through the public comment period (see DATES), and ends when the USCG has completed the following actions:

- Invites the participation of Federal, State, and local agencies, any affected Indian tribe and other interested persons;
- Determines the actions, alternatives, and impacts described in 40 CFR 1508.25;
- Identifies and eliminates from detailed study those issues that are not significant or that have been covered elsewhere;
- Identifies other relevant environmental review and consultation requirements on the future of the LORAN–C Program;
- Indicates the relationship between timing of the environmental review and other aspects of the proposed action; and
- At its discretion, exercises the options provided in 40 CFR 1501.7(b).

Once the scoping process is complete, the USCG will prepare a draft PEIS, and will publish a **Federal Register** notice announcing its public availability. (If you want that notice to be sent to you, please contact the USCG Project Office point-of-contact identified in **FOR FURTHER INFORMATION CONTACT**.) You will have an opportunity to review and comment on the draft PEIS. Additionally, the USCG anticipates holding public meetings in approximately December 2007 to present the draft PEIS and receive public comments regarding that document. The USCG will subsequently consider all comments received and then prepare the final PEIS. As with the draft PEIS, the USCG will announce the availability of the final PEIS and once again give interested parties an opportunity for review and comment.

Dated: June 26, 2007.

Brian M. Salerno,

Rear Admiral USCG, Assistant Commandant, Policy and Planning (CG–5).

[FR Doc. 07–3475 Filed 7–12–07; 3:13 pm]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Open Meeting/Conference Call, Board of Visitors for the National Fire Academy

AGENCY: U.S. Fire Administration, Federal Emergency Management Agency, DHS.

ACTION: Notice of open meeting via conference call.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Federal Emergency Management Agency announces the following committee meeting:

Name: Board of Visitors (BOV) for the National Fire Academy.

Date of Meeting: August 1, 2007.

Place: Building H, Room 300, National Emergency Training Center, Emmitsburg, Maryland.

Time: 1:30–3:30 p.m.

Proposed Agenda: Introduction of New Board Members and Review National Fire Academy Program Activities.

SUPPLEMENTARY INFORMATION: In accordance with section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, the Federal Emergency Management Agency announces that the committee meeting will be open to the public in the Emmitsburg commuting

area with seating available on a first-come, first-served basis. The meeting is open to the public; however, teleconference lines are limited. Members of the general public who plan to participate in the meeting should contact the Office of the Superintendent, National Fire Academy, U.S. Fire Administration, 16825 South Seton Avenue, Emmitsburg, MD 21727, (301) 447–1117, on or before July 31, 2007. Dial-in information will be provided to those wishing to participate via telephone.

Minutes of the meeting will be prepared and will be available for public viewing in the Office of the U.S. Fire Administrator, U.S. Fire Administration, Federal Emergency Management Agency, Emmitsburg, Maryland 21727. Copies of the minutes will be available upon request within 60 days after the meeting.

The National Fire Academy Board of Visitors is administered by the U.S. Fire Administration which is part of the Federal Emergency Management Agency in the Department of Homeland Security.

Dated: July 12, 2007.

Charlie Dickinson,

Deputy Assistant Administrator, U.S. Fire Administration.

[FR Doc. E7–13842 Filed 7–16–07; 8:45 am]

BILLING CODE 9110–17–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability, Final Restoration Plan

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: The U.S. Fish and Wildlife Service (Service), on behalf of the Department of the Interior (DOI), National Oceanic and Atmospheric Administration (NOAA), and New York State Department of Environmental Conservation (New York), as natural resource trustees, announces the release of the Final Restoration Plan (RP) for the Mattiace Petrochemical Superfund Site (Site). The Final RP presents the selected restoration alternative, consisting of a single restoration project that compensates for impacts to natural resources caused by contaminant releases associated with the Site.

ADDRESSES: Requests for copies of the RP may be made to: U.S. Fish and Wildlife Service, New York Field Office, 3817 Luker Road, Cortland, NY 13045.

FOR FURTHER INFORMATION CONTACT: Ken Karwowski, Environmental Contaminants Program, U.S. Fish and Wildlife Service, New York Field Office, 3817 Luker Road, Cortland, NY 13045.

Interested parties may also call Ken Karwowski at 607–753–9334 or e-mail him at *Ken_Karwowski@fws.gov* for further information.

SUPPLEMENTARY INFORMATION: During the period of March 1996 through December 2000, natural resource damage settlements were achieved for the Mattiace Petrochemical Superfund Site. NOAA and the State of New York were settling Trustees with the DOI. A variety of hazardous chemicals were discharged from the Site into Glen Cove Creek, located in the Town of Oyster Bay, Nassau County, New York. Chemical releases and remedial activities at the Site adversely affected natural resources such as anadromous, catadromous, euryhaline, and marine finfish; shellfish; invertebrates; waterfowl; other migratory birds; and reptiles. The funds available from the settlement for restoration activities total approximately $155,000.

The RP is being released in accordance with the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended, commonly known as Superfund (42 U.S.C. 9601 *et seq.*), the Natural Resource Damage Assessment Regulations found at 43 CFR part 11, and the National Environmental Policy Act (NEPA). The Final RP is intended to describe the Trustees' selected alternative to restore natural resource injuries associated and affected by the Site.

The RP describes a number of habitat restoration and protection alternatives and discusses the environmental consequences of each. The restoration effort with the greatest potential to restore natural resources and services that were injured by contaminants or remedial activities is preferred. Based on an evaluation of the various restoration alternatives, the selected alternative consists of a single restoration project involving tidal marsh/wetland restoration and protection.

Copies of the RP are available from the Service's New York Field Office at 3817 Luker Road, Cortland, NY 13045. Additionally, the RP is available for viewing at the following Web site: *http://nyfo.fws.gov/ec/MattiaceFRP.pdf*. No written comments on the Draft Restoration Plan were received for consideration in the final restoration plan/environmental assessment.

Author: The primary author of this notice is Ken Karwowski, U.S. Fish and Wildlife Service, New York Field Office, 3817 Luker Road, Cortland, NY 13045.

Authority: The authority for this action is the CERCLA of 1980, as amended, commonly known as Superfund (42 U.S.C. 9601 *et seq.*), and the Natural Resource Damage Assessment Regulations found at 43 CFR part 11.

Dated: June 19, 2007.

Marvin E. Moriarty,

Regional Director, Region 5, U.S. Fish and Wildlife Service, U.S. Department of the Interior, DOI Designated Authorized Official.

[FR Doc. E7–13840 Filed 7–16–07; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Sport Fishing and Boating Partnership Council

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: We, the Fish and Wildlife Service, announce a public meeting of the Sport Fishing and Boating Partnership Council (Council).

DATES: We will hold the meeting from 8:30 a.m. to 5 p.m. on Wednesday, August 8, 2007, (Alaska time) and Thursday, August 9, 2007. Members of the public wishing to participate in the meeting must notify Douglas Hobbs by close of business on Thursday, August 2, 2007, per instructions in the **SUPPLEMENTARY INFORMATION** section of this notice. Submit written statements for this meeting no later than Monday, July 30, 2007.

ADDRESSES: The meeting will be held at the Alaska Islands and Ocean Visitor Center, 95 Sterling Highway, Suite 1, Homer, Alaska 99603; telephone (907) 235–6961.

FOR FURTHER INFORMATION CONTACT: Douglas Hobbs, Council Coordinator, 4401 North Fairfax Drive, Mailstop 3103–AEA, Arlington, Virginia 22203, (703) 358–2336 (phone), (703) 358–2548 (fax), or *doug_hobbs@fws.gov* (e-mail).

SUPPLEMENTARY INFORMATION: In accordance with the requirements of the Federal Advisory Committee Act, 5 U.S.C. App., we give notice that the Sport Fishing and Boating Partnership Council will hold the meeting from 8:30 a.m. to 5 p.m. on Wednesday, August 8, 2007 (Alaska time) and Thursday, August 9, 2007.

Background

The Council was formed in January 1993 by the Secretary of the Interior (Secretary) to advise the Secretary,

through the Director, U.S. Fish and Wildlife Service, about nationally significant recreational boating, fishing, and aquatic resource conservation issues. The Council represents the interests of the public and private sectors of the sport fishing and boating, and conservation communities and is organized to enhance partnerships among industry, constituency groups, and government. The 18-member Council, appointed by the Secretary, includes the Director of the Service and the president of the Association of Fish and Wildlife Agencies, who both serve in ex officio capacities. Other Council members are Directors from State agencies responsible for managing recreational fish and wildlife resources and individuals who represent the interests of saltwater and freshwater recreational fishing, recreational boating, the recreational fishing and boating industries, recreational fisheries resource conservation, tribal resource management agencies, aquatic resource outreach and education, and tourism. Background information on the Council is available at *http://www.fws.gov/sfbpc.*

The Council will convene to discuss: (1) The Council's continuing role in providing input to the Fish and Wildlife Service on the Service's strategic plan for its Fisheries Program; (2) The Council's role in providing input into the Fish and Wildlife Service's Sport Fish Restoration Program; (3) The Council's work in addressing the issue of boating and fishing access; (4) The Council's work to assess the Clean Vessel Act Grant Program; (5) The Council's role in communicating with partners and stakeholders about the Sport Fish Restoration and Boating Trust Fund; (6) The Council's role in the continued implementation of the National Fish Habitat Action Plan; (7) Future strategic issues that the Council will address through its activities; and (8) The Council's role in providing the Secretary with information about the implementation of the Strategic Plan for the National Outreach and Communications Program, authorized by the 1998 Sportfishing and Boating Safety Act, that is now being implemented by the Recreational Boating and Fishing Foundation, a private, nonprofit organization. The final agenda will be posted on the Internet at *http://www.fws.gov/sfbpc.*

Procedures for Public Input

We are reserving time at 1:30 p.m. (Alaska time) on Thursday, August 9, 2007, for oral public comments, and will assign speaking times on a first-come, first-served basis. Questions from the public will not be considered during this comment period, which is intended to allow interested members of the public to submit relevant written or oral information for the Council to consider in the course of its business. We are limiting each individual or group's oral presentation during the oral public comment period to 3 minutes per speaker, with no more than a total of one-half hour for all speakers. Speakers wishing to submit a full statement should do so at the meeting. We invite those speakers unable to be placed on the agenda, or to attend in person, to submit written statements.

To be placed on our public speaker list for this meeting, contact Douglas Hobbs, Council Coordinator, in writing (preferably via e-mail), by July 30, 2007, at the contact information under **FOR FURTHER INFORMATION CONTACT**. We must receive all written statements by July 30, 2007, so that the information may be made available to the Council for their consideration prior to this teleconference. Submit your written statements to the Council Coordinator in the following formats: One hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat PDF, WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format).

To ensure that ample seating is available, we recommend that anyone wishing to attend this meeting register by close of business August 2, 2007. Please submit your name, time of arrival, e-mail address, and phone number to Douglas Hobbs, and he will provide you with instructions for admittance. Mr. Hobbs' e-mail address is *doug_hobbs@fws.gov*, and his phone number is (703) 358–2336.

Summary minutes of the conference will be maintained by the Council Coordinator at 4401 N. Fairfax Drive, MS–3101–AEA, Arlington, VA 22203, and will be available for public inspection during regular business hours. You may purchase personal copies for the cost of duplication.

Dated: June 19, 2007.

Kevin Adams,

Acting Director.

[FR Doc. E7–13792 Filed 7–16–07; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ–411–1040–JH]

Call for Nominations for Gila Box Advisory Committee

AGENCY: Safford Field Office, Bureau of Land Management (BLM), Interior.

ACTION: Call for nominations for the Gila Box Riparian National Conservation Area (NCA) Advisory Committee.

SUMMARY: The BLM is publishing this Notice under Section 9(a)(2) of the Federal Advisory Committee Act to solicit public nominations for four members on the Gila Box Riparian NCA Advisory Committee. The Advisory Committee was created through Title 2, Section 201, of the Arizona Desert Wilderness Act of 1990 to provide informed advice to the Safford Field Manager on management of public lands in the Gila Box Riparian NCA in southeastern Arizona.

Any individual or organization may nominate one or more persons to serve on the Advisory Committee. Persons wishing to nominate themselves or other individuals should submit an application form, which is available from the BLM Safford Field Office or online at *http://www.blm.gov/az* as a link in the News Release section. The application must include at least one letter of recommendation that addresses the nominee's qualifications.

DATES: Nominations and reference letters should be mailed to the BLM address on the application form, and must be received no later than August 30, 2007.

FOR FURTHER INFORMATION CONTACT: For more information contact: Jeff Wilbanks, BLM Safford Field Office, 711 14th Avenue, Safford, AZ 85546; call (928) 348–4573; or e-mail *Jeff_Wilbanks@blm.gov.*

SUPPLEMENTARY INFORMATION: To ensure membership of the Advisory Committee is balanced in terms of categories of interest represented, nominees must be qualified to provide informed advice in specific areas related to the primary purposes for which the NCA was created. These include wildlife conservation, riparian ecology, hydrology, outdoor recreation, watershed management, environmental education, cultural resources, or other related disciplines.

Committee members are selected by the Secretary of the Interior to serve a three-year term, with terms beginning on the date of appointment. The Advisory Committee will meet 1–2

times each year. Members serve without salary, but are reimbursed for travel and per diem expenses at current rates for government employees.

Terms of two committee members will begin serving immediately upon their appointment. Terms of the other two committee members will begin with the expiration of two current memberships that will expire on March 31, 2008. All four current members may apply to serve another term on the Committee.

Dated: July 10, 2007.

Tom Schnell,

Acting Field Manager.

[FR Doc. E7–13796 Filed 7–16–07; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

National Historic Oregon Trail Interpretive Center Advisory Board; Notice of Reestablishment

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of reestablishment of the National Historic Oregon Trail Interpretive Center Advisory Board.

SUMMARY: This notice is published in accordance with Section 9(a)(2) of the Federal Advisory Committee Act of 1972, Public Law 92–463. Notice is hereby given that the Secretary of the Interior has reestablished the Bureau of Land Management's National Historic Oregon Trail Interpretive Center Advisory Board. The purpose of the Advisory Board will be to advise the Bureau of Land Management's Vale District Manager regarding policies, programs, and long-range planning for the management use, and further development of the Interpretive Center; establish a framework for enhanced partnership and participation between the Bureau and the Oregon Trail Preservation Trust; ensure a financially secure, world-class historical and educational facility, operated through a partnership between the Federal Government and the community. This cooperative relationship enriches and maximizes visitor experiences in the region, and improves the coordination of advice and recommendations from the publics served.

FOR FURTHER INFORMATION CONTACT: Douglas Herrema, National Landscape Conservation System (100), Bureau of Land Management, 1620 L Street, NW., Mail Stop 301, Washington, DC 20036, telephone (202) 452–7787.

Certification Statement

I hereby certify that the reestablishment of the National Historic Oregon Trail Interpretive Center Advisory Board is necessary and in the public interest in connection with the Secretary of the Interior's responsibilities to manage the lands, resources, and facilities administered by the Bureau of Land Management.

Dated: May 29, 2007.

Dirk Kempthorne,

Secretary of the Interior.

[FR Doc. 07–3460 Filed 7–16–07; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of extension of an information collection (1010–0150).

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), MMS is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns the paperwork requirements in form MMS–144, Rig Movement Notification Report.

DATES: Submit written comments by September 17, 2007.

ADDRESSES: You may submit comments by any of the following methods listed below. Please use the Information Collection Number 1010–0150 as an identifier in your message.

- E-mail MMS at *rules.comments@mms.gov.* Identify with Information Collection Number 1010–0150 in the subject line.
- Fax: 703–787–1093. Identify with Information Collection Number 1010–0150.
- Mail or hand-carry comments to the Department of the Interior; Minerals Management Service; Attention: Cheryl Blundon; 381 Elden Street, MS–4024; Herndon, Virginia 20170–4817. Please reference ''Information Collection 1010–0150'' in your comments.

FOR FURTHER INFORMATION CONTACT: Cheryl Blundon, Regulations and Standards Branch at (703) 787–1607. You may also contact Cheryl Blundon to obtain a copy, at no cost, of the form that requires the subject collection of information.

SUPPLEMENTARY INFORMATION: *Title:* Form MMS–144, Rig Movement Notification Report.

OMB Control Number: 1010–0150.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior (Secretary) to prescribe rules and regulations to administer leasing of the OCS. Such rules and regulations will apply to all operations conducted under a lease. Operations on the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition. Section 1332(6) of the Act requires that ''operations in the [O]uter Continental Shelf should be conducted in a safe manner by well-trained personnel using technology, precautions, and techniques sufficient to prevent or minimize the likelihood of blowouts, loss of well control, fires, spillages, physical obstruction to other users of the waters or subsoil and seabed, or other occurrences which may cause damage to the environment or to property, or endanger life or health.''

This ICR concerns the regulations in 30 CFR 250 Subparts D, E, and F, specifically §§ 403(c), 502, and 602, on the movement of drilling, completion, and workover rigs and related equipment on and off an offshore platform or from well to well on the same offshore platform. The requirement for operators to notify MMS of rig movements is only specifically stated in § 250.403(c). Since MMS is mandated to perform timely inspections on rigs and platforms, we must have accurate information with regard to their location on the OCS. We use this information in scheduling inspections with regard to priority and cost effectiveness.

However, because of the increased volume of activity in the Gulf of Mexico Region (GOMR), it is now standard MMS procedure to require this notification as a condition of approval for well workover, recompletion, or abandonment operations. Because of this we have included the rig movement notification with the other general information collection requirements of these regulations under OMB Control Numbers 1010–0141, 1010–0067, and 1010–0043 (30 CFR 250, Subparts D, E, and F, respectively). The MMS District

Offices use the information reported to ascertain the precise arrival and departure of all rigs in OCS waters. The accurate location of these rigs is necessary to better facilitate the scheduling of inspections by MMS personnel.

We will protect information from respondents considered proprietary under the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2) and under regulations at 30 CFR 250.197, ''Data and information to be made available to the public or for limited inspection.'' No items of a sensitive nature are collected. Responses are mandatory.

Frequency: On occasion.

Estimated Number and Description of Respondents: Approximately 130 Federal OCS oil and gas lessees.

Estimated Reporting and Recordkeeping ''Hour'' Burden: We estimate respondents will average 6 minutes to fill out and complete Form MMS–144. The total annual estimate is 180 burden hours.

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden: We have identified no cost burdens associated for this collection.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency ''* * * to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *''. Agencies must specifically solicit comments to: (a) Evaluate whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden of the respondents, including the use of automated collection techniques or other forms of information technology.

Agencies must also estimate the ''non-hour costs'' burdens to respondents or recordkeepers resulting form the collection of information. Therefore, if you have costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. You should describe the methods you use to estimate major cost factors, including system and technology acquisition, expected useful life of capital equipment, discount rate(s), and the period over which you incur costs. Capital and startup costs include, among other items, computers and software you purchase to prepare for collecting information, monitoring, and record storage facilities. You should not include estimates for equipment or services purchased: (1) Before October 1, 1995; (ii) to comply with requirements not associated with the information collection; (iii) for reasons other than to provide information or keep records for the Government; or (iv) as part of customary and usual business or private practices.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make any necessary adjustments to the burden in our submission to OMB.

Public Comment Procedures: Before including your address, phone number, email address, or other personal identifying information in you comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

MMS Information Collection Clearance Officer: Arlene Bajusz (202) 208–7744.

Dated: June 20, 2007.

E.P. Danenberger,

Chief, Office of Offshore Regulatory Programs.

[FR Doc. 07–3476 Filed 7–16–07; 8:45 am]

BILLING CODE 4310–MR–M

DEPARTMENT OF THE INTERIOR

National Park Service

Resource Protection Study, Draft Environmental Impact Statement, Curecanti National Recreation Area, CO

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of Availability of the Draft Environmental Impact Statement (EIS) for the Resource Protection Study (RPS), Curecanti National Recreation Area.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), the National Park Service announces the availability of a Draft Environmental Impact Statement for the Resource Protection Study for Curecanti National Recreation Area, Colorado.

Alternatives Evaluated

Alternative 1

Under Alternative 1, the No Action Alternative, NPS would continue to manage the natural, cultural, and recreational resources of Curecanti National Recreation Area (NRA), and associated facilities, pursuant to Reclamation law, NPS law, the 1965 Memorandum of Agreement between NPS and Reclamation (1965 MOA), and other applicable laws and regulations. Reclamation would continue to mange the three dams and reservoirs, power plants, access roads, and other related facilities, to meet the purposes of the Colorado River Storage Project Act (CRSP); and the East Portal area to meet the purposes of the Uncompahgre Project; pursuant to Reclamation law, the 1965 MOA, and other applicable laws and regulations. There would be no significant change in the NRA boundary. However, a permanent NPS presence would not be assured under this alternative.

Alternative 2

Under Alternative 2, the Proposed Action, NPS would manage the same natural, cultural, and recreational resources and facilities as Alternative 1, pursuant to Reclamation law, NPS law, including new legislation establishing the NRA with 10,040 acres of additional agreed-upon neighboring agency lands, a revised MOA with Reclamation, and other applicable laws and regulations. Reclamation would manage their same facilities as Alternative 1, pursuant to Reclamation law, the revised MOA, and other applicable laws and regulations. NPS would be authorized to work in partnership with private landowners within a Conservation Opportunity Area of 24,300 acres outside the NRA boundary, to implement a variety of tools, including acquiring interests in land from willing landowners, which would promote the long-term conservation of resources. A permanent NPS presence would be assured under this alternative, which is also the environmentally preferred alternative.

DATES: The National Park Service will accept comments on the Draft Environmental Impact Statement from the public. Comments will be accepted for 90 days from the date the

Environmental Protection Agency publishes the Notice of Availability. No public meetings are scheduled at this time. However, public meetings will be scheduled in the future, and will be advertised by newsletters and news media in the local areas of Gunnison and Montrose Counties, Colorado, and on the project's Web site, described below.

ADDRESSES: The entire Draft RPS/EIS, and a Summary Document will be available for public review and comment on the project's Web site, described below; and at the following locations in Colorado: (A) Curecanti NRA, 102 Elk Creek, Gunnison, CO 81230, telephone: (970) 641–2337; (B) Montrose Public Lands Center, 2505 South Townsend Avenue, Montrose, CO 81401, telephone (970) 240–5300; (C) Gunnison Public Library; (D) Montrose Public Library; (E) Hotchkiss Public Library; (F) Delta Public Library; and (G) Grand Junction Public Library.

FOR FURTHER INFORMATION CONTACT: (A) Dave Roberts, Management Assistant, telephone: (970) 240–5432 (Montrose, CO); (B) Connie Rudd, Superintendent, telephone: (970) 641–2337 x. 220 (Gunnison, CO); or (C) Jeff Heywood, Project Leader, telephone: (303) 969–2835 (Lakewood, CO).

SUPPLEMENTARY INFORMATION: If you wish to comment, you may do so via the Internet at: *http://parkplanning.nps.gov.* (Under ''Choose a Park,'' select Curecanti NRA, and click on ''GO''; then click on ''Curecanti National Recreation Area Resource Protection Study''; then in the left column, click on ''Open for Public Comment''; then follow the directions for entering comments.) Or you may mail comments to: Curecanti Resource Projection Study Comments, Attn: Dave Roberts, 2465 South Townsend Avenue, Montrose, CO 81401. If you submit comments via the Internet, you should receive electronic confirmation. If not, contact Dave Roberts at (970) 240–5432. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: May 17, 2007.

Michael D. Snyder,

Director, Intermountain Region, National Park Service.

[FR Doc. 07–3487 Filed 7–16–07; 8:45 am]

BILLING CODE 4310–E4–M

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference Advisory Committee on Rules of Civil Procedure

AGENCY: Judicial Conference of the United States, Advisory Committee on Rules of Civil Procedure.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Rule of Civil Procedure will hold a two-day meeting. The meeting will be open to public observation but not participation.

DATES: November 8–9, 2007.

Time: 8:30 a.m. to 5 p.m.

ADDRESSES: Thurgood Marshall Federal Judiciary Building, 4th Floor Agency Conference Room, One Columbus Circle, NE., Washington, DC 20544.

FOR FURTHER INFORMATION CONTACT: John K. Rabiej, Chief, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502–1820.

Dated: July 9, 2007.

James Ishida,

Senior Attorney Advisor, Rules Committee Support Office.

[FR Doc. 07–3467 Filed 7–16–07; 8:45 am]

BILLING CODE 2210–55–M

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference Advisory Committee on Rules of Appellate Procedure

AGENCY: Judicial Conference of the United States, Advisory Committee on Rules of Appellate Procedure.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Rules of Appellate Procedure will hold a two-day meeting. The meeting will be open to public observation but not participation.

DATES: November 1–2, 2007.

Time: 8:30 a.m. to 5 p.m.

ADDRESSES: Four Seasons Hotel, 75 14th Street, Atlanta, Georgia 30309.

FOR FURTHER INFORMATION CONTACT: John K. Rabiej, Chief, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502–1820.

Dated: July 9, 2007.

James Ishida,

Senior Attorney Advisor, Rules Committee Support Office.

[FR Doc. 07–3468 Filed 7–16–07; 8:45 am]

BILLING CODE 2210–55–M

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference Committee on Rules of Criminal Procedure

AGENCY: Judicial Conference of the United States, Advisory Committee on Rules of Criminal Procedure.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Rules of Criminal Procedure will hold a two-day meeting. The meeting will be open to public observation but not participation.

DATES: October 1–2, 2007.

Time: 8:30 a.m. to 5 p.m.

ADDRESSES: Hotel Park City, 2001 Park Avenue, Park City, Utah 84068.

FOR FURTHER INFORMATION CONTACT: John K. Rabiej, Chief, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502–1820.

Dated: July 9, 2007.

James Ishida,

Senior Attorney Advisor, Rules Committee Support Office.

[FR Doc. 07–3469 Filed 7–16–07; 8:45 am]

BILLING CODE 2210–55–M

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference Advisory Committee on Rules of Evidence Procedure

AGENCY: Judicial Conference of the United States, Advisory Committee on Rules of Evidence Procedure.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Rules of Evidence Procedure will hold a one-day meeting. The meeting will be open to public observation but not participation.

DATES: November 16, 2007.

Time: 8:30 a.m. to 5 p.m.

ADDRESSES: Thurgood Marshall Federal Judiciary Building, Mecham Conference Center, One Columbus Circle, NE., Washington, DC 20544.

FOR FURTHER INFORMATION CONTACT: John K. Rabiej, Chief, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502–1820.

Dated: July 9, 2007.

James Ishida,

Senior Attorney Advisor, Rules Committee Support Office.

[FR Doc. 07–3470 Filed 7–16–07; 8:45 am]

BILLING CODE 2210–55–M

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference Advisory Committee on Rules of Bankruptcy Procedure

AGENCY: Judicial Conference of the United States, Advisory Committee on Rules of Bankruptcy Procedure.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Rules of Bankruptcy Procedure will hold a two-day meeting. The meeting will be open to public observation but not participation.

DATES: September 6–7, 2007.

Time: 8:30 a.m. to 5 p.m.

ADDRESSES: Teton Mountain Lodge & Spa, 3385 West Village Drive, Teton Village, Wyoming 83025.

FOR FURTHER INFORMATION CONTACT: John K. Rabiej, Chief, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502–1820.

Dated: July 9, 2007.

James Ishida,

Senior Attorney Advisor, Rules Committee Support Office.

[FR Doc. 07–3471 Filed 7–16–07; 8:45 am]

BILLING CODE 2210–55–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,759]

Agilent Technologies Global Infrastructure Organization Loveland, Colorado; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on June 28, 2007 in response to a petition filed by a company official on behalf of a worker of Agilent Technologies, Electronic Measurements Group, Loveland, Colorado, in support of Agilent Technologies, Global Infrastructure Organization, Santa Clara, California.

The worker on whose behalf the petition is filed is covered by an active certification, (TA–W–60,320, as amended) which expires on November 21, 2008. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC this 5th day of July 2007.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–13777 Filed 7–16–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–60,320; TA–W–60,320A]

Agilent Technologies, Global Infrastructure Organization, Santa Clara, CA; Including an Employee in Support of Agilent Technologies, Global Infrastructure Organization, Santa Clara, CA Located in Loveland, CO; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification Regarding Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on November 21, 2006, applicable to workers of Agilent Technologies, Global Infrastructure Organization, Santa Clara, California. The notice was published in the **Federal Register** on December 8, 2006 (71 FR 71195).

At the request of company officials, the Department reviewed the certification for workers of the subject firm. New information shows that a worker separation occurred involving an employee in support of the Santa Clara, California facility of Agilent Technologies, Global Infrastructure Organization located in Loveland, Colorado.

Mr. David Herder provided management function services of the Global Infrastructure Organization's programs and suppliers for the Santa Clara, California location of the subject firm.

Based on these findings, the Department is amending this certification to include an employee in support of the Santa Clara, California facility of Agilent Technologies, Global Infrastructure Organization, located in Loveland, Colorado.

The intent of the Department's certification is to include all workers of Agilent Technologies, Global Infrastructure Organization, Santa Clara, California who were adversely affected by increased company imports.

The amended notice applicable to TA–W–60,320 is hereby issued as follows:

''All workers of Agilent Technologies, Global Infrastructure Organization, Santa Clara, California (TA–W–60,320), and including an employee in support of Agilent Technologies, Global Infrastructure Organization, Santa Clara, California, located in Loveland, Colorado (TA–W–60,320A), who became totally or partially separated from employment on or after October 24, 2005, through November 21, 2008, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974 and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.''

Signed at Washington, DC this 5th day of July 2007.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–13780 Filed 7–16–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,748]

The Apparel Group, Foxcroft Sportswear Division, Fall River, MA; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on June 26, 2007 in response to a worker petition filed by a company official on behalf of workers at The Apparel Group, Foxcroft Sportswear Division, Fall River, Massachusetts.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC this 3rd day of July, 2007.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–13788 Filed 7–16–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,032]

Baker Furniture, Grand Rapids, Michigan; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Baker Furniture, Grand Rapids, Michigan. The application did not contain new information supporting a conclusion that the determination was erroneous, and also did not provide a justification for reconsideration of the determination that was based on either mistaken facts or a misinterpretation of facts or of the law. Therefore, dismissal of the application was issued.

TA–W–61,032; Baker Furniture Grand Rapids, Michigan (July 3, 2007).

Signed at Washington, DC this 9th day of July 2007.

Linda G. Poole,

Certifying Officer Division of Trade Adjustment Assistance.

[FR Doc. E7–13781 Filed 7–16–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,324]

Ford Motor Company, Vehicle Operations Division, Wixom Assembly Plant, Wixom, MI; Notice of Affirmative Determination Regarding Application for Reconsideration

By application dated June 22, 2007, the United Automobile, Aerospace & Agricultural Implement Workers of America requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance, applicable to workers and former workers of the subject firm. The determination was signed on May 7, 2007 and published in the **Federal Register** on May 24, 2007 (72 FR 29182).

The initial investigation resulted in a negative determination based on the finding that imports of vehicles like or directly competitive with the Lincoln Towncar did not contribute importantly to worker separations at the subject firm and no shift of production to a foreign source occurred.

The Department reviewed the request for reconsideration and has determined that the petitioner has provided additional information. Therefore, the Department will conduct further investigation to determine if the workers meet the eligibility requirements of the Trade Act of 1974.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed in Washington, DC, this 10th day of July, 2007.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–13786 Filed 7–16–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

[TA–W–61,281]

Employment and Training Administration: Form Tech Industries, Llc, Canal Fulton, OH; Notice of Revised Determination on Reconsideration

On June 27, 2007, the Department issued an Affirmative Determination Regarding Application on Reconsideration applicable to workers and former workers of the subject firm. The notice will soon be published in the **Federal Register**.

The previous investigation initiated on April 11, 2007, resulted in a negative determination issued on May 9, 2007, was based on the finding that imports of machine parts, such as shafts and sheaves for CVT transmissions did not contribute importantly to worker separations at the subject firm and no shift of production to a foreign source occurred. The denial notice was published in the **Federal Register** on May 24, 2007 (72 FR 29182).

In the request for reconsideration, the petitioner provided additional information regarding the subject firm's declining customers.

The Department requested additional list of customers from the subject firm and conducted a survey of a major declining customer regarding its purchases of like or directly competitive products with machine parts, such as shafts and sheaves for CVT transmission. It was revealed that the major declining customer increased its reliance on imports of machine parts, such as shafts and sheaves for CVT transmission while decreasing their purchases from the subject firm during the relevant period. The increases in imports accounted for a meaningful portion of the subject plant's lost sales.

In accordance with Section 246 the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor herein presents the results of its investigation regarding certification of eligibility to apply for alternative trade adjustment assistance (ATAA) for older workers.

In order for the Department to issue a certification of eligibility to apply for ATAA, the group eligibility requirements of Section 246 of the Trade Act must be met. The Department has determined in this case that the requirements of Section 246 have been met.

A significant number of workers at the firm are age 50 or over and possess skills that are not easily transferable. Competitive conditions within the industry are adverse.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that increased imports of articles like or directly competitive with those produced at Form Tech Industries, LLC, Canal Fulton, Ohio, contributed importantly to the declines in sales or production and to the total or partial separation of workers at the subject firm. In accordance with the provisions of the Act, I make the following certification:

''All workers of Form Tech Industries, LLC, Canal Fulton, Ohio, who became totally or partially separated from employment on or after April 3, 2006, through two years from the date of this certification, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.''

Signed in Washington, DC this 11th day of July 2007.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–13784 Filed 7–16–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,268]

Hewlett-Packard Company, Technology Solutions Group—Global Mission Critical Solution Center—Nonstop Tech/Proactive, Austin, TX; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Hewlett-Packard Company, Technology Solutions Group—Global Mission Critical Solution Center—Nonstop Tech/Proactive, Austin, Texas. The application did not contain new information supporting a conclusion that the determination was erroneous, and also did not provide a justification for reconsideration of the determination that was based on either mistaken facts or a misinterpretation of facts or of the law. Therefore, dismissal of the application was issued.

TA–W–61,268; Hewlett-Packard Company Technology Solutions Group—Global Mission Critical Solution Center—Nonstop Tech/Proactive, Austin, Texas (July 3, 2007).

Signed at Washington, DC this 9th day of July 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–13783 Filed 7–16–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221 (a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than July 27, 2007.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than July 27, 2007.

The petitions filed in this case are available for inspection at the Office of the Director, Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room C–5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 10th day of July 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

APPENDIX

[TAA petitions instituted between 7/2/07 and 7/6/07]

TA–W	Subject Firm (Petitioners)	Location	Date of institution	Date of petition
61769	Hot Sox Warehouse (Comp)	Secaucus, NJ	07/02/07	06/28/07
61770	JDSU/Los Coches Assembly and Test (Comp)	Milpitas, CA	07/02/07	06/29/07
61771	Keeco LLC (State)	San Francisco, CA	07/02/07	06/29/07
61772	Emerson Network Power—Embedded Computing (Comp)	Madison, WI	07/02/07	06/29/07
61773	Robert Bosch Tool Corporation/Gilmour (Comp)	Somerset, PA	07/02/07	06/29/07
61774	NxStage Medical Inc. (State)	Lawrence, MA	07/02/07	06/29/07
61775	Tandy Brands Accessories (Comp)	Yoakum, TX	07/02/07	06/28/07
61776	Nordsom Corporation—Lincoln Alabama Facility (Comp)	Lincoln, AL	07/03/07	07/02/07
61777	Intersil Corporation (Wkrs)	Palm Bay, FL	07/03/07	07/02/07
61778	Coolbrands International/Integrated Brands (Wkrs)	Ronkonkoma, NY	07/03/07	06/27/07
61779	Siemens Power Transmission and Distribution (Comp)	Wendell, NC	07/03/07	06/29/07
61780	Harman Becker Automotive Systems, Inc. (Comp)	Martinsville, IN	07/05/07	06/28/07
61781	ThyssenKrupp Forging (Wkrs)	Danville, IL	07/05/07	06/22/07
61782	Dent Manufacturing Inc. (Comp)	Northhampton, PA	07/05/07	06/19/07
61783	H. Koch and Sons Co. (Wkrs)	Anaheim, CA	07/05/07	06/25/07
61784	SPSS, Inc. (Wkrs)	Oconomowoc, WI	07/05/07	07/03/07
61785	Risdon International, Inc. (State)	Middletown, CT	07/05/07	07/03/07
61786	SPM Corporation (Wkrs)	Woburn, MA	07/05/07	07/02/07
61787	National City Mortgage Corp. (Wkrs)	Miamisburg, OH	07/05/07	06/10/07
61788	TI Automotive Systems (Comp)	Chesterfield, MI	07/05/07	07/02/07
61789	Fraser Papers Limited (Comp)	Madawaska, ME	07/05/07	06/26/07
61790	State Farm Insurance (Wkrs)	Newark, OH	07/05/07	07/03/07
61791	Mahle Industries, Inc. (Comp)	Franklin, KY	07/05/07	07/03/07
61792	Precision Resource (Comp)	Shelton, CT	07/05/07	07/03/07
61793	Phillips Brothers, Inc. (Comp)	Springfield, IN	07/05/07	07/05/07
61794	Rockland Industries (Comp)	Baltimore, MD	07/06/07	07/02/07
61795	Convergys Information Managment Group (Wkrs)	Wilkes-Barre, PA	07/06/07	06/30/07
61796	Greatbatch Hittman, Inc. (Comp)	Columbia, MD	07/06/07	07/06/07

[FR Doc. E7–13778 Filed 7–16–07; 8:45 am]
BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,438]

TMP Directional Marketing, LLC Graphics Division, Fort Wayne, IN; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at TMP Directional Marketing, LLC, Graphics Division, Fort Wayne, Indiana. The application did not contain new information supporting a conclusion that the determination was erroneous, and also did not provide a justification for reconsideration of the determination that was based on either mistaken facts or a misinterpretation of facts or of the law. Therefore, dismissal of the application was issued.

TA–W–61,438; TMP Directional Marketing, LLC Graphics Division, Fort Wayne, Indiana (July 3, 2007)

Signed at Washington, DC this 9th day of July 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–13787 Filed 7–16–07; 8:45 am]
BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,180]

Welex, Inc., Blue Bell, PA; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Welex, Inc., Blue Bell, Pennsylvania. The application did not contain new information supporting a conclusion that the determination was erroneous, and also did not provide a justification for reconsideration of the determination that was based on either mistaken facts or a misinterpretation of facts or of the law. Therefore, dismissal of the application was issued.

TA–W–61,180; Welex, Inc. Blue Bell, Pennsylvania (July 3, 2007).

Signed at Washington, DC this 9th day of July 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–13782 Filed 7–16–07; 8:45 am]
BILLING CODE 4510–FN–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Renewal of Advisory Committee on Preservation.

This notice is published in accordance with the provisions of section 9(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.) and advises of the renewal of the National Archives and Records Administration's (NARA) Advisory Committee on Preservation for a two-year period. In accordance with Office of Management and Budget (OMB) Circular A–135, OMB approved the inclusion of the Advisory Committee on Preservation in NARA's ceiling of discretionary advisory committees.

The Archivist of the United States has determined that the renewal of the Advisory Committee on Preservation is in the public interest due to the expertise and valuable advice the committee members provide on technical preservation issues affecting all types of media. NARA uses the Committee's recommendations in its implementation of strategies for preserving the permanently valuable records of the Federal Government.

Dated: July 12, 2007.

Mary Ann Hadyka,

Committee Management Officer.

[FR Doc. E7–13836 Filed 7–16–07; 8:45 am]
BILLING CODE 7515–01–P

NATIONAL COUNCIL ON DISABILITY

Sunshine Act Meetings

TYPE: Quarterly Meeting.

DATES AND TIMES:
July 24, 2007, 8:30 a.m.–3:30 p.m.
July 25, 2007, 8:30 a.m.–3 p.m.
July 26, 2007, 9 a.m.–4 p.m.

LOCATION: Crowne Plaza Hotel Metro, 733 West Madison, Chicago, Illinois.

STATUS:
July 24, 2007, 8:30 a.m.–3:30 p.m.—Open.
July 25, 2007, 8:30 a.m.–3 p.m.—Open.
July 26, 2007, 8 a.m.–9:00 a.m.—Closed.
July 26, 2007, 9 a.m.–4 p.m.—Open.

AGENDA: Public Comment Sessions; Livable Communities/Mental Health Best Practices Panel Presentation; Emergency Preparedness Panel Presentation; Reports from the Chairperson, Council Members, and the Executive Director; Strategic Planning; Budget Planning; ADA Reports Release News Conference; Unfinished Business; New Business; Announcements; Adjournment.

SUNSHINE ACT MEETING CONTACT: Mark S. Quigley, Director of Communications, NCD, 1331 F Street, NW., Suite 850, Washington, DC 20004; 202–272–2004 (voice), 202–272–2074 (TTY), 202–272–2022 (fax).

AGENCY MISSION: NCD is an independent Federal agency and is composed of 15 members appointed by the President, by and with the advice and consent of the Senate. NCD provides advice to the President, Congress, and executive branch agencies promoting policies, programs, practices, and procedures that (A) guarantee equal opportunity for all individuals with disabilities, regardless of the nature or severity of the disability; and (B) empower individuals with disabilities to achieve economic self-sufficiency, independent living, and inclusion and integration into all aspects of society.

ACCOMMODATIONS: Those needing reasonable accommodations should notify NCD immediately.

LANGUAGE TRANSLATION: In accordance with E.O. 13166, Improving Access to Services for Persons with Limited English Proficiency, those people with disabilities who are limited English proficient and seek translation services for these meetings should notify NCD immediately.

Dated: July 12, 2007.

Michael C. Collins,

Executive Director.

[FR Doc. 07–3484 Filed 7–13–07; 11:08 am]
BILLING CODE 6820–MA–M

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting Notice

TIME AND DATE: 9:30 a.m., Thursday, July 26, 2007.

PLACE: NTSB Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594.

STATUS: The one item is open to the public.

MATTER TO BE CONSIDERED:

7838D *Aviation Accident Report*—Attempted Takeoff from Wrong Runway, Comair Flight 5191, Bombardier CL–600–2B19,

N431CA, Lexington, Kentucky, August 27, 2006.

NEWS MEDIA CONTACT: Telephone: (202) 314–6100.

Individuals requesting specific accommodations should contact Chris Bisett (202) 314–6305 by Friday, July 20, 2007.

The public may view the meeting via a live or archived webcast by accessing a link under ''News & Events'' on the NTSB home page at *www.ntsb.gov.*

FOR FURTHER INFORMATION CONTACT: Vicky D'Onofrio, (202) 314–6410.

Dated: July 13, 2007.

Vicky D'Onofrio,

Federal Register Liaison Officer.

[FR Doc. 07–3491 Filed 7–13–07; 1:34 pm]

BILLING CODE 7533–01–M

NUCLEAR REGULATORY COMMISSION

Sunshine Federal Register Notice

DATES: Weeks of July 16, 23, 30, August 6, 13, 20, 2007.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of July 16, 2007

Wednesday, July 18, 2007

10 a.m. Discussion of Security Issues (closed—ex. 1 & 3).

1 p.m. Briefing on Digital Instrumentation and Control (Public Meeting). (Contact: William Kemper, (301) 415–7585).

This meeting will be webcast live at the Web address, *www.nrc.gov*.

Week of July 23, 2007—Tentative

Tuesday, July 24, 2007

9:30 a.m. Preparation for the 2008 Convention on Nuclear Safety (closed—ex. 9).

2 p.m. Briefing on Palo Verde Nuclear Generating Station (Public Meeting). (Contact: Michael Markley, (301) 415–5723).

This meeting will be webcast live at the Web address, *www.nrc.gov*.

Wednesday, July 25, 2007

2 p.m. Discussion of Management Issues (closed—ex. 2).

Week of July 30, 2007—Tentative

Thursday, August 2, 2007

1:30 p.m. Briefing on Risk-Informed, Performance-Based Regulation (Public Meeting). (Contact: John Monninger, (301) 415–6189).

This meeting will be webcast live at the Web address, *www.nrc.gov*.

Week of August 6, 2007—Tentative

There are no meetings scheduled for the Week of August 6, 2007.

Week of August 13, 2007—Tentative

There are no meetings scheduled for the Week of August 13, 2007.

Week of August 20, 2007—Tentative

Tuesday, August 21, 2007

1:30 p.m. Meeting with OAS and CRCPD (Public Meeting). (Contact: Shawn Smith, (301) 415–2620).

This meeting will be webcast live at the Web address, *www.nrc.gov*.

Wednesday, August 22, 2007

9:30 a.m. Periodic Briefing on New Reactor Issues (Public Meeting).

This meeting will be webcast live at the Web address, *www.nrc.gov*.

* * * * *

* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Michelle Schroll, (301) 415–1662.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *www.nrc.gov/about-nrc/policy-making/schedule.html*.

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify the NRC's Disability Program Coordinator, Rohn Brown, at 301–492–2279, TDD: 301–415–2100, or by e-mail at *REB3@nrc.gov*. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov*.

Dated: July 12, 2007.

Rochelle C. Bavol,

Office of the Secretary.

[FR Doc. 07–3481 Filed 7–13–07; 11:09 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Biweekly Notice; Applications and Amendments to Facility Operating Licenses; Involving No Significant Hazards Considerations

I. Background

Pursuant to section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. The Act requires the Commission publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from June 21, 2007 to July 3, 2007. The last biweekly notice was published on July 3, 2007 (72 FR 36520).

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final

determination. Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rulemaking, Directives and Editing Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner/requestor intends to rely in proving the contention at the hearing. The petitioner/requestor must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner/requestor intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner/requestor to relief. A petitioner/requestor who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; (2) courier, express mail, and expedited delivery services: Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff; (3) E-mail addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, *HearingDocket@nrc.gov*; or (4) facsimile transmission addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, Attention: Rulemaking and Adjudications Staff at (301) 415–1101, verification number is (301) 415–1966. A copy of the request for hearing and

petition for leave to intervene should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and it is requested that copies be transmitted either by means of facsimile transmission to (301) 415–3725 or by e-mail to *OGCMailCenter@nrc.gov*. A copy of the request for hearing and petition for leave to intervene should also be sent to the attorney for the licensee.

Nontimely requests and/or petitions and contentions will not be entertained absent a determination by the Commission or the presiding officer of the Atomic Safety and Licensing Board that the petition, request and/or the contentions should be granted based on a balancing of the factors specified in 10 CFR 2.309(a)(1)(i)–(viii).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the ADAMS Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html*. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov*.

Nuclear Management Company, LLC, Docket Nos. 50–282 and 50–306, Prairie Island Nuclear Generating Plant (PINGP), Units 1 and 2, Goodhue County, Minnesota

Date of amendment request: May 10, 2007.

Description of amendment request: The proposed amendments would modify the Technical Specifications (TS) by removing the specific isolation time for the main steam isolation valves from the associated TS Surveillance Requirements (SRs) and by replacing it with the requirement to verify the valve isolation time is within limits. The changes are consistent with Nuclear Regulatory Commission (NRC) approved Industry/Technical Specification Task Force (TSTF)–491, Removal of the Main Steam and Main Feedwater Valve Isolation Time from Technical Specifications, Revision 2. The proposed amendments deviate from TSTF–491 in that the current PINGP TS and associated SRs for the main feedwater isolation valves do not include valve closure times, and thus these changes in TSTF–491 are not applicable to the PINGP TSs and are not adopted.

The NRC staff issued a notice of opportunity for comment in the **Federal Register** on October 5, 2006 (71 FR 58884), on possible amendments concerning the consolidation line item improvement process (CLIIP), including a model safety evaluation and a model no significant hazards consideration determination. The NRC staff subsequently issued a notice of availability of the models for referencing in license amendment applications in the **Federal Register** on December 29, 2006 (71 FR 78472) as part of the CLIIP. In its application dated May 10, 2007, the licensee affirmed the applicability of the following determination.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated

The proposed change allows relocating main steam and main feedwater valve isolation times to the Licensee Controlled Document that is referenced in the Bases. The proposed change is described in Technical Specification Task Force (TSTF) Standard TS Change Traveler TSTF–491 related to relocating the main steam and main feedwater valves isolation times to the Licensee Controlled Document that is referenced in the Bases and replacing the isolation time with the phrase, within limits.

The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed). The proposed changes relocate the main steam and main feedwater isolation valve times to the Licensee Controlled Document that is referenced in the Bases. The requirements to perform the testing of these isolation valves are retained in the TS. Future changes to the Bases or licensee-controlled document will be evaluated pursuant to the requirements of 10 CFR 50.59, Changes, test and experiments, to ensure that such changes do not result in more than minimal increase in the probability or consequences of an accident previously evaluated.

The proposed changes do not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, and configuration of the facility or the manner in which the plant is operated and maintained. The proposed changes do not adversely affect the ability of structures, systems and components (SSCs) to perform their intended safety function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed changes do not affect the source term, containment isolation, or radiological consequences of any accident previously evaluated. Further, the proposed changes do not increase the types and the amounts of radioactive effluent that may be released, nor significantly increase individual or cumulative occupation/public radiation exposures.

Therefore, the changes do not involve a significant increase in the probability or consequences of any accident previously evaluated.

Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From any Previously Evaluated

The proposed changes relocate the main steam and main feedwater valve isolation times to the Licensee Controlled Document that is referenced in the Bases. In addition, the valve isolation times are replaced in the TS with the phrase ''within limits.'' The changes do not involve a physical altering of the plant (i.e., no new or different type of equipment will be installed) or a change in methods governing normal plant operation. The requirements in the TS continue to require testing of the main steam and main feedwater isolation valves to ensure the proper functioning of these isolation valves.

Therefore, the changes do not create the possibility of a new or different kind of accident from any previously evaluated.

Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety

The proposed changes relocate the main steam and main feedwater valve isolation times to the Licensee Controlled Document that is referenced in the Bases. In addition, the valve isolation times are replaced in the TS with the phrase ''within limits.'' Instituting the proposed changes will continue to ensure the testing of main steam and main feedwater isolation valves. Changes to the Bases or license controlled document are performed in accordance with 10 CFR 50.59. This approach provides an effective level of regulatory control and ensures that main steam and feedwater isolation valve testing is conducted such that there is no significant reduction in the margin of safety.

The margin of safety provided by the isolation valves is unaffected by the proposed changes since there continue to be TS requirements to ensure the testing of main steam and main feedwater isolation valves. The proposed changes maintain sufficient controls to preserve the current margins of safety.

The NRC staff has reviewed the licensees analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

Attorney for licensee: Jonathan Rogoff, Esquire, Vice President, Counsel & Secretary, Nuclear Management Company, LLC, 700 First Street, Hudson, WI 54016.

NRC Acting Branch Chief: Travis L. Tate.

Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50–321 and 50–366, Edwin I. Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia

Date of amendment request: October 30, 2006.

Description of amendment request: The proposed amendment would revise Technical Specification (TS) Section 5.3.1, Administrative controls, to (1) Improve administrative flexibility and clarity in the wording of the specification and (2) replace a specific position title with a generic position title for the senior individual in charge of health physics.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed change to Technical Specifications Administrative Controls Section 5.3.1 involves the use of a more generic designation for the unit staff position responsible for Health Physics without reducing the level of authority required for that position. The proposed change also allows the flexibility to use an accredited program for qualifying personnel to fill unit staff positions, which represents an acceptable alternative to the qualification requirements for these positions as currently specified in the Technical Specifications. Since the proposed changes are administrative in nature, they do not involve any physical changes to any structures, systems, or components, nor will their performance requirements be altered. The proposed changes also do not affect the operation, maintenance, or testing of the plant. Therefore, the response of the plant to previously analyzed accidents will not be affected. Consequently, the proposed changes do not involve a significant increase or any increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any previously evaluated?

The proposed changes to the Technical Specifications will have no adverse impact on the overall qualification of the unit staff. The use of a more generic designation for the unit staff position responsible for Health Physics and the alternative use of an accredited program that has been endorsed by the NRC will ensure the educational requirements and power plant experience for each unit staff position are properly satisfied and will continue to fulfill applicable regulatory requirements. Also, since no change is being made to the design, operation, maintenance, or testing of the plant, no new methods of operation or failure modes are introduced by the proposed changes. Therefore, the possibility of a new or different kind of accident from any previously evaluated is not created.

3. Does the proposed change involve a significant decrease in the margin of safety?

The proposed changes to the Technical Specifications will have no adverse impact on the onsite organizational features necessary to assure safe operation of the plant. Lines of authority for plant operation are unaffected by the proposed changes. Also, the adoption of the more generic designation of the individual responsible for Health Physics will reduce the regulatory burden of having to devote limited resources to process a license amendment whenever a title change for this position is implemented. Accordingly, this reduction in regulatory burden and the option to use an accredited program endorsed by NRC to qualify the unit staff will improve plant efficiency without compromising plant safety. Therefore, the proposed changes do not involve a significant decrease in the margin of safety.

The NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ernest L. Blake, Jr., Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Branch Chief: Evangelos C. Marinos.

Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50–321 and 50–366, Edwin I. Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia

Date of amendment request: June 5 and June 11, 2007.

Description of amendment request: The proposed amendment would revise Technical Specification (TS) 3.1.4, Control Rod Scram Times, using the consolidated line-term improvement process. These changes are based on TS Task Force (TSTF) change traveler TSTF–460, that has been approved generically for the boiling water reactor (BWR) Standard TS, NUREG–1433 (BWR/4). The frequency of Surveillance Requirement 3.1.4.2, control rod scram time testing, is revised from ''120 days cumulative operation in MODE 1'' to ''200 days cumulative operation in MODE 1.''

The NRC staff issued a notice of availability of a model safety evaluation and model no significant hazards consideration (NSHC) determination for referencing in license amendment applications in the **Federal Register** on August 23, 2004 (69 FR 51854). The licensee affirmed the applicability of the model NSHC determination in its application and supplement dated June 5 and June 11, 2007.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change extends the frequency for testing control rod scram time testing from every 120 days of cumulative Mode 1 operation to 200 days of cumulative Mode 1 operation. The frequency of surveillance testing is not an initiator of any accident previously evaluated. The frequency of surveillance testing does not affect the ability to mitigate any accident previously evaluated, as the tested component is still required to be operable. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change extends the frequency for testing control rod scram time testing from every 120 days of cumulative Mode 1 operation to 200 days of cumulative Mode 1 operation. The proposed change does not result in any new or different modes of plant operation. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change extends the frequency for testing control rod scram time testing from every 120 days of cumulative Mode 1 operation to 200 days of cumulative Mode 1 operation. The proposed change continues to test the control rod scram time to ensure the assumptions in the safety analysis are protected. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ernest L. Blake, Jr., Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Branch Chief: Evangelos C. Marinos.

Virginia Electric and Power Company, Docket Nos. 50–280 and 50–281, Surry Power Station, Unit Nos. 1 and 2, Surry County, Virginia

Date of amendment request: June 25, 2007.

Description of amendment request: The proposed change increases the

maximum Technical Specification (TS) service water (SW) temperature limit from 95 °F to 100 °F, and revises the TS Figure 3.8–1, which provides allowable containment air partial pressure versus SW temperature.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Operating with increased maximum service water temperature limits does not affect the frequency of accident initiating events. Therefore, the probability of an accident previously analyzed is not increased. Plant systems supported by SW have been evaluated for operation with a service water temperature limit of 100 °F, and it determined that there is no operational impact when operating at the higher SW temperature.

Although the service water temperature limit is being increased, the containment will continue to meet its design basis acceptance criteria following a large-break loss of coolant accident as identified in the UFSAR [Updated Final Safety Analysis Report]. Therefore, there is no increase in the consequences of any accident previously evaluated resulting from operation of Surry Units 1 and 2 with an increased service water temperature limit.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

There are no new failure modes or mechanisms associated with operating Surry Units 1 and 2 with an increased service water temperature limit of 100 °F. As noted above, the increased service water temperature limit does not affect plant operation, since plant systems supported by SW have been evaluated for operation with a SW temperature limit of 100 °F and no operational impact was identified. Therefore, there are no new or different kinds of accidents created by operation of Surry Units 1 and 2 with increased service water temperature limits.

3. Does the proposed change involve a significant reduction in the margin of safety?

The containment analysis acceptance criteria continue to be met when operating with the proposed increased maximum service water temperature limit. Containment integrity will not be challenged and will continue to meet its design basis acceptance criteria following a large break loss of coolant accident. Therefore, the existing margin of safety is not significantly reduced by operation of Surry Units 1 and 2 with increased service water temperature limits.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lillian M. Cuoco, Esq., Senior Counsel, Dominion Resources Services, Inc., Millstone Power Station, Building 475, 5th Floor, Rope Ferry Road, Rt. 156, Waterford, Connecticut 06385.

NRC Branch Chief: Evangelos C. Marinos.

Notice of Issuance of Amendments to Facility Operating Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) The applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html*. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov*.

AmerGen Energy Company, LLC, Docket No. 50–289, Three Mile Island Nuclear Station, Unit 1 (TMI–1), Dauphin County, Pennsylvania

Date of application for amendment: September 15, 2006, as supplemented by letters dated February 26, May 22, and June 5, 2007.

Brief description of amendment: The amendment revised Technical Specification Section 6.8.5, ''Reactor Building Leakage Rate Testing Program,'' to allow a one-time deferral of the next Type A, containment integrated leak rate test from ''no later than September 2008'' to ''prior to startup from T1R18 refueling outage. The T1R18 refueling outage will begin no later than November 1, 2009.''

Date of issuance: June 29, 2007.

Effective date: As of the date of issuance and shall be implemented within 60 days.

Amendment No. 259.

Facility Operating License No. DPR–50. Amendment revised the license and the technical specifications.

Date of initial notice in ***Federal Register****:* December 19, 2006 (71 FR 75989).

The supplements dated February 26, May 22, and June 5, 2007 provided additional information that clarified the application, did not expand the scope of the application as originally noticed and did not change the NRC staff's original proposed no significant hazards determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated June 29, 2007.

No significant hazards consideration comments received: No.

Carolina Power & Light Company, Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of application for amendment: July 17, 2006.

Brief description of amendment: This amendment revises the containment design pressure requirements in Surveillance Requirements 3.6.8 and 5.5.16 due to a revision in the loss-of-coolant accident containment pressure analysis.

Date of issuance: June 15, 2007.

Effective date: As of the date of issuance and shall be implemented within 60 days.

Amendment No. 215.

Renewed Facility Operating License No. DPR–23. Amendment revises the technical specifications.

Date of initial notice in ***Federal Register****:* August 29, 2006 (71 FR 51225).

The Commission's related evaluation of the amendment is contained in a safety evaluation dated June 15, 2007.

No significant hazards consideration comments received: No.

Duke Power Company LLC, et al., Docket Nos. 50–413 and 50–414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina

Date of application for amendments: June 5, 2006 as supplemented April 4, 2007.

Brief description of amendments: The amendments revised the Technical Specification (TS) Section 3.8.1, ''AC Sources—Operating,'' surveillance requirement (SR) 3.8.1.13. The changes revised TS SR 3.8.1.13 and its associated Bases to state that the SR only verifies that non-emergency diesel generator (DG) trips are bypassed. The licensee stated that this change is based upon and consistent with Industry Technical Specification Task Force (TSTF), Standard TS Traveler, TSTF–400–A, Revision 1, ''Clarify Surveillance Requirement on Bypass of DG Automatic Trips.''

Date of issuance: June 25, 2007.

Effective date: As of the date of issuance and shall be implemented within 30 days from the date of issuance.

Amendment Nos.: 236, 232.

Facility Operating License Nos. NPF–68 and NPF–81: Amendments revised the licenses and the technical specifications.

Date of initial notice in ***Federal Register****:* December 5, 2006 (71 FR 70555).

The supplement dated April 4, 2007, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 25, 2007.

No significant hazards consideration comments received: No.

Duke Power Company LLC, Docket Nos. 50–369 and 50–370, McGuire Nuclear Station,Units 1 and 2, Mecklenburg County, North Carolina

Date of application for amendments: June 5, 2006, as supplemented April 4, 2007.

Brief description of amendments: The amendments revised TS 3.8.1, ''AC Sources—Operating,'' surveillance requirement (SR) 3.8.1.13. The changes revise the SR 3.8.1.13 and its associated Bases to state that the SR only verifies that non-emergency diesel generator (DG) trips are bypassed. The licensee stated that this change is based upon and consistent with Industry Technical Specification Task Force (TSTF), Standard TS Traveler, TSTF–400–A, Revision 1, ''Clarify Surveillance Requirement on Bypass of DG Automatic Trips.''

Date of issuance: June 25, 2007.

Effective date: As of the date of issuance and shall be implemented within 30 days from the date of issuance.

Amendment Nos.: 242, 223.

Renewed Facility Operating License Nos. NPF–9 and NPF–17: Amendments revised the licenses and the technical specifications.

Date of initial notice in ***Federal Register****:* December 5, 2006 (71 FR 70555).

The supplement dated April 4, 2007, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 25, 2007.

No significant hazards consideration comments received: No.

Entergy Nuclear Operations, Inc., Docket No. 50–333, James A. FitzPatrick Nuclear Power Plant, Oswego County, New York

Date of application for amendment: February 15, 2007.

Brief description of amendment: The proposed amendment would revise Technical Specification (TS) Section 3.10.1, ''Inservice Leak and Hydrostatic Testing Operation,'' to expand its scope to include provisions for temperature excursions greater than 212 °F as a consequence of inservice leak or hydrostatic testing, and to allow performance of control rod scram time testing and other required testing when initiated in conjunction with the performance of an inservice leak or hydrostatic test, while considering operational conditions to be in Mode 4. The changes are consistent with NRC approved Revision 0 to Technical Specification Task Force (TSTF) Improved Standard Technical Specification Change Traveler, TSTF–484, ''Use of TS 3.10.1 for Scram Time Testing Activities.''

Date of issuance: June 21, 2007.

Effective date: As of the date of issuance, and shall be implemented within 30 days.

Amendment No.: 288.

Facility Operating License No. DPR–59: The amendment revised the License and the Technical Specifications.

Date of initial notice in ***Federal Register****:* April 10, 2007 (72 FR 17947).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated June 21, 2007.

No significant hazards consideration comments received: No.

Entergy Operations, Inc., Docket No. 50–368, Arkansas Nuclear One, Unit No. 2, Pope County, Arkansas

Date of application for amendment: March 15, 2007.

Brief description of amendment: The amendment revises the Surveillance Requirement (SR) 4.6.2.1.d to require verification that containment spray nozzles are unobstructed following maintenance that could result in nozzle blockage, in lieu of the current SR of performing the test every 5 years.

Date of issuance: July 2, 2007.

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment No.: 272.

Renewed Facility Operating License No. NPF–6: Amendment revised the Technical Specifications/license.

Date of initial notice in ***Federal Register:*** April 24, 2007 (72 FR 20381).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 2, 2007.

No significant hazards consideration comments received: No.

Exelon Generation Company, LLC, Docket Nos. 50–237 and 50–249, Dresden Nuclear Power Station, Units 2 and 3, Grundy County, Illinois

Date of application for amendment: June 2, 2006, as supplemented by letters dated August 18, 2006, October 5, 2006, and January 11, 2007.

Brief description of amendment: The amendments revise technical specification to increase the allowable as-found main steam safety valve code safety function lift setpoint tolerance from ±1 percent to ±3 percent to align Dresden Nuclear Power Station, Units 2 and 3, with the American Society of Mechanical Engineers Code for Operation and Maintenance of Nuclear Power Plants and reduce the number of non-safety significant Licensee Event Reports written due to TS violations caused by setpoint drifting.

Date of issuance: June 21, 2007.

Effective date: As of the date of issuance and shall be implemented within 60 days.

Amendment Nos.: 223 and 215.

Renewed Facility Operating License Nos. DPR–19 and DPR–25: The amendments revised the Technical Specifications and License.

Date of initial notice in ***Federal Register:*** August 15, 2006 (71 FR 46929).

The August 18, 2006, October 5, 2006, and January 11, 2007, supplements contained clarifying information and did not change the NRC staff's initial proposed finding of no significant hazards consideration.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 21, 2007.

No significant hazards consideration comments received: No.

Exelon Generation Company, LLC, Docket Nos. 50–373 and 50–374, LaSalle County Station, Units 1 and 2, LaSalle County, Illinois

Date of application for amendments: March 16, 2006, as supplemented by letter dated April 6, 2007.

Brief description of amendments: The amendments revise allowable values for four reactor core isolation cooling leak detection functions in Technical Specification Table 3.3.6.1–1, ''Primary Containment Isolation Instrumentation.''

Date of issuance: June 29, 2007.

Effective date: As of the date of issuance and shall be implemented within 60 days.

Amendment Nos.: 182/169.

Facility Operating License Nos. NPF–11 and NPF–18: The amendments revised the Technical Specifications and License.

Date of initial notice in ***Federal Register:*** August 15, 2006 (71 FR 46929).

The April 6, 2007 supplement, contained clarifying information and did not change the NRC staff's initial proposed finding of no significant hazards consideration.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 29, 2007.

No significant hazards consideration comments received: No.

FirstEnergy Nuclear Operating Company, et al., Docket No. 50–440, Perry Nuclear Power Plant, Unit No. 1, Lake County, Ohio

Date of application for amendment: December 29, 2006.

Brief description of amendment: The amendment modifies the technical specifications requirements for scram discharge volume vent and drain valves.

Date of issuance: June 22, 2007.

Effective date: As of the date of issuance and shall be implemented within 90 days.

Amendment No.: 145.

Facility Operating License No. NPF–58: This amendment revised the Technical Specifications and License.

Date of initial notice in ***Federal Register:*** March 13, 2007 (72 FR 11388).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated June 22, 2007.

No significant hazards consideration comments received: No.

FPL Energy Duane Arnold, LLC, Docket No. 50–331, Duane Arnold Energy Center, Linn County, Iowa

Date of application for amendment: July 17, 2006, as supplemented by letter dated March 20, 2007.

Brief description of amendment: The amendment revises the Technical Specification (TS) Limiting Condition for Operation (LCO) 3.6.3.1 to eliminate the requirement for the Containment Atmospheric Dilution system, allowing its removal from the Duane Arnold Energy Center. In a letter dated June 1, 2007, the licensee withdrew its request to change LCO 3.6.3.2, ''Primary Containment oxygen Concentration,'' to lengthen the duration of time for the primary containment to be de-inerted.

Date of issuance: June 28, 2007.

Effective date: As of the date of issuance and shall be implemented within 30 days.

Amendment No.: 265.

Facility Operating License No. DPR–49: The amendment revises the Technical Specification.

Date of initial notice in ***Federal Register:*** November 21, 2006 (71 FR 67395).

The supplemental information provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the Nuclear Regulatory Commission's staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated June 28, 2007.

No significant hazards consideration comments received: No.

Nuclear Management Company, LLC, Docket Nos. 50–282 and 50–306, Prairie Island Nuclear Generating Plant, Units 1 and 2, Goodhue County, Minnesota

Date of application for amendments: July 6, 2006, as supplemented by letters dated September 15 and December 26, 2006.

Brief description of amendments: The amendments incorporate new Large-Break Loss-of-Coolant Accident (LBLOCA) analyses using the realistic LBLOCA methodology in the Nuclear Regulatory Commission approved WCAP–16009–P–A, ''Realistic Large Break LOCA Evaluation Methodology using Automated Statistical Treatment of Uncertainty Method (ASTRUM)'' and revise TS 5.6.5.b to include reference to WCAP–16009–P–A.

Date of issuance: June 28, 2007.

Effective date: As of the date of issuance and shall be implemented with the next fuel cycle (Unit 1 Cycle 25) commencing following the Winter 2008 refueling for Unit 1, and implemented within 90 days for Unit 2.

Amendment Nos.: 179 and 169.

Facility Operating License Nos. DPR–42 and DPR–60: Amendments revised the Technical Specifications.

Date of initial notice in ***Federal Register:*** September 12, 2006 (71 FR 53718).

The supplemental letters contained clarifying information and did not change the initial no significant hazards consideration determination, and did not expand the scope of the original **Federal Register** notice.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 28, 2007.

No significant hazards consideration comments received: No.

Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of application for amendments: December 29, 2006.

Brief description of amendments: The amendments revised Technical Specification (TS) Section 5.5.8, ''Inservice Testing Program,'' in order to update references to the American Society of Mechanical Engineers Boiler and Pressure Vessel Code. Specifically, the change adopted the administrative, editorial, and clarification TS changes contained in TS Task Force (TSTF)–479, Revision 0, ''Changes to Reflect Revision of 10 CFR [Title 10 of the *Code of Federal Regulations*] 50.55a,'' and TSTF–497, Revision 0, ''Limit Inservice Testing Program SR [Surveillance Requirement] 3.0.2 Application to Frequencies of 2 years or less.''

Date of issuance: June 25, 2007.

Effective date: As of its date of issuance and shall be implemented within 90 days from the date of issuance.

Amendment Nos.: Unit 1–196; Unit 2–197

Facility Operating License Nos. DPR–80 and DPR–82: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register:*** February 13, 2007 (72 FR 6784).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 25, 2007.

No significant hazards consideration comments received: No.

Facility Operating License Nos. DPR–80 and DPR–82: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register:*** February 13, 2007 (72 FR 6784).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 25, 2007.

No significant hazards consideration comments received: No.

Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of application for amendments: December 29, 2006.

Brief description of amendments: The amendments revise TS 5.5.16, ''Containment Leakage Rate Testing Program,'' to comply with the requirements of 10 CFR 50.55a(g)(4) for components classified as Code Class CC.

Date of issuance: June 26, 2007.

Effective date: As of its date of issuance and shall be implemented within 90 days from the date of issuance.

Amendment Nos.: Unit 1–197; Unit 2–198.

Facility Operating License Nos. DPR–80 and DPR–82: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register:*** February 13, 2007 (72 FR 6785).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 26, 2007.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50–321 and 50–366, Edwin I. Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia

Date of application for amendments: January 30, 2007, as supplemented April 11, 2007.

Brief description of amendments: The amendments revised staff position duties and titles in Sections 2 and 5 of the Technical Specifications.

Date of issuance: June 7, 2007.

Effective date: As of the date of issuance and shall be implemented within 30 days from the date of issuance.

Amendment Nos.: 252, 196.

Renewed Facility Operating License Nos. DPR–57 and NPF–5: Amendments revised the licenses and the technical specifications.

Date of initial notice in ***Federal Register:*** February 13, 2007 (72 FR 6790).

The supplement dated April 11, 2007, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 7, 2007.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Docket Nos. 50–424 and 50–425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of application for amendments: January 30, 2007, as supplemented April 11, 2007.

Brief description of amendments: The amendments revised staff position duties and titles in Sections 2 and 5 of the Technical Specifications.

Date of issuance: June 12, 2007.

Effective date: As of the date of issuance and shall be implemented within 30 days from the date of issuance.

Amendment Nos.: 148, 128.

Renewed Facility Operating License Nos. NPF–68 and NPF–81: Amendments revised the licenses and the technical specifications.

Date of initial notice in ***Federal Register:*** February 13, 2007 (72 FR 6791).

The supplement dated April 11, 2007, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 12, 2007.

No significant hazards consideration comments received: No.

STP Nuclear Operating Company, Docket Nos. 50–498 and 50–499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: March 30, 2006, as supplemented by letters dated October 2, 2006, and February 26, 2007.

Brief description of amendments: The amendments revise TS 3.3.3.6, ''Accident Monitoring Instrumentation,'' with respect to the required action for inoperable wide range reactor coolant temperature, wide range steam generator water level, and auxiliary feedwater flow instruments.

Date of issuance: June 13, 2007.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: Unit 1–177; Unit 2–164.

Facility Operating License Nos. NPF–76 and NPF–80: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register:*** June 6, 2006 (71 FR 32608). The supplemental letters dated October 2, 2006, and February 26, 2007, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 13, 2007.

No significant hazards consideration comments received: No.

STP Nuclear Operating Company, Docket Nos. 50–498 and 50–499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: April 4, 2006.

Brief description of amendments: The amendment request changed the name of one licensee, Texas Genco, LP (Texas Genco), to NRG South Texas LP. The name change results from the purchase of Texas Genco's parent company by NRG Energy, Inc. as approved by the NRC in January 2006.

Date of issuance: June 29, 2007.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment Nos.: Unit 1–178; Unit 2–165.

Facility Operating License Nos. NPF–76 and NPF–80: The amendments revised the Facility Operating Licenses.

Date of initial notice in ***Federal Register:*** May 9, 2007 (72 FR 26428).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 29, 2007.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this sixth day of July 2007.

For the Nuclear Regulatory Commission.

Catherine Haney,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E7–13537 Filed 7–16–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Notice of Availability of Model Application Concerning Technical Specification Task Force (TSTF) Traveler To Provide Actions for One Steam Supply to Turbine Driven AFW/EFW Pump Inoperable Using the Consolidated Line Item Improvement Process

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

SUMMARY: Notice is hereby given that the staff of the Nuclear Regulatory Commission (NRC) has prepared a model license amendment request (LAR), model safety evaluation (SE), and model proposed no significant hazards consideration (NSHC) determination related to changes to Actions in the Standard Technical Specifications (STS) relating to One Steam Supply to Turbine Driven Auxiliary Feedwater/Emergency Feedwater (AFW/EFW) Pump Inoperable. This change establishes a Completion Time in the Standard Technical Specifications for the Condition where one steam supply to the turbine driven AFW/EFW pump is inoperable concurrent with an inoperable motor driven AFW/EFW train.

The purpose of these models is to permit the NRC to efficiently process amendments that propose to adopt the associated changes into plant-specific technical specifications (TS). Licensees of nuclear power reactors to which the models apply can request amendments confirming the applicability of the SE and NSHC determination to their reactors.

DATES: The NRC staff issued a **Federal Register** Notice (72 FR 12845, March 19, 2007) which provided a model LAR, model SE, and model NSHC related to one steam supply to turbine driven auxiliary feedwater/emergency feedwater pump inoperable; similarly the NRC staff herein provides the model LAR, a revised model SE, and the model NSHC. The NRC staff can most efficiently consider applications based upon the model LAR, which references the model SE, if the application is submitted within one year of this **Federal Register** Notice.

FOR FURTHER INFORMATION CONTACT: Trent L. Wertz, Technical Specifications Branch, Division of Inspection and Regional Support, Office of Nuclear Reactor Regulation, Mail Stop O–12H2, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone 301–415–1568.

SUPPLEMENTARY INFORMATION:

Background

Regulatory Issue Summary 2000–06, ''Consolidated Line Item Improvement Process for Adopting Standard Technical Specification Changes for Power Reactors,'' was issued on March 20, 2000. The consolidated line item improvement process (CLIIP) is intended to improve the efficiency and transparency of NRC licensing processes. This is accomplished by processing proposed changes to the Standard Technical Specifications (STS) (NUREGs 1430—1434) in a manner that supports subsequent license amendment applications. The CLIIP includes an opportunity for the public to comment on proposed changes to the STS following a preliminary assessment by the NRC staff and finding that the change will likely be offered for adoption by licensees. The CLIIP directs the NRC staff to evaluate any comments received for a proposed change to the STS and to either reconsider the change or proceed with announcing the availability of the change to licensees. Those licensees opting to apply for the subject change to TS are responsible for reviewing the NRC staff's evaluation, referencing the applicable technical justifications, and providing any necessary plant specific information. Each amendment application submitted in response to the notice of availability would be processed and noticed in accordance with applicable rules and NRC procedures.

This notice involves establishing a Completion Time in the Limiting Condition for Operation (LCO) 3.7.5 of the STS for the Condition where one steam supply to the turbine driven AFW/EFW pump is inoperable concurrent with an inoperable motor driven AFW/EFW train. This notice also involves two additional changes to the STS that establish specific Conditions and Action requirements: (1) For when two motor driven AFW/EFW trains are inoperable at the same time and; (2) for when the turbine driven AFW/EFW train is inoperable either (a) due solely to one inoperable steam supply, or (b) due to reasons other than one inoperable steam supply. The changes were proposed by the Technical Specification Task Force (TSTF) in TSTF Traveler TSTF–412, Revision 3, which is accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site *http://www.nrc.gov/reading-rm/adams.html* (Accession No. ML070100363). Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC Public Document Room Reference staff by telephone at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.*

Applicability

This change is applicable to all pressurized water reactors (PWRs) designed by Babcock and Wilcox (B&W), Westinghouse, and Combustion Engineering (CE). To efficiently process the incoming license amendment applications, the NRC staff requests that each licensee applying for the changes use the CLIIP to submit a License Amendment Request (LAR) that conforms to the enclosed Model Application (Enclosure 1). Any deviations from the Model Application should be explained in the licensee's submittal. Significant deviations from the approach, or inclusion of additional changes to the license, will result in staff rejection of the submittal. Instead, licensees desiring significant variations and/or additional changes should submit a LAR that does not claim to adopt TSTF–412. Variations from the approach recommended in this notice may require additional review by the NRC staff and may increase the time and resources needed for the review.

Public Notices

The staff issued a **Federal Register** Notice (72 FR 12845, March 19, 2007) that requested public comment on the NRC's pending action to establish a Completion Time in the Limiting Condition for Operation (LCO) 3.7.5 of the STS for the Condition where one steam supply to the turbine driven AFW/EFW pump is inoperable concurrent with an inoperable motor driven AFW/EFW train. This notice also involves two additional changes to the STS that establish specific Conditions and Action requirements: (1) For when two motor driven AFW/EFW trains are inoperable at the same time and; (2) for

when the turbine driven AFW/EFW train is inoperable either (a) due solely to one inoperable steam supply, or (b) due to reasons other than one inoperable steam supply. In particular, following an assessment and draft safety evaluation by the NRC staff, the staff sought public comment on proposed changes to the STS, designated TSTF–412 Revision 3.

In response to the notice soliciting comments from the interested members of the public about NRC's pending action to establish a Completion Time in the Standard Technical Specifications for the Condition where one steam supply to the turbine driven AFW/EFW pump is inoperable concurrent with an inoperable motor driven AFW/EFW train, the staff received one comment (from a licensee). The comment on the model SE is summarized and discussed below:

1. COMMENT: The first sentence in the third paragraph under ''STS 3.7.5, Condition C (as Proposed),'' in Section 3.0 of the Proposed Model Safety Evaluation states the following:

''The STS typically allows a 72 hour Completion Time for Conditions where the remaining operable equipment is able to mitigate postulated accidents without assuming a concurrent single active failure.'' Since there are several TSs in the STS that allow a longer Completion time than 72 hours for conditions where the remaining operable equipment is able to mitigate postulated accidents without assuming a concurrent single active failure (such as seven days in TS 3.5.2, 3.6.6, and 3.7.10 in NUREG–1432), it is recommended that the sentence be changed to the following: ''The STS typically allows a 72 hour or longer Completion Time for Conditions where the remaining operable equipment is able to mitigate postulated accidents without assuming a concurrent single active failure.''

Response: The NRC staff agrees with the comment and has modified the model SE.

Dated at Rockville, Maryland, this 11th day of July, 2007.

For the Nuclear Regulatory Commission.

Timothy J. Kobetz,

Chief Technical Specifications Branch, Division of Inspection and Regional Support, Office of Nuclear Reactor Regulation.

The following example of a license amendment request (LAR) was prepared by the NRC staff to facilitate the adoption of Technical Specifications Task Force (TSTF) Traveler TSTF–412, Revision 3 ''Provide Actions for One Steam Supply to Turbine Driven AFW/EFW Pump Inoperable.'' The model provides the expected level of detail and content for a LAR to adopt TSTF–412, Revision 3. Licensees remain responsible for ensuring that their plant-specific LAR fulfills their administrative requirements as well as NRC regulations.

PROPOSED MODEL LICENSE AMENDMENT REQUEST

U.S. Nuclear Regulatory Commission,
Document Control Desk,
Washington, DC 20555.

SUBJECT: PLANT NAME

DOCKET NO. 50–

APPLICATION FOR TECHNICAL SPECIFICATION IMPROVEMENT TO REVISE ACTIONS FOR ONE STEAM SUPPLY TO TURBINE DRIVEN AUXILIARY FEEDWATER / EMERGENCY FEEDWATER PUMP INOPERABLE USING THE CONSOLIDATED LINE ITEM IMPROVEMENT PROCESS

Gentlemen: In accordance with the provisions of 10 CFR 50.90 of Title 10 of the *Code of Federal Regulations* (10 CFR), [LICENSEE] is submitting a request for an amendment to the technical specifications (TS) for [PLANT NAME, UNIT NOS.].

The proposed amendment establishes Conditions, Required Actions, and Completion Times in the Standard Technical Specifications (STS) for the Condition where one steam supply to the turbine driven Auxiliary Feedwater/Emergency Feedwater (AFW/EFW) pump is inoperable concurrent with an inoperable motor driven AFW/EFW train. In addition, this amendment establishes changes to the STS that establish specific Actions: (1) For when two motor driven AFW/EFW trains are inoperable at the same time and; (2) for when the turbine driven AFW/EFW train is inoperable either (a) due solely to one inoperable steam supply, or (b) due to reasons other than one inoperable steam supply. The change is consistent with NRC-approved Technical Specification Task Force (TSTF) Traveler, TSTF–412, Revision 3, ''Provide Actions for One Steam Supply to Turbine Driven AFW/EFW Pump Inoperable.'' The availability of this technical specification improvement was announced in the *Federal Register* on [DATE OF NOTICE OF AVAILABILITY] as part of the consolidated line item improvement process (CLIIP).

Enclosure 1 provides a description of the proposed change and confirmation of applicability. Enclosure 2 provides the existing TS pages marked-up to show the proposed change. Enclosure 3 provides the existing TS Bases pages marked-up to reflect the proposed change. There are no new regulatory commitments associated with this proposed change.

[LICENSEE] requests approval of the proposed license amendment by [DATE], with the amendment being implemented [BY DATE OR WITHIN X DAYS].

In accordance with 10 CFR 50.91, a copy of this application, with enclosures, is being provided to the designated [STATE] Official.

I declare under penalty of perjury under the laws of the United States of America that I am authorized by [LICENSEE] to make this request and that the foregoing is true and correct. [Note that request may be notarized in lieu of using this oath or affirmation statement].

If you should have any questions regarding this submittal, please contact [ ].

Sincerely,
Name, Title

Enclosures: 1. Description and Assessment
2. Proposed Technical Specification Changes
3. Proposed Technical Specification Bases Changes

cc: NRR Project Manager
Regional Office
Resident Inspector
State Contact

Enclosure 1 to Model License Amendment Request Description and Assessment

1.0 DESCRIPTION

The proposed License amendment establish a new Completion Time in Standard Technical Specifications Section [3.7.5] where one steam supply to the turbine driven AFW/EFW pump is inoperable concurrent with an inoperable motor driven AFW/EFW train. This amendment also establishes specific Conditions and Action requirements: (1) For when two motor driven AFW/EFW trains are inoperable at the same time and; (2) for when the turbine driven AFW/EFW train is inoperable either (a) due solely to one inoperable steam supply, or (b) due to reasons other than one inoperable steam supply.

The changes are consistent with NRC approved Industry/Technical Specification Task Force (TSTF) Standard Technical Specification Change Traveler, TSTF–412, Revision 3, ''Provide Actions for One Steam Supply to Turbine Driven AFW/EFW Pump Inoperable.'' The availability of this

technical specification improvement was announced in the **Federal Register** on [DATE] ([xx FR xxxxx]) as part of the consolidated line item improvement process (CLIIP).

2.0 ASSESSMENT

2.1 Applicability of Published Safety Evaluation

[LICENSEE] has reviewed the safety evaluation published on [DATE] ([xx FR xxxxx]) as part of the CLIIP. This verification included a review of the NRC staff's evaluation as well as the supporting information provided to support TSTF–412, Revision 3. [LICENSEE] has concluded that the justifications presented in the TSTF proposal and the safety evaluation prepared by the NRC staff are applicable to [PLANT, UNIT NOS.] and justify this amendment for the incorporation of the changes to the [PLANT] Technical Specifications.

2.2 Optional Changes and Variations

[LICENSEE] is not proposing any variations or deviations from the technical specification changes described in TSTF–412, Revision 3, or the NRC staff's model safety evaluation published in the **Federal Register** on [DATE] ([xx FR xxxxx]).

3.0 REGULATORY ANALYSIS

A description of the proposed change and its relationship to applicable regulatory requirements and guidance was provided in the Notice of Availability published on [DATE] ([xx FR xxxxx]). **[Pre-General Design Criteria plants need to include applicable plant specific regulatory requirements].**

3.1 No Significant Hazards Determination

[LICENSEE] has reviewed the proposed no significant hazards consideration determination published on [DATE] as part of the CLIIP. [LICENSEE] has concluded that the proposed determination presented in the notice is applicable to [PLANT] and the determination is hereby incorporated by reference to satisfy the requirements of 10 CFR 50.91(a).

3.2 Verification and Commitments

There are no new regulatory commitments associated with this proposed change.

4.0 ENVIRONMENTAL EVALUATION

[LICENSEE] has reviewed the environmental evaluation included in the model safety evaluation published in the **Federal Register** on [DATE] ([xx FR xxxxx]) as part of the CLIIP. [LICENSEE] has concluded that the NRC staff's findings presented in that evaluation are applicable to [PLANT] and the evaluation is hereby incorporated by reference for this application.

Enclosure 2 to Model License Amendment Request: PROPOSED TECHNICAL SPECIFICATION CHANGES

Enclosure 3 to Model License Amendment Request: CHANGES TO TS BASES PAGES

PROPOSED MODEL SAFETY EVALUATION

U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
Consolidated Line Item Improvement

Technical Specification Task Force Traveler TSTF–412, Revision 3, Provide Actions for One Steam Supply to the Turbine Driven AFW/EFW Pump Inoperable

1.0 INTRODUCTION

By application dated [DATE], [LICENSEE NAME] (the licensee), submitted a request for changes to the [PLANT NAME], Technical Specifications (TS) (Agencywide Documents Access and Management System (ADAMS) Accession No. [MLxxxxxxxxx]). The requested changes adopt TSTF–412, Revision 3, ''Provide Actions for One Steam Supply to the Turbine Driven AFW/EFW Pump Inoperable.'' NRC approval of these changes was announced in the **Federal Register** on [DATE] [xx FR xxxxx]. The requested change would establish a Completion Time for the Condition where one steam supply to the turbine driven AFW/EFW pump is inoperable concurrent with an inoperable motor driven AFW/EFW train and establish specific Conditions and Required Actions: (1) When two motor driven AFW/EFW trains are inoperable at the same time and; (2) when the turbine driven AFW/EFW train is inoperable either (a) due solely to one inoperable steam supply, or (b) due to reasons other than one inoperable steam supply.

These changes were described in a Notice of Availability published in the **Federal Register** on [DATE] ([xx FR xxxxx]).

2.0 REGULATORY EVALUATION

In 10 CFR 50.36, the Commission established its regulatory requirements related to the content of Technical Specifications (TS). Pursuant to 10 CFR 50.36(c), TS are required to include items in the following categories: (1) Safety limits, limiting safety system settings, and limiting control settings; (2) limiting conditions for operation (LCOs); (3) surveillance requirements (SRs); (4) design features; and (5) administrative controls. The rule does not specify the particular requirements to be included in a plant's TS.

Also, in 10 CFR 50 Appendix A the Commission established regulatory requirements related to Auxiliary Feedwater Systems. General Design Criteria 34 and 44 state that the AFW system is required to assure (1) the capability to transfer heat loads from the reactor system to a heat sink under both normal operating and accident conditions; (2) the redundancy of components for performance of the safety function under accident conditions, assuming a single active component failure; and (3) the capability to isolate components, subsystems, or piping if required to maintain system safety function.

3.0 TECHNICAL EVALUATION

TS 3.7.5, Auxiliary Feedwater (AFW)/ Emergency Feedwater (EFW) System

The AFW/EFW System is designed to automatically supply sufficient water to the steam generator(s) to remove decay heat upon the loss of normal feedwater supply with steam generator pressure at the set point of the Main Steam Safety Valves (MSSVs). Subsequently, the AFW/EFW System supplies sufficient water to cool the unit to Residual Heat Removal (RHR) System entry conditions, with steam being released through the Atmospheric Dump Valves (ADVs).

AFW/EFW Systems typically consist of two motor driven AFW/EFW pumps and one steam turbine driven pump configured into three trains. The capacity of the motor driven and steam driven AFW/EFW pumps can vary by plant. Motor driven pumps typically provide 50% or 100% of the required AFW/EFW flow capacity as assumed in the accident analysis. Motor driven AFW/EFW pumps are typically powered from an independent Class 1E power supply and each pump train typically feeds half of the steam generators, although each pump has the capability to be realigned from the control room to feed other steam generators. The steam turbine driven AFW/EFW pump provides either 100% or 200% of the required capacity to all steam generators. The steam turbine driven pump receives steam from two main steam lines upstream of the main

steam isolation valves. Each of the steam feed lines will supply 100% of the requirements of the turbine driven AFW/EFW pump.

LCO 3.7.5 Condition A (as proposed)

Condition A is modified to refer to the inoperability of a turbine driven AFW/EFW train due to an inoperable steam supply, instead of referring to the inoperability of a turbine driven AFW/EFW pump. This change is being proposed in order to make Condition A train oriented instead of component oriented, consistent with the other Conditions that are included in STS 3.7.5. The train oriented approach is consistent with the preferred approach that is generally reflected in the STS, and therefore the proposed change is considered to be acceptable.

STS 3.7.5, Condition C (as proposed)

A new Condition C with two possible Required Actions (C.1 OR C.2) is proposed for the turbine driven AFW/EFW train being inoperable due to one inoperable steam supply and one motor driven AFW/EFW train being inoperable at the same time. Required Action C.1 requires restoration of the affected steam supply to operable status within either 24 or 48 hours, depending on the capability of the motor driven AFW/EFW train that remains operable. Alternatively, Required Action C.2 requires restoration of the inoperable motor driven AFW/EFW train within either 24 or 48 hours, again depending on the capability of the motor driven AFW/EFW train that remains operable. New Condition C provides two proposed Completion Times that are dependent upon the capacity of the remaining operable motor driven AFW/EFW train to provide AFW/EFW to the steam generators.

A proposed 24 hour Completion Time is applicable to plants that may provide insufficient flow to the steam generators (SGs) in accordance with accident analyses assumptions if a main steam line break (MSLB) or feedwater line break (FLB) were to occur that renders the remaining steam supply to the turbine driven AFW/EFW pump inoperable (a concurrent single failure is not assumed). Insufficient feedwater flow could result, for example, if a single motor driven AFW/EFW train does not have sufficient capacity to satisfy accident analyses assumptions, or if the operable pump is feeding the faulted SG (i.e. the SG that is aligned to the operable steam supply for the turbine driven AFW/EFW pump). [This would typically apply to plants with each AFW/EFW motor driven pump having less than 100% of the required flow.] A proposed 48 hour Completion Time is applicable when the remaining operable motor driven AFW/EFW train is capable of providing sufficient feedwater flow in accordance with accident analyses assumptions. [This would typically apply to plants with each AFW/EFW motor driven pump having greater than or equal to 100% of the required flow.]

The STS typically allows a 72 hour or longer Completion Time for Conditions where the remaining operable equipment is able to mitigate postulated accidents without assuming a concurrent single active failure. In this particular case, a 24 hour Completion Time is proposed for the situation where the AFW/EFW system would be able to perform its function for most postulated events, and would only be challenged by a MSLB or FLB that renders the remaining operable steam supply to the turbine driven AFW/EFW pump inoperable. Additionally, depending on the capacity of the operable motor driven AFW/EFW pump, it may be able to mitigate MSLB and FLB accidents during those instances when it is not aligned to the faulted SG. The selection of 24 hours for the Completion Time is based on the remaining operable steam supply to the turbine driven AFW/EFW pump and the continued functionality of the turbine driven AFW/EFW train, the remaining operable motor driven AFW/EFW train, and the low likelihood of an event occurring during this 24 hour period that would challenge the capability of the AFW/EFW system to provide feedwater to the SGs. The proposed Completion Time for this particular situation is consistent with what was approved for Waterford 3 by License Amendment 173 for a similar Condition (ADAMS Accession No. ML012840538), and it is consistent with the STS in that the proposed Completion Time is much less than the 72 hours that is allowed for the situation where accident mitigation capability is maintained. Therefore, the NRC staff agrees that the proposed 24 hour Completion Time is acceptable for this particular situation.

A 48 hour Completion Time is proposed for the situation where the remaining operable motor driven AFW/EFW train is able to mitigate postulated accidents in accordance with accident analyses assumptions without assuming a concurrent single active failure. The selection of 48 hours is based on the continued capability of the AFW/EFW system to perform its function, while at the same time recognizing that this Condition represents a higher level of degradation than one inoperable AFW/EFW train which is currently allowed for up to 72 hours by STS 3.7.5. The proposed 48 hour Completion Time represents an appropriate balance between the more severe 24 hour situation discussed in the previous paragraph and the less severe Condition that is afforded a 72 hour Completion Time by the current STS. Therefore, the NRC staff agrees that the proposed 48 hour Completion Time is acceptable for this particular situation.

STS 3.7.5, Condition D (as proposed)

The current Condition C is renamed as Condition D. This Condition has been modified to incorporate changes brought on by the addition of new Condition C. The first of the two listed Conditions under Condition D has been modified and now applies to the situation where the Required Action and associated Completion Time of Condition A, B, or C are not met. This section of Condition D is modified to also apply to the new Condition C when the Completion Time that is specified for new Condition C is not met. The NRC staff considers this to be appropriate and consistent with existing STS 3.7.5 requirements to place the plant in a mode where the Condition does not apply when the Required Actions are not met.

The second listed Condition under Condition D (following the first ''OR'') is modified from ''Two AFW/EFW trains inoperable in MODE 1, 2, or 3'' to ''Two AFW/EFW trains inoperable in MODE 1, 2, or 3 for reasons other than Condition C.'' This change is necessary to recognize the situation specified by Condition C (as proposed) where one motor driven AFW/EFW train is allowed to be inoperable at the same time that the turbine driven AFW/EFW train is inoperable due to an inoperable steam supply to the pump turbine. Therefore, the NRC staff considers the proposed change to be acceptable.

The Required Actions associated with this Condition were renamed from C.1 AND C.2 to D.1 AND D.2 but not otherwise changed. Required Action D.1 requires the plant to be in Mode 3 in 6 hours, and Required Action D.2 requires the plant to be in Mode 4 in 18 hours. This change is purely editorial as no other changes are involved. Therefore, this proposed change is acceptable.

STS 3.7.5, Condition E (as proposed)

Because current Condition C is renamed as Condition D, current Condition D is renamed as Condition E. This change is purely editorial as no other changes are involved. Therefore, the proposed change is acceptable.

STS 3.7.5, Condition F (as proposed)

Because current Condition D is renamed as Condition E, current Condition E is renamed as Condition F. This change is purely editorial as no other changes are involved. Therefore, the proposed change is acceptable.

4.0 STATE CONSULTATION

In accordance with the Commission's regulations, the [STATE] State official was notified of the proposed issuance of the amendments. The State official had [(1) no comments or (2) the following comments—with subsequent disposition by the NRC staff].

5.0 ENVIRONMENTAL CONSIDERATION

The amendment changes a requirement with respect to the installation or use of a facility component located within the restricted area as defined in 10 CFR Part 20 and changes surveillance requirements. The NRC staff has determined that the amendment involves no significant increase in the amounts and no significant change in the types of any effluents that may be released offsite, and that there is no significant increase in individual or cumulative occupational radiation exposure. The Commission has previously issued a proposed finding that the amendment involves no significant hazards consideration, and there has been [(1) no public comment on such finding (2) the following comments with subsequent disposition by the NRC staff ([xx FR xxxxx, DATE]). Accordingly, the amendment meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Pursuant to 10 CFR 51.22(b) no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the amendment.

6.0 CONCLUSION

The Commission has concluded, based on the considerations discussed above, that (1) there is reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner, (2) such activities will be conducted in compliance with the Commission's regulations, and (3) the issuance of the amendments will not be inimical to the common defense and security or to the health and safety of the public.

The proposed changes are consistent with NRC practices and policies as generally reflected in the STS and as reflected by applicable precedents that have been approved. Therefore, the NRC staff has determined that the proposed changes to STS 3.7.5 should be approved.

MODEL NO SIGNIFICANT HAZARDS CONSIDERATION DETERMINATION

Description of amendment request: The requested change, applicable to all pressurized water reactors (PWRs) designed by Babcock and Wilcox (B&W), Westinghouse, and Combustion Engineering (CE), would provide changes to the Actions in the Standard Technical Specifications (STS) relating to One Steam Supply to Turbine Driven Auxiliary Feedwater / Emergency Feedwater (AFW/EFW) Pump Inoperable. The proposed change is described in Technical Specification Task Force (TSTF) Standard TS Change Traveler TSTF–412, Revision 3, and was described in the Notice of Availability published in the **Federal Register** on [DATE] ([xx FR xxxxx]).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of any accident previously evaluated?

Response: No

The Auxiliary/Emergency Feedwater (AFW/EFW) System is not an initiator of any design basis accident or event, and therefore the proposed changes do not increase the probability of any accident previously evaluated. The proposed changes to address the condition of one or two motor driven AFW/EFW trains inoperable and the turbine driven AFW/EFW train inoperable due to one steam supply inoperable do not change the response of the plant to any accidents.

The proposed changes do not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, and configuration of the facility or the manner in which the plant is operated and maintained. The proposed changes do not adversely affect the ability of structures, systems, and components (SSCs) to perform their intended safety function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed changes do not affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of any accident previously evaluated. Further, the proposed changes do not increase the types and amounts of radioactive effluent that may be released offsite, nor significantly increase individual or cumulative occupational/public radiation exposures.

Therefore, the changes do not involve a significant increase in the probability or consequences of any accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No

The proposed changes do not result in a change in the manner in which the AFW/EFW System provides plant protection. The AFW/EFW System will continue to supply water to the steam generators to remove decay heat and other residual heat by delivering at least the minimum required flow rate to the steam generators. There are no design changes associated with the proposed changes. The changes to the Conditions and Required Actions do not change any existing accident scenarios, nor create any new or different accident scenarios.

The changes do not involve a physical alteration of the plant (*i.e.*, no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. In addition, the changes do not impose any new or different requirements or eliminate any existing requirements. The changes do not alter assumptions made in the safety analysis. The proposed changes are consistent with the safety analysis assumptions and current plant operating practice.

Therefore, the changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No

The proposed changes do not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The safety analysis acceptance criteria are not impacted by these changes. The proposed changes will not result in plant operation in a configuration outside the design basis.

Therefore, it is concluded that the proposed change does not involve a significant reduction in a margin of safety.

Based on the above, the proposed change involves no significant hazards consideration under the standards set forth in 10 CFR 50.92(c), and accordingly, a finding of no significant hazards consideration is justified.

Dated at Rockville, Maryland, this th day of , 2007.

For the Nuclear Regulatory Commission.

Project Manager
Plant Licensing Branch [ ]

Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation

[FR Doc. E7–13845 Filed 7–16–07; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Proposed Collection; Comment Request for Review of a Revised Information Collection; Federal Employees Health Benefits (FEHB) Open Season Express; Interactive Voice Response (IVR) System

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) intends to submit to the Office of Management and Budget (OMB) a request for review of a revised information collection. The Federal Employees Health Benefits (FEHB) Open Season Express Interactive Voice Response (IVR) System and the Open Season Web site, Open Season Online, are used by retirees and survivors. They collect information for changing FEHB enrollments, collecting dependent and other insurance information for self and family enrollments, requesting plan brochures, requesting a change of address, requesting cancellation or suspension of FEHB benefits, asking to make payment to the Office of Personnel Management when the FEHB payment is greater than the monthly annuity amount, or for requesting FEHB plan accreditation and Customer Satisfaction Survey information.

Comments are particularly invited on: Whether this information is necessary for the proper performance of functions of the Office of Personnel Management and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

We receive approximately 215,000 responses per year to the IVR system and the online Web. Each response takes approximately 10 minutes to complete. The annual burden is 35,833 hours.

For copies of this proposal, contact Mary Beth Smith-Toomey on (202) 606–8358, FAX (202) 418–3251 or via e-mail to: *MaryBeth.Smith-Toomey@opm.gov.* Please include a mailing address with your request.

DATES: Comments on this proposal should be received within 60 calendar days from the date of this publication.

ADDRESSES: Send or deliver comments to—

Ed Foelster, Chief, Methods and Procedures Branch, Operations Support Group, Center for Retirement and Insurance Services, U.S. Office of Personnel Management, 1900 E Street, NW., Room 3349, Washington, DC 20415–3540.

For Information Regarding Administrative Coordination—

Contact: Cyrus S. Benson, Team Leader, Publications Team, RIS Support Services/Support Group, (202) 606–0623.

U.S. Office of Personnel Management.

Tricia Hollis,

Chief of Staff.

[FR Doc. E7–13760 Filed 7–16–07; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Proposed Collection; Comment Request for Extension of a Currently Approved Information Collection: OPM 1530

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) intends to submit to the Office of Management and Budget (OMB) a request for extension of a currently approved information collection. OPM Form 1530, Report of Medical Examination of Person Electing Survivor Benefit Under the Civil Service Retirement System, is used to collect information regarding an annuitant's health so that OPM can determine whether the insurable interest survivor benefit election can be allowed.

Comments are particularly invited on: Whether this information is necessary for the proper performance of functions of the Office of Personnel Management, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Approximately 500 OPM Form 1530 will be completed annually. We estimate it takes approximately 90 minutes to complete the form. The annual burden is 750 hours.

For copies of this proposal, contact Mary Beth Smith-Toomey on (202) 606–8358, FAX (202) 418–3251 or via e-mail to: *MaryBeth.Smith-Toomey@opm.gov.* Please include a mailing address with your request.

DATES: Comments on this proposal should be received within 60 calendar days from the date of this publication.

ADDRESSES: Send or deliver comments to—

Pamela S. Israel, Chief, Operations Support Group, Center for Retirement and Insurance Services, U.S. Office of Personnel Management, 1900 E Street, NW., Room 3349, Washington, DC 20415–3540.

For Information Regarding Administrative Coordination—

Contact: Cyrus S. Benson, Team Leader, Publications Team, RIS Support Services/Support Group, (202) 606–0623.

U.S. Office of Personnel Management.

Tricia Hollis,

Chief of Staff.

[FR Doc. E7–13761 Filed 7–16–07; 8:45 am]

BILLING CODE 6325–38–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 19h–1; SEC File No. 270–247; OMB Control No. 3235–0259.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

• Rule 19h–1 (17 CFR 240.19h–1): SRO notification of admission and/or continuance despite statutory disqualification.

Rule 19h–1 (''Rule'') under the Securities Exchange Act of 1934 (15

U.S.C. 78a *et seq.*) prescribes the form and content of notices and applications by self-regulatory organizations (''SROs'') regarding proposed admissions to, or continuances in, membership, participation or association with a member of any person subject to a statutory disqualification.

The Commission uses the information provided in the submissions filed pursuant to Rule 19h–1 to review decisions by SROs to permit the entry into or continuance in the securities business of persons who have committed serious misconduct. The filings submitted pursuant to the Rule also permit inclusion of an application to the Commission for consent to associate with a member of an SRO notwithstanding a Commission order barring such association.

The Commission reviews filings made pursuant to the Rule to ascertain whether it is in the public interest to permit the employment in the securities business of persons subject to statutory disqualification. The filings contain information that is essential to the staff's review and ultimate determination on whether an association or employment is in the public interest and consistent with investor protection.

It is estimated that approximately 5 respondents will make submissions pursuant to this rule annually and that they each will make 5 responses, for a total burden of 200 hours, based upon past submissions (25 × 8 = 200). The staff estimates that the average number of hours necessary to complete a submission pursuant to Rule 19h–1 is 8 hours. The average cost per hour for completion of a submission is approximately $101. Therefore, the total cost of compliance for the respondents is $20,200. (25 responses × 8 hours per response × $101 per hour).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

General comments regarding the estimated burden hours should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or send an e-mail to: *David_Rostker@omb.eop.gov* and (ii) R. Corey Booth, Director/Chief Information Officer, Securities and Exchange Commission, C/O Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: *PRA_Mailbox@sec.gov*. Comments must be submitted to OMB within 30 days of this notice.

Dated: July 9, 2007.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–13746 Filed 7–16–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 6a–4; SEC File No. 270–496; OMB Control No. 3235–0554.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995,[1] the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Section 6 of the Securities Exchange Act of 1934 (''Act'')[2] sets out a framework for the registration and regulation of national securities exchanges. Under the Commodity Futures Modernization Act of 2000, a futures market may trade security futures products by registering as a national securities exchange. Rule 6a–4[3] sets forth these registration procedures and directs futures markets to submit a notice registration on Form 1–N. Form 1–N calls for information regarding how the futures market operates, its rules and procedures, its criteria for membership, its subsidiaries and affiliates, and the security futures products it intends to trade. Rule 6a–4 also would require entities that have submitted an initial Form 1–N to file: (1) Amendments to Form 1–N in the event of material changes to the information provided in the initial Form 1–N; (2) periodic updates of certain information provided in the initial Form 1–N; (3) certain information that is provided to the futures market's members; and (4) a monthly report summarizing the futures market's trading of security futures products. The information required to be filed with the Commission pursuant to Rule 6a–4 is designed to enable the Commission to carry out its statutorily mandated oversight functions and to ensure that registered and exempt exchanges continue to be in compliance with the Act.

The respondents to the collection of information are futures markets.

The Commission estimates that the total annual burden for all respondents to provide the amendments and periodic updates under Rule 6a–4 would be 105 hours (15 hours/respondent per year x seven respondents) and $10,066 ($1438/response × seven responses/year). The Commission estimates that the total annual burden for the filing of the supplemental information and the monthly reports required under Rule 6a–4 would be 87.5 hours (25 filings/respondent × seven respondents x 0.5 hours/response). The SEC estimates that the total annual cost for all supplemental filings would be $3675 (25 filings/respondent per year × 7 respondents × $21/response).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Comments should be directed to (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an e-mail to: *David_Rostker@omb.eop.gov*; and (ii) R. Corey Booth, Director/Chief Information Officer, Securities and Exchange Commission, c/o Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: *PRA_Mailbox@sec.gov*. Comments must be submitted within 30 days of this notice.

Dated: July 10, 2007.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–13751 Filed 7–16–07; 8:45 am]

BILLING CODE 8010–01–P

[1] 44 U.S.C. 3501 *et seq.*

[2] 15 U.S.C. 78f.

[3] 17 CFR 240.6a–4.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56037; File Nos. 4–533 and 4–534]

Joint Industry Plan; American Stock Exchange LLC, New York Stock Exchange LLC, and NYSE Arca, Inc. and Chicago Stock Exchange, Inc., The Nasdaq Stock Market, Inc., National Association of Securities Dealers, Inc., National Stock Exchange, Inc., and Philadelphia Stock Exchange, Inc.; Notice of Filing of Proposed National Market System Plans for the Selection and Reservation of Securities Symbols

July 10, 2007.

I. Introduction

Securities symbols are a key element in the operation of a national market system and essential to the dissemination of trade information in a common format. Historically, securities symbols have been assigned under an informal understanding among the listing markets. It has been the practice of the New York Stock Exchange LLC (''NYSE'') to list securities of companies using one-, two-, or three-character symbols. Other exchanges, including the American Stock Exchange LLC (''Amex'') and regional exchanges, have also listed securities of companies using two- and three-character symbols. Until recently, The Nasdaq Stock Market, Inc. (''Nasdaq'') has always listed securities of companies using four- or five-character symbols.[1] Because securities symbols are an important part of a listed company's identity and because there is a limited supply of securities symbols—particularly one-, two-, and three-character symbols—developing a formal process to reserve, select, and allocate symbols among listing markets and their companies would help promote a fair and orderly national market system and prevent investor confusion.

In 1975, Congress directed the Securities and Exchange Commission (''Commission''), through its enactment of section 11A of the Securities Exchange Act of 1934 (''Act''),[2] to facilitate the establishment of a national market system to link together the individual markets that trade securities. Congress found that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure fair competition among exchange markets.[3] Congress directed the Commission to authorize or require self-regulatory organizations (''SROs'') to act jointly with respect to matters as to which they share authority in planning, developing, operating, or regulating a national market system.[4] Consistent with the principles of section 11A of the Act, in February 2005, Commission staff asked the listing markets to commence joint discussions to develop a national market system plan for the process of reserving, selecting, and allocating securities ticker symbols.[5]

On March 23, 2007, pursuant to Rule 608 of Regulation NMS under the Act[6] (''Rule 608''), Amex, NYSE, and NYSE Arca filed with the Commission a proposed plan for the purpose of the selection and reservation of securities symbols (''Three-Characters Plan''). On March 23, 2007, Nasdaq, NASD, NSX, and Phlx also filed with the Commission a proposed plan for the purpose of the selection and reservation of securities symbols (''Five-Characters Plan''). On April 23, 2007, CHX, Nasdaq, NASD, NSX, and Phlx filed a supplement to the Five-Characters Plan.[7]

Although the two plans are identical in many respects, they also differ on several significant matters. The primary difference between the two plans is their scope. The Three-Characters Plan would only cover one-, two-, and three-character symbols; the Five-Characters Plan would cover one-, two-, three-, four-, and five-character symbols. In addition, the plans differ with regard to the number of, and the length of time that, symbols may be reserved, the portability of symbols for issuers that move their listing from one market to another, the allocation of costs relating to the plan, and the process of withdrawing from the plan. Pursuant to Rule 608, the Commission is publishing this notice of, and soliciting comments on, both the Three-Characters Plan and the Five-Characters Plan.

Section 11A of the Act grants the Commission broad authority to authorize or require SROs, either by rule or order, to act jointly with respect to planning, developing, operating, or regulating a national market system.[8] Thus, the Commission may establish a single symbol reservation national market system plan by approving either the Three-Characters Plan or the Five-Characters Plan or may approve both the Three-Characters Plan and the Five-Characters Plan, in each case with such changes or subject to such conditions as the Commission may deem necessary or appropriate.[9] In addition, the Commission has authority to require SROs to participate in any approved national market system plan or plans, or otherwise act jointly with respect to matters related to the national market system.[10]

The Commission requests comment on whether all SROs that list securities should be required to join any symbol reservation national market system plan approved by the Commission. If commenters believe that SROs that list securities should not be required to join such an approved national market system plan, the Commission requests commenters to address how to preclude duplicative symbols from being selected and reserved, how to resolve disputes about symbols, or how otherwise to address concerns the plans are designed to address.

II. Background

Pursuant to Rule 601 of Regulation NMS under the Act,[11] all SROs are required to report every trade in listed equity securities[12] and Nasdaq securities[13] made through their facilities, and to make such information public. Each SRO reports every transaction to the ticker tape using the ticker symbol for that security, the volume of the trade, and the price of the trade. Currently, there are three ticker tapes: Tape A reports the stocks that are listed on NYSE, Tape B reports the stocks that are listed on Amex, as well as securities listed on any other national securities exchange (except securities

[1] *See infra* note 19 and accompanying text.

[2] 15 U.S.C. 78k–1.

[3] 15 U.S.C. 78k–1(a)(1)(C).

[4] 15 U.S.C. 78k–1(a)(3)(B).

[5] *See* Letters from Annette L. Nazareth, then Director of the Division of Market Regulation, Commission, to Amex, Boston Stock Exchange (''BSE''), Chicago Board Options Exchange (''CBOE''), Chicago Stock Exchange (''CHX''), International Stock Exchange (''ISE''), Nasdaq, National Association of Securities Dealers, Inc. (''NASD''), National Stock Exchange, Inc. (''NSX''), NYSE, Pacific Exchange (the predecessor to NYSE Arca, Inc. (''NYSE Arca'')) and Philadelphia Stock Exchange, Inc. (''Phlx''), dated February 7, 2005.

[6] 17 CFR 242.608.

[7] In the Supplement, CHX joined as a party proposing the Five-Characters Plan. In addition, the Supplement contained a revised version of the Five-Characters Plan. The parties to the Five-Characters Plan revised the plan as follows: (i) Changed the definition of securities for which an SRO must maintain facilities for the quoting and trade reporting of such securities in order to be party to the plan and corresponding changes throughout the plan and (ii) deleted the statement that new parties to the plan would pay an equal share of all development costs.

[8] *See* 15 U.S.C. 78k–1(a)(3).

[9] *See* 17 CFR 242.608(b)(2).

[10] 15 U.S.C. 78k–1(a)(3)(B).

[11] 17 CFR 242.601.

[12] 17 CFR 242.600(b)(34) defines ''listed equity security'' as ''any equity security listed and registered, or admitted to unlisted trading privileges, on a national securities exchange.''

[13] 17 CFR 242.600(b)(41) defines ''Nasdaq security'' as ''any registered security listed on The Nasdaq Stock Market, Inc.''

also listed on NYSE and Nasdaq), and Tape C reports the stocks that are listed on Nasdaq. Tapes A and B disseminate market information pursuant to the Consolidated Tape Association Plan (''CTA Plan''), while Tape C disseminates market information pursuant to the Nasdaq Unlisted Trading Privileges Plan (''Nasdaq Plan'').

The term ''ticker symbol'' originates from the ticker tape.[14] Instead of reporting trades using the full name of the security, a symbol was used to save time and resources when telegraph operators typed each transaction.[15] The most heavily traded stocks were assigned one-character symbols to speed up communication.[16] As noted earlier, it has been the practice of the NYSE to list companies using one-, two-, and three-character symbols. Other exchanges, including Amex and regional exchanges, have also listed companies using two- and three-character symbols. Until recently, Nasdaq, formerly a facility of the NASD, was the only market that did not list securities with one-, two-, and three-character symbols; instead, Nasdaq had always listed securities with four- and five-character symbols. In November 2005, however, Nasdaq announced its intention to begin listing companies with one-, two-, and three-character symbols.[17] Since that time, Nasdaq has made a series of announcements detailing its plans, and has worked with the industry to test trading systems to ensure the proper functionality for such symbols.[18] In March 2007, Nasdaq filed with the Commission a proposed rule change to allow companies transferring their listings to Nasdaq to retain their three-character symbols.[19]

As the securities markets have grown over the years, one-, two-, and three-character symbols, traditionally used by the exchanges, have become scarce. There are 26 combinations for one-character symbols, 676 combinations for two-character symbols, and 17,576 combinations for three-character symbols, for a total of 18,278 one-, two-, and three-character symbols. Several factors have also been increasing the demand for one-, two-, and three-character symbols. In recent years, exchanges have begun listing new and innovative products, such as exchange-traded funds, that are also now competing with listed companies for symbols. In addition, Nasdaq has expressed its intention to start using one-, two-, and three-character symbols.[20] Finally, the proliferation of standardized options has decreased the availability of three-character symbols.[21]

Concerns about constraints on symbol supply heighten the need to revisit the existing informal symbol reservation system. Currently, the process of designating securities symbols is not done pursuant to a formal national market system plan or agreement, but is conducted informally among the SROs. Each SRO keeps its own records of reserved symbols. If an SRO wishes to reserve a particular symbol, the SRO will first consult its own list of reserved symbols to confirm that the desired symbol has not been reserved by another SRO. Once the listing SRO has verified that a particular symbol is not already reserved according to its own records of reserved symbols, the listing SRO will notify the other SROs that it wishes to reserve such symbol. If no other SRO objects, then the listing SRO has successfully reserved that symbol and each SRO would update its own records of reserved symbols accordingly.

While the existing informal reservation system has performed the function of allocating symbols among the listing markets in the past, the weakness in the current system could potentially have significant market consequences as exchanges compete more aggressively for listings and the supply of available symbols becomes more restricted over time. The absence of universal reservation records, for example, could cause confusion about the availability of certain symbols and could lead to disputes between listing markets about the availability of a symbol. Such disputes raise the potential for investor confusion and symbol duplication. Under the existing system, listing markets may reserve an excess amount of symbols indefinitely, which may exacerbate the strain on symbol supply. The fear of symbol supply constraints could even drive listing markets to reserve an excess amount of symbols, either to protect their interests in the event of needing such symbols in the future or to give themselves advantages over their competitors in securing future listings. Moreover, the existing system does not limit the potential for symbol reservations to be used for anti-competitive purposes. For example, a listing market could use the existing symbol reservation system to withhold unused symbols from their competitors, trade reserved symbols only with certain, allied exchanges, or use their power to withhold desired symbols to compel other listing markets not to trade symbols with their direct competitors. Also, the existing system does not universally permit issuers transferring their listings to a new exchange to keep their ticker symbols. For example, the exchange where an issuer listed originally could dispute the new listing exchange's right to use the issuer's ticker symbol, which could disrupt the process of transferring the listing. In addition, issuers with one-, two-, or three-character symbols currently may not transfer their listings to Nasdaq,[22] though they may do so to any other national securities exchange. These weaknesses in the existing informal symbol reservation system could potentially lead to conditions that hamper competition among the listing markets and disrupt the marketplace.

III. Description of the Plans

The two proposed plans are identical in numerous respects. A brief summary of the most significant aspects of the plans, highlighting their distinctions, is provided below. The full text of the separate plans submitted by the SROs is available on the Commission's Web site at: *http://www.sec.gov/rules/sro/4–534.pdf* and *http://www.sec.gov/rules/sro/4–533revised.pdf,* respectively, at

[14] The ticker tape started in 1867, when all trades made on an exchange were sent out by telegraph and printed on a piece of paper. Although the process is now automated, the securities industry participants continue to refer to the electronic reporting of information as the ''tape.'' *See* Hal McIntyre, How the U.S. Securities Industry Works, 194–95 (The Summit Group Press) (2000).

[15] *See, e.g.*, Brendan I. Koerner, How Are Ticker Symbols Allotted?, Slate, September 18, 2003, available at: *http://www.slate.com/id/2088587/.*

[16] *See id.*

[17] *See, e.g.*, Head Trader Alert 2005–133 (November 14, 2005), available at: *http://www.nasdaqtrader.com/Trader/News/2005/headtraderalerts/hta2005–133.stm.*

[18] *See, e.g.*, Head Trader Alert 2006–144 (September 29, 2006), available at: *http://www.nasdaqtrader.com/Trader/News/2006/headtraderalerts/hta2006–144.stm,* Head Trader Alert 2006–193 (November 16, 2006), available at: *http://www.nasdaqtrader.com/Trader/News/2006/headtraderalerts/hta2006–193.stm* and Head Trader Alert 2006–201 (December 6, 2006), available at: *http://www.nasdaqtrader.com/Trader/News/2006/headtraderalerts/hta2006–201.stm,* Head Trader Alert 2007–008 (January 25, 2007), available at: *http://www.nasdaqtrader.com/Trader/News/2007/headtraderalerts/hta2007–008.stm.*

[19] *See* Securities Exchange Act Release No. 55563 (March 30, 2007), 72 FR 16391 (April 4, 2007) (SR–NASDAQ–2007–031). *See also* Securities Exchange Act Release No. 55519 (March 26, 2007), 72 FR 15737 (April 2, 2007) (SR–NASDAQ–2007–025) (allowing a single company, Delta Financial Corp., to retain its three-character symbol upon transferring its listing from Amex to Nasdaq).

[20] *See supra* notes 17–19.

[21] The options exchanges have expressed their intention to shift to a different symbology in 2009. See *http://www.theocc.com/initiatives/symbology/default.jsp.*

[22] *See supra* note 19.

the respective SROs, and at the Commission's Public Reference Room.

A. Preambles

The preambles to the plans are nearly identical.[23] The Three-Characters Plan would establish a body composed of the signatory SROs called the International Symbols Reservation Authority. Similarly, the Five-Characters Plan would establish a body composed of the signatory SROs called the Intermarket Symbols Reservation Authority.[24]

B. Scope of Plans

Each of the proposed plans would cover only root symbols, without any suffix or special conditional identifier.[25]

• The Three-Characters Plan would be the exclusive means of allocating and using symbols of one-, two-, or three-characters in length and would not govern the use of four- or five-character symbols.[26] Specifically, the Three-Characters Plan would cover the allocation of all securities symbols disseminated through the CTA Plan, the Consolidated Quote Plan (''CQ Plan''), the Options Price Reporting Authority (''OPRA''), and any market data distribution network maintained by a party [27] to the plan or an affiliate of a party to the plan.

• The Five-Characters Plan would be the means of allocating and using symbols of one-, two-, three-, four-, or five-characters in length.[28] The Five-Characters Plan would cover securities that are NMS securities as currently defined in Rule 600(a)(46) of Regulation NMS [29] and any other equity securities quoted, traded and/or trade reported through an SRO facility.

The Commission requests comment on whether it would be advisable for it to approve one plan or two plans. For example, commenters views are requested on whether the Commission could approve a plan covering only one-, two-, and three-character symbols and a plan covering one-, two-, three-, four-, and five-character ticker symbols. Would there be any potential inefficiencies and inconsistencies arising from having two plans that would render that situation unworkable or undesirable? Would there be any special benefit derived from having two plans that might justify the additional burden of administering two plans? The Commission also requests comment on whether it is advisable to have a single plan covering one-, two-, three-, four-, and five-character symbols. Would there be any difficulties with having a single plan for the allocation of all symbols? What are the benefits of having only one plan? In addition, the Commission requests comment on how having either a single plan or two plans would assure fair competition among all parties and, in particular, new listing markets.

C. Parties to the Plans

The proposed plans' provisions regarding qualifications to be a party to the plan are described below:

• The Three-Characters Plan would allow an SRO to join the plan if it maintains a market for the listing and trading of securities that are identified by one-, two-, or three-character symbols and that are identified as ''eligible'' securities for ''Network A'' or ''Network B'' as those terms are defined in the CTA Plan.[30] A party would also have to have the actual technical and physical capability through its facilities to immediately quote and report trades in securities using one-, two-, or three-character symbols. In addition, the plan would require, as a condition to becoming a new participant, that an SRO pay a proportionate share of the aggregate development costs, with the result that each party's share of all development costs [31] is approximately the same, and sign a current copy of the plan.

• The Five-Characters Plan would allow an SRO to join the plan if it maintains a market for the listing of securities that are identified by one-, two-, three-, four-, or five-character symbols.[32] A party would also have to have the actual technical and physical capability through its facilities to immediately quote and report trades in securities using one-, two-, or three-character symbols, if it seeks to reserve symbols of one-, two-, or three-characters in length, and using four- or five-character symbols, if it seeks to reserve symbols of four- or five-characters in length. In addition, this plan would require, as a condition to becoming a new participant, that an SRO pay a proportionate share of the aggregate development costs, based on the number of symbols it reserves, and sign a current copy of the plan.[33]

The Commission requests comment on the proposed plans' requirements for SROs to join each plan. In particular, the Commission requests comment on whether it is appropriate to limit, as the Three-Character Plan proposes, participation in the plan to SROs that maintain a market for the listing and trading of eligible securities for Network A and Network B. Would such a requirement impede fair competition? More generally, would the proposed plans' provisions on eligibility assure fair competition among all parties and, in particular, new listing markets?

D. Administration of ISRA

Section II of each of the plans sets forth the administration of the ISRA. A Policy Committee would administer the ISRA and, unless expressly provided otherwise in the plan, the Policy Committee would make all policy decisions on behalf of the ISRA in furtherance of the functions and objectives of the ISRA under the Act and the plan. Specifically, the Policy Committee would: (1) Oversee the operation of the Symbol Reservation System; [34] (2) make all determinations pertaining to contracts with parties to the plan and persons who provide goods or services to the ISRA; and (3) determine all other questions pertaining to the planning, developing, and operating of the ISRA, including those pertaining to budgetary or financial matters.

Both of the proposed plans provide that one voting member and one alternate voting member representing each party would compose the Policy Committee.[35] Each party would have one vote on all matters voted upon by the Policy Committee and actions of the ISRA under each plan would be authorized by a majority vote of the Policy Committee members, subject to Commission approval when required by applicable securities law.[36] Authorized actions under each plan would be binding upon all the parties. However, an aggrieved party may present contrary views to any regulatory body or in any other appropriate forum.[37]

Both plans also provide that a meeting of the Policy Committee would be held

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[23] *See* preambles of the proposed plans.

[24] International Symbols Reservation Authority and Intermarket Symbols Reservation Authority are referred to herein as ''ISRA.''

[25] *See* Section IV(a) of the proposed plans.

[26] *See* Sections I(b) and IV(a) of the Three-Characters Plan.

[27] The Commission notes that under Rule 600 of Regulation NMS, SROs who are parties to a national market system plan are referred to as ''participants'' while the proposed plans refer to such SROs as ''parties.'' *See* 17 CFR 242.600(b)(53). For purposes of this notice, the term ''participants'' and ''parties'' shall have the same meaning.

[28] *See* Sections I(b) and IV(a) of the Five-Characters Plan.

[29] 17 CFR 600(a)(46).

[30] *See* Section I(b) and (c) of the Three-Characters Plan.

[31] For additional discussion regarding the plan's provision relating to costs, *see* discussion *infra* Part III(G).

[32] *See* Section I(b) and (c) of the Five-Characters Plan.

[33] For additional discussion regarding the plan's provision relating to costs, *see* discussion *infra* Part III(G).

[34] *See* discussion *infra* Part III(F).

[35] *See* Section II(c) of the proposed plans.

[36] *See* Section II(d) of the proposed plans.

[37] *Id.*

at least annually and that other meetings would be held as determined by the Policy Committee.[38] Each plan also specifies the notice provisions for regular and special meetings, and the organization of the meetings.

The Commission requests comment on the proposed plans' provisions relating to the administration of the ISRA by the Policy Committee. In particular, the Commission requests comment on the powers of the Policy Committee, as well as whether the committee's decision-making process by majority vote is appropriate. In addition, the Commission requests comment on the appeal procedures for an aggrieved party. Should the plans specify what is meant by the phrase ''other appropriate forum''? Do the proposed plans provide enough clarity as to how an aggrieved party could pursue relief under the plans?

E. Performance of Functions

Section III of each of the proposed plans establishes that the ISRA would delegate the operation of the Symbol Reservation System to an independent third party (the ''Processor'') and would enter into contracts with the Processor relating to the operation of the Symbol Reservation System. The Processor would receive reservation requests from the parties and reserve and allocate symbols among the parties in accordance with the terms of the plan. To this end, the Processor would create and maintain a symbol reservation database.[39]

The Commission requests comment on the proposed plans' provisions related to the delegation of the operation of the Symbol Reservation System to a Processor.

F. The Symbol Reservation System

Section IV of each of the proposed plans sets forth the operating details of the Symbol Reservation System. Here, the plans diverge in key ways.

1. Reservation and Use of Symbols

a. Submission of Initial Reservation Requests

Each plan would provide that, within a specified time period after the plan's approval, a participant in the plan may submit to the Processor requests for the initial reservation of symbols.[40] Both plans provide that a party may reserve symbols for: (i) The listing of common stock or any other security, including options; (ii) the dissemination of a securities index or other index information; or (iii) any other purpose authorized by a majority vote. In addition, the Five-Characters Plan provides that a party may reserve symbols for the trading of any over-the-counter security. Initial reservation requests may be for perpetual or limited-time reservations, as discussed below.

Perpetual Reservations

Each of the proposed plans would permit a party to reserve a limited number of symbols in perpetuity (''perpetual reservations'').[41]

• The Three-Characters Plan provides that NYSE and Amex each could reserve up to 200 symbols as perpetual reservations; other parties to the plan each could reserve up to 40 symbols as perpetual reservations.

• The Five-Characters Plan provides that there would be two perpetual reservation lists—one list for one-, two-, and three-character symbols and one list for four- and five-character symbols. Each party to the plan could reserve up to 20 one-, two-, or three-character symbols as perpetual reservations, and up to 20 four- or five-character symbols as perpetual reservations.

Both proposed plans provide that a party could not add symbols to its perpetual reservation list after the initial reservation process, except when reserving a symbol for re-use.[42] In addition, both plans would provide that a party that requests perpetual reservations for more symbols than permitted would be required to place its symbols requests in priority ranking.

The Commission requests comment on the plans' proposals to include perpetual reservations lists. Should SROs be permitted to reserve symbols in perpetuity? Commenters are requested to explain why SROs should or should not be permitted to reserve symbols into perpetuity. Would there be any public benefit derived from having perpetual reservations? What impact would allowing perpetual reservations have on competition, particularly for new markets? The Commission also requests commenters' views on the number of symbols an SRO should be permitted to reserve under any such list. Specifically, the Commission requests comment on whether all SROs should be given the same number of perpetual reservations, as proposed under the Five-Characters Plan, or whether it is reasonable to provide certain SROs a greater number of such reservations, as proposed under the Three-Characters Plan. In particular, the Commission requests comment on what basis would be appropriate for certain SROs to receive more perpetual reservations than other SROs. For example, should the primary listing markets receive a greater number of perpetual reservations?

Finally, the Commission requests commenters' views on how the proposed provisions on perpetual reservations would affect new listing markets. How would an SRO that joins the plan after the initial reservation process be able to reserve symbols? Would the existence of perpetual reservations present a significant barrier to entry by new listing markets? Would it prevent or reduce competition from new listing markets? Would conducting another initial reservation process for all plan participants upon a new market joining the plan provide a more level playing field for a new entrant? How else could the provisions on perpetual reservations be adjusted to account for new listing markets?

(2) Limited-Time Reservations

Under both plans, symbols could also be reserved for 24 months (''limited-time reservations'').[43]

• The Three-Characters Plan provides that Amex and NYSE each could reserve up to 1,500 symbols as limited-time reservations and NYSE Arca could reserve up to 500 symbols as limited-time reservations. The Three-Characters Plan does not specify the number of limited-time reservations for other parties. Instead, this plan would need to be amended when an additional party joins the plan to specify how many limited-time reservations such party is entitled.

• The Five-Characters Plan would provide two limited-time reservation lists—one list for one-, two-, and three-character symbols and one list for four- and five-character symbols. Each party could reserve up to 1,500 symbols under the one-, two-, or three-character limited-time reservations list and up to 1,500 symbols under the four-or five-character limited-time reservations list. Moreover, under the Five-Characters Plan, a party may not make any limited-time reservations with respect to a particular symbol unless the party has a reasonable basis to utilize the symbol within the next 24 months.

As with perpetual reservation requests, under both plans, a party that requests limited-time reservations for more symbols than permitted would be required to place its symbols requests in priority ranking.

[38] *See* Section II(e) of the proposed plans.

[39] *See infra* Part III(F)(4) for further discussion.

[40] *See* Section IV(b)(1) of the proposed plans.

[41] *See* Section IV(b)(1)(A) of the proposed plans.

[42] *See* discussion *infra* Part III(F)(3).

[43] *See* Section IV(b)(1)(B) of the proposed plans.

The Commission requests comment on the plans' proposals to include limited-time reservations. Should SROs be permitted to make limited-time reservations? Commenters are requested to explain why SROs should or should not be permitted to reserve symbols for a limited-time. Would there be any public benefit derived from having limited-time reservations? What impact would allowing limited-time reservations have on competition, particularly for new markets? The Commission also requests comment on the requirement for a ''reasonable basis'' for reserving a symbol, as articulated in the Five-Characters Plan. Specifically, should the plan be more specific as to what would be a ''reasonable basis'' or who would make such a determination and how?

The Commission requests comment on the number of symbols an SRO should be permitted to reserve as limited-time reservations. The Commission also requests comment on the length of time symbols may be reserved as limited-time reservations. Is 24 months an appropriate length of time—should it be shorter or longer? In addition, the Commission requests comment on whether all SROs should receive the same number of limited-time reservations, as provided under the Five-Characters Plan, or whether it is appropriate for certain SROs to receive a greater number of such reservations, as proposed under the Three-Characters Plan. In particular, the Commission requests comment on what basis would be appropriate for certain SROs to receive more limited-time reservations than other SROs. For example, should the primary listing markets receive a greater number of limited-time reservations? Finally, the Commission requests commenters' views on how the proposed provisions on limited-time reservations would affect new listing markets. How would an SRO join the plan after the initial reservation process reserve symbols? Would limited-time reservations prevent or reduce competition from new listing markets and present a significant barrier to entry by new listing markets? Would conducting a new initial reservation process for all plan participants upon a new market joining the plan provide a more level playing field for a new entrant? How else could the provisions on limited-time reservations be adjusted to account for new listing markets?

b. Processing of Initial Reservation Requests

(1) Claims to a Legacy Reservation

Both plans would permit a party to have priority over other parties in reserving a symbol that it claims was properly reserved under the current informal system (''legacy reservation''), prior to the effective date of the plan.

- Under the Three-Characters Plan, if there is only one party that claims such prior reservation of a symbol, such party would have priority over other SROs to retain its reservation of that symbol.[44] Such a symbol would be included on a party's perpetual or limited-time reservation list.
- Under the Five-Characters Plan, if there is only one party that claims such prior reservation of a symbol, such party would have priority over other SROs to retain reservation of that symbol only if the party represents that it has a reasonable basis to believe that it would utilize such symbol within the next six months.[45] Under the Five-Characters Plan, such reservation would not count towards the party's perpetual reservations or limited-time reservations, but instead be reserved as a separate, additional legacy reservation. However, if the party does not use such symbol within the allotted six-month period, it would lose the reservation unless the party requests an extension for an additional six-month period. In requesting such an extension, the party would have to have a reasonable basis to believe that it would utilize such symbol within the additional six-month period.

Both plans would provide the same process for resolving claims by more than one party to a legacy reservation.[46] This process is as follows: First, the Processor would notify all such parties of the conflicting claims. Then the parties would have five business days to reach a mutually acceptable agreement as to which party would be permitted to reserve the symbol. In the absence of an agreement, the Policy Committee would resolve the issue by a majority vote of the parties not claiming the symbol. Where there is no agreement but the Policy Committee is able to determine which party has the earliest proper claim to such symbol, the plans would require it to resolve the disagreement in favor of such party.

The Commission requests comment on the proposed plans' processes for recognizing legacy reservations. Should parties have the right to reserve, under the plans, symbols for which they claim to have a legacy reservation? Should a party only be able to retain a legacy reservation if it is able to represent that it has a reasonable basis to believe that it would utilize such symbol within the next six months, as provided under the Five-Characters Plan? If so, the Commission requests comment on the requirement to have ''a reasonable basis'' for retaining legacy reservations. Specifically, should the plan be more specific as to what would be a ''reasonable basis'' or who would make such a determination and how?

The Commission also requests comment on the proposed process for resolving claims to legacy reservations. Could the requirement of a majority vote for resolving such claims affect fair competition among the parties? How could this process be adjusted to address any competitive concerns? The Commission also requests comment on how decisions to grant extensions of legacy reservations, as proposed under the Five-Characters Plan, would be made. Should the plan be more specific as to who would make a determination that a reasonable basis for an extension exists and how?

(2) Other Initial Reservations

Both plans would provide the same process for initial reservations of symbols that have not been properly reserved prior to the effective date of the plan.[47] If only one party seeks to reserve a symbol, then the Processor would reserve such symbol for that party. If multiple parties seek to reserve a symbol, the Processor would reserve the symbol based on a random ordering established by the Policy Committee. If a symbol is not available for reservation, both plans would provide that the Processor would place the requesting party on a wait list.[48] Further, both plans would provide that the Processor would process a party's symbol reservation requests by first reserving symbols up to the party's limit for its perpetual reservations list and then reserving the remaining requested symbols up to the limit for its limited-time reservations.[49]

The Commission requests comment on the proposed plans' processes for initial reservation requests. In particular, the Commission requests comment on how the proposed processes would affect new listing markets. Would the proposed processes

[44] *See* Section IV(b)(2) of the Three-Characters Plan.

[45] *See* Section IV(b)(2) of the Five-Characters Plan.

[46] *See* Section IV(b)(2)(B) of the proposed plans.

[47] *See* Section IV(b)(2)(C)–(E) of the proposed plans.

[48] *See* discussion *infra* Part III(F)(2).

[49] *See* section IV(b)(2)(F) of the proposed plans.

for initial reservation requests affect competition? Should there be a special initial reservation process for a new listing market that joins the plan? Would a new listing market be adversely affected by the proposed methods of allocating initial reservation requests and its impact on the availability of symbols? How could the proposed plans assure fair competition among all parties and, in particular, new listing markets? How should the random order of priority for reserving a symbol requested by multiple parties be designed? For example, should the order be selected anew for every symbol? Would another assignment methodology be more appropriate or fair?

c. Subsequent Reservations

Both plans contain substantially identical provisions on reserving symbols after the initial reservation process.[50] Specifically, if a party submits to the Processor a request for a limited-time reservation and the symbol is available, the Processor would reserve such symbol, provided that the party has not already reached its maximum number of allowed limited-time reservations. If it has reached its maximum number of limited-time reservations, the party could surrender a reserved symbol in order to reserve the new symbol. If a symbol requested is not available, the Processor would place the requesting party on the waiting list for such symbol.

The Commission requests comment on the proposed plans' provisions for the subsequent reservations of symbols. In particular, the Commission requests comment on whether the proposed provisions assure fair competition among all parties and, in particular, new listing markets.

d. Non-Use or Release of Symbols Within Time Period

Both plans provide that the Processor would release any limited-time reservation symbols not used within the 24-month time period.[51] A party could also voluntarily release a reserved symbol. In either case, upon the release of a symbol, the Processor would notify the parties on the waiting list, if any, of the symbol's availability. If there is no waiting list or if no party on the waiting list elects to reserve such symbol, the Processor would notify all parties to the plan of the availability of the symbol. If more than one party requests the reservation of such symbol within two business days of the notice, the Processor would assign the symbol to one party and place the other parties on the waiting list pursuant to a random order of priority established by the Policy Committee.

The Commission requests comment on the proposed plans' provisions for the non-use or release of symbols. How should the random order of priority for the waiting list be designed? For example, should the order be selected anew for every symbol? Would another assignment methodology be more appropriate or fair? Would the proposed plans' processes for the non-use or release of symbols affect competition?

e. Request for Release of a Symbol

Both plans would provide the same method for a party to request the release by another party of a reserved symbol.[52] Specifically, if a party has an immediate need to use a symbol that another party has reserved, the requesting party would ask the party that reserved the symbol, and any other parties on the waiting list, whether such parties would be willing to release the reserved symbol. If the parties do not agree to release the symbol, the requesting party would not obtain the reserved symbol. If the parties do agree to release the symbol, the requesting party could include such symbol as one of its limited-time reservations. If the requesting party is already at the maximum number of limited-time reservations, under the Three-Characters Plan, it would have to voluntarily surrender another reserved symbol before reserving the requested symbol. Under the Five-Characters Plan, if the requesting party is already at the maximum number of limited-time reservations, the party could either surrender or re-designate another symbol before reserving the requested symbol. If the requesting party does not use a released symbol within the 24-month period, absent the consent of all parties initially required to be contacted, the reservation and waiting list priority in effect when the requesting party first made its request for the release of the symbol would again be in effect.

The Commission requests comment on the proposed plans' processes for releasing symbols. The Commission requests commenters' views on whether a requesting party that is at the maximum number of limited-time reservations should be allowed to either surrender or re-designate another symbol in order to reserve the requested symbol. The Commission notes that the Five-Characters Plan does not define or describe the process of ''re-designating'' a symbol. The Commission requests comment on whether it is necessary for the plan to describe the process of ''re-designation.'' The Commission also requests comment on how a symbol could be ''re-designated'' if a requesting party is at its maximum number of limited-time reservations. Finally, the Commission requests comment on whether the proposed provisions on releasing symbols assure fair competition among all parties and, in particular, new listing markets.

2. Waiting List

Both plans would provide substantially identical waiting list processes.[53] Specifically, when one or more parties request to reserve a symbol that another party has reserved, the Processor would place such parties on the waiting list for that symbol. The waiting list would be based on time priority—that is, the earliest request would have precedence. However, if more than one party seeks to use a symbol already in use within either 30 days of the effective date of the plan or two business days of notice of a symbol's availability, the Policy Committee would establish a random order of such parties to determine priority on the waiting list.

When a symbol becomes available, the Processor would notify the party with priority on the waiting list. Such party would then have two business days to reserve that symbol; otherwise, the Processor would repeat the process as necessary with all parties on the waiting list, in order of priority. The maximum number of symbols for which a party may be on the waiting list at any time would be 100 symbols.

The Commission requests comment on the proposed plans' waiting list provisions. In particular, the Commission requests comment on whether 100 symbols is an appropriate number of symbols for the waiting list. With respect to a party's request to use a symbol already in use either within 30 days of the effective date of the plan or within two business days of notice of a symbol's availability, the Commission requests comment on whether such time periods are appropriate. In addition, the Commission requests comment on whether the proposed provisions for waiting lists assure fair competition among all parties and, in particular, new listing markets. Finally, how should the random order of priority for the waiting list be designed? For example, should the order be selected anew for every symbol? Would another assignment

[50] *See* Section IV(b)(3) of the proposed plans.

[51] *See* Section IV(b)(5) of the proposed plans.

[52] *See* Section IV(b)(6) of the proposed plans.

[53] *See* Section IV(c) of the proposed plans.

methodology be more appropriate or fair?

3. Reuse of a Symbol and Portability of Symbols in Use

The plans propose different approaches to the reuse and portability of symbols.[54]

• The Three-Characters Plan would provide that if a party ceases to use a symbol,[55] such party automatically reserves that symbol, notwithstanding any other limits on the number of reserved symbols under the plan. The Three-Characters Plan would include within an SRO's right to automatically reserve a symbol it ceases to use the situation in which an issuer transfers its listing from one SRO to another.

This plan would provide that the SRO from which the issuer delisted its security would have the rights to the symbol for that security, unless it consents to the transfer of the symbol to the new SRO. If the SRO to which the issuer transferred its listing believes there is a compelling business reason why it should have the rights to the symbol (if it is a two-or three-character symbol, but not a one-character symbol), the new SRO may submit to the Processor the determination of which SRO shall have the rights in that symbol.[56] The Processor could only grant the rights in the symbol to the new SRO if the Processor determines that such SRO's business reasons for obtaining such rights substantially outweigh the business needs of the other SRO to that symbol. The Processor's decision would be final and not subject to appeal.

• The Five-Characters Plan would also provide that if a party ceases to use a symbol, such party automatically reserves that symbol, notwithstanding any other limits on the number of reserved symbols under the plan. However, this plan would provide an exception to this automatic reservation right when an issuer transfers its listing from one SRO to another. In this case, the SRO to which a listing is transferred would have the rights to that issuer's symbol.

Both plans provide that a symbol being reused pursuant to such provisions could be reserved as a perpetual reservation if the party has not yet reserved the full number of perpetual reservations available to it.[57] Otherwise, such symbol would be reserved as a limited-time reservation and the additional symbol could exceed the limit of the maximum number of limited-time reservations permitted to a party under the plan. Finally, both plans would provide that a symbol could not be reused by a party to identify a new security unless the party reasonably determines that such use would not cause investor confusion.

The Commission requests comment on the proposed plans' provisions relating to the reuse of symbols. In particular, the Commission requests comment on the proposed plans' provisions regarding the portability of a securities symbol to a new listing market when an issuer transfers its listing. When an issuer moves its listing to a new listing market, should either the former listing market or the new listing market retain the right to use the issuer's symbol? How would awarding the rights to the symbol to the former listing market affect competition? How would awarding such rights to the new listing market affect competition? Should there be a process for resolving symbol disputes between the former listing market and the new listing market or should the plans categorically award the rights to the symbol to one market or the other? If the former, the Commission requests comment on the Three-Characters Plan's proposed process for resolving such disputes.

Under the Three-Characters Plan, the new listing market may request the transferred symbol if it believes that there is a compelling business reason for the transferred symbol. The Commission requests comment on whether the plan should be more specific as to what would be a ''compelling business reason'' and how the Processor should assess the various business needs of the two listing markets to make the decision as to who should have the rights to the symbol. Should the business reasons of the two listing markets be the only factor in the Processor's determination? Or should other factors also be considered? If so, what other factors should be considered? Is the Three-Characters Plan's provision that the Processor's decision is final and not subject to appeal fair and reasonable? Or would it be more appropriate to provide the parties with an alternative venue for pursuing relief? Finally, the Commission requests comment on whether single-character symbols should be subject to the same portability provisions as two- and three-character symbols.

4. Database

Both plans would provide that the Processor would create and maintain a symbol reservation database.[58] Except as required by applicable law, the Processor would grant access to the database only to the parties and the Commission. The database would show all symbols currently in use and the party using such symbols.[59] In this regard, both plans would require a party to notify the Processor when the party begins using a reserved symbol. In addition, the database would show all symbols reserved on the perpetual reservations and limited-time reservations lists, including the reserving party and the expiration date for limited-time reservations. The database would also show the waiting list and the priority order of the waiting list for each symbol. The Commission requests comment on the proposed plans' provisions related to the database.

G. Financial Matters

Sections I and V of the plans set forth the manner in which the parties would share the initial development costs, as well as continuing costs. The proposed plans differ significantly in their method of cost allocation.

• Under the Three-Characters Plan, the parties would share the initial development costs equally. The Three-Characters Plan would also provide that the continuing costs and expenses of ISRA would be shared equally among the parties at the end of each calendar year. The continuing costs would only be prorated for a party that had not been a party for the entire calendar year. Section I of the Three-Characters Plan would provide that any new party that joins the plan would pay to the existing parties a proportionate share of the aggregate development costs previously paid by such existing parties, with the result that each party's share of all development costs is approximately the same.

• Under the Five-Characters Plan, the parties would share the initial development costs pro-rata based on the number of symbols initially reserved by each party. Section V of the Five-Characters Plan would provide that any new party that joins the plan would also be responsible for a pro-rata portion of the initial development costs based upon the number of symbols initially reserved by such new party during the

[54] *See* Section IV(d) and (f) of the proposed plans.

[55] For example, through merger or delisting of the issuer whereby the security is no longer listed.

[56] The Three-Characters Plan would not permit disputes over one-character symbols to be submitted to the Processor.

[57] The plans also provide that a party could move a symbol from its perpetual reservations list to its limited-time reservations list in order to place the symbol being reused on its perpetual reservations list.

[58] *See* Section IV(e) of the proposed plans.

[59] *See* Section IV(b)(4) of the proposed plans.

first twelve months of the new party's membership in the plan. The Five-Characters Plan would provide that the continuing costs and expenses of ISRA would be shared among the parties pro-rata based on the number of additional symbols reserved in each calendar year, estimated quarterly. In addition, under the Five-Characters Plan, the Policy Committee may develop alternative cost-allocation methodologies for special non-initial development projects.

The Commission requests comment on the proposed plans' provisions relating to financial matters. In particular, should the initial development and continuing costs be allocated by the number of parties, or by the number of reserved symbols of a party? Are there other cost allocation methodologies the Commission should consider? In addition, the Commission requests comment on the proposed plans' effects on new listing markets. Do the proposed plans' provisions on allocation of costs assure fair competition among all parties and, in particular, new listing markets? Would new listing markets be adversely affected by either formula for allocating initial development costs? The Commission also requests comment on whether the proposed plans should address the scenario of a former party who later wishes to rejoin the plan. Specifically, should such an entity be viewed as a new party who would be required to pay a share of the initial development costs according to the prescribed formula for new parties?

H. Confidentiality

Section VI of both plans would provide that the Processor would maintain all information received from the parties in strictest confidence and that the only information that the Processor would make available to the parties is the symbol reservation database. The Three-Characters Plan would also specifically provide that the Processor would make available to the parties any notices or other information specifically called for by the plan. Both plans would provide that the Processor would not make the symbol reservation database available to any person except the Commission or the parties, unless otherwise required by applicable law.

The Commission requests comment on the proposed plans' provisions with respect to the Processor's responsibility to keep information confidential.

I. Term of Plan Withdrawal—Non-transferability of Rights Under the Plan

Section VII of both plans would establish the method for a party to withdraw from the plan. Specifically, to withdraw from the plan, a party would be required to provide at least six months prior written notice to the other parties. The withdrawing party would remain liable for its proportionate share of costs and expenses during the time it was a party to the plan, but would have no further obligations after the withdrawal. The Three-Characters Plan specifically states that withdrawal by a party would not result in any rebate or adjustment in the initial development costs paid, or payable, at the time of termination.

The Commission requests comment on the proposed plans' provisions related to withdrawal. If a party withdraws from the plan, to what extent should that party be responsible for costs paid or payable at the time of its termination from the plan? Should a party that lists securities be permitted to withdraw from the plan? The Commission requests comment on whether it should require all listing markets to join any approved national market system plan for the selection and reservation of securities symbols.

In addition, under both plans, an SRO would cease to be a party to the plan when it ceases to maintain a facility for the quoting and trade reporting of securities transactions or ceases to use symbols subject to the plan.[60] An SRO could continue to be a party of the plan upon the agreement of the remaining parties. To be approved as a continuing party, the Three-Characters Plan would require the unanimous vote of the remaining parties, while the Five-Characters Plan would require a majority vote.

The Commission requests comment on whether a vote is appropriate to allow an SRO that no longer maintains a facility for quoting or trade reporting of securities transactions or ceases to use symbols subject to the plan to remain a party to the plan. If so, the Commission requests comment on whether a unanimous or majority vote is appropriate. In particular, the Commission requests comment on how the requirement of either a majority vote, as proposed by the Five-Characters Plan, or unanimous vote, as proposed by the Three-Characters Plan, would affect competition among the listing markets.

Finally, both plans would provide that the right of a party to participate in the Symbol Reservation System under the plan is not transferable without the consent of the other parties.[61] However, if a party is subject to a merger, combination, or other reorganization or the sale of all or substantially all of its assets, including its registration as an SRO, both plans would provide that the surviving entity would automatically become subject to the plan and could use the Symbol Reservation System.

The Commission requests comment on the proposed plans' provisions for the transfer of a party's rights under the plans. The Three-Characters Plan would subject the transferability provision to section I(d) of the plan. Section I(d) of the Three-Characters Plan states that an SRO that is a party to the plan would cease to be a party at such time as it ceases to maintain a facility for the quoting and trade reporting of securities or ceases to use symbols subject to the plan, unless such SRO asks to continue as a party and the other parties to the plan, by a unanimous vote, approve such SRO to continue as a party. Would the proposed plans' provisions for the transfer of a party's rights affect competition?

The Commission requests comment on this cross-reference to Section I(d), and notes that such cross-reference is not proposed in the Five-Characters Plan.

J. Amendments to the Plan

Section VIII of both plans would provide that the plan may be amended from time to time when authorized by the affirmative vote of all the parties, subject to any required approval of the Commission. The Commission notes that SROs proposing an amendment to a national market system plan must file such amendment with the Commission under Rule 608 of Regulation NMS.[62] The Commission requests comment on the proposed unanimity requirement for amending the plans. Would a majority or super-majority vote be more appropriate?

K. Implementation of the Plans

Both plans anticipate that the plan would be implemented upon the Commission's approval.[63]

L. Development and Implementation Phases

Parties to the Three-Characters Plan contemplate that the development and implementation phase would take place according to a timetable agreed to by the parties and the Processor. Parties to the Five-Characters Plan would determine

[60] *See* Section I(d) of the proposed plans.

[61] *See* Section VII of the proposed plans.

[62] The Commission may also propose amendments to any effective national market system plan. *See* 17 CFR 242.608(d)(2).

[63] Section IV in each plan provides that each party's initial symbol reservation requests would be due to the Processor within 30 days of Commission approval.

the development and implementation phase at a later time.

The Commission requests comment on whether the plans should specify the timetable for implementation. If so, what would be an appropriate timetable? In addition, the Commission requests comment on whether the plans should address the interim period when the symbol reservation system is not yet implemented and the parties are operating under the existing informal reservation system.

M. Impact on Competition

Parties to both plans do not believe that their plan would impose any burden on competition. Parties to the Five-Characters Plan believe that the plan would promote competition among exchanges by: (1) Providing all exchanges equal ability to use all symbols, (2) preserving full portability of symbols, and (3) allowing all exchanges equal ability to reserve symbols subject to equal application of reasonable time limits.

In addition to the questions above, the Commission requests comment on whether the proposed plans have adequately addressed the impact that they might have on competition. If not, what issues have not been adequately addressed?

N. Written Understanding or Agreements Relating to Interpretation of or Participation in Plan

Parties to both plans state that they do not have any written understanding or agreement relating to the interpretation of, or participation in, their plan.

O. Operation of Facility Contemplated by the Plan

Parties to both plans state that they do not intend to operate a ''facility'' as that term is defined under the Act.[64]

P. Terms and Conditions of Access

Section I of each of the plans contains a provision for the admission of new participants, under which any SRO that meets the eligibility standards of the plan may become a party thereto by signing a current copy of the plan and paying to the other parties a share of the aggregate development costs previously paid by such parties to the Processor.

The Commission requests comment on the proposed plans' provision with respect to new participants. In particular, the Commission requests commenters' view on whether the provisions set forth fair terms for access for all parties and, in particular, new listing markets.

[64] *See* 15 U.S.C. 78c(a)(2).

Q. Method and Frequency of Processor Evaluation

Parties to the Three-Characters Plan contemplate that they would evaluate the Processor on a periodic basis, with a formal evaluation timetable, after they have selected the Processor. Parties to the Five-Characters Plan would determine the method and frequency of the evaluation of the Processor at a later time.

R. Dispute Resolution

Generally, parties to the Three-Characters Plan would seek to resolve disputes by means of negotiation and discussion among their ISRA Policy Committee representatives; parties to the Five-Characters Plan would seek to resolve disputes by communication among parties. Except in the specific instances noted below, both plans do not provide for a specific mechanism for the resolution of disputes arising under the plan but acknowledge that all parties retain the right to present their views on issues relating to the plan and their rights in the appropriate forum.

There are two instances in which the proposed plans provide mechanisms for dispute resolution. Under Section IV(b)(2)(B) of each of the plans, the Policy Committee would resolve disputes related to the initial reservation requests. Under Section IV(f) of the Three-Characters Plan, the Processor would resolve disputes with respect to which SRO would retain the rights to the symbol when an issuer moves its listing to a new SRO.

The Commission requests comment on the proposed plans' provisions on dispute resolution. Specifically, the Commission requests commenters' view whether the proposed plans should prescribe the appropriate forums that aggrieved parties may seek to present their views.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed plans are consistent with the Act. The Commission invites comments on whether the foregoing assures fair competition among all parties, including new listing markets. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Numbers 4–533 and 4–534 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Numbers 4–533 and 4–534. The file numbers should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro/nms.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed plans that are filed with the Commission, and all written communications relating to the proposed plans between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Numbers 4–533 and 4–534 and should be submitted on or before August 16, 2007.

By the Commission.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–13693 Filed 7–16–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of July 16, 2007:

A Closed Meeting will be held on Tuesday, July 17, 2007 at 2 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries

will attend the Closed Meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), (8), (9)(B), and (10) and 17 CFR 200.402(a)(3), (5), (7), (8), 9(ii) and (10), permit consideration of the scheduled matters at the Closed Meeting.

Commissioner Casey, as duty officer, voted to consider the items listed for the closed meeting in closed session, and determined that no earlier notice thereof was possible.

The subject matter of the Closed Meeting scheduled for Tuesday, July 17, 2007 will be:

Formal orders of investigations;
Institution and settlement of injunctive actions;
Institution and settlement of administrative proceedings of an enforcement nature;
Resolution of litigation claims;
Regulatory matter regarding financial institution;
An adjudicatory matter; and
Other matters related to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: The Office of the Secretary at (202) 551–5400.

Dated: July 11, 2007.

Nancy M. Morris,

Secretary.

[FR Doc. E7–13811 Filed 7–16–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56046; File No. SR–Amex–2007–62]

Self-Regulatory Organizations; American Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Short Term Option Series Pilot Program

July 11, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 27, 2007, the American Stock Exchange LLC (''Exchange'' or ''Amex'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the Exchange. The Exchange has designated this proposal as non-controversial under Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to extend its Short Term Option Series pilot program (''Pilot Program'') for an additional year, through July 12, 2008. The text of the proposed rule change is available on the Exchange's Web site (*http://www.amex.com*), at the Exchange's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On July 12, 2006, the Commission approved a one-year extension of the Pilot Program, which was initially approved on July 12, 2005.[5] The Exchange is now proposing to extend the Pilot Program for an additional year, through July 12, 2008.

The Exchange believes that Short Term Option Series provide investors with a flexible and valuable tool to manage risk exposure, minimize capital outlays, and be more responsive to the timing of events affecting the securities that underlie option contracts. At the same time, the Exchange is cognizant of the need to be cautious in introducing a product that can increase the number of outstanding strike prices. In order to respond to potential customer demand and to remain competitive, the Exchange proposes to extend the Pilot Program for another year.

In its original proposal to establish the Pilot Program, the Exchange stated that if it were to propose an extension of the program, the Exchange would submit a Pilot Program report (''Report'') that would provide analysis of the Pilot Program covering the entire period during which the Pilot Program was in effect. Since the Exchange did not list any Short Term Option Series during this past year of the Pilot Program, there is no data available to prepare the Report at this time, and the Exchange has not submitted a Report with this proposal to extend the Pilot Program.

The Exchange notes that it possesses the adequate systems capacity to trade any Short Term Option Series, should any be listed in the future.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6 of the Act[6] in general, and furthers the objectives of Section 6(b)(5) of the Act[7] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes that continuing the Pilot Program for Short Term Option Series can stimulate customer interest in options and provide a flexible and valuable tool to manage risk exposure, minimize capital outlays and be more responsive to the timing of events affecting the securities that underlie option contracts.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities Exchange Act Releases No. 54131 (July 12, 2006), 71 FR 40760 (July 18, 2006) (File No. SR–Amex–2006–66) and 52014 (July 12, 2005), 70 FR 41244 (July 18, 2005) (File No. SR–Amex–2005–35).

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing For Commission Action

The Exchange has designated the proposed rule change as one that: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for 30 days from the date of filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. Therefore, the foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and subparagraph (f)(6) of Rule 19b–4 thereunder.[9] The Exchange has asked the Commission to waive the operative delay to permit the Pilot Program extension to become operative prior to the 30th day after filing.[10]

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the benefits of the Pilot Program to continue without interruption.[11] Therefore, the Commission designates the proposal operative upon filing.[12]

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6).

[10] As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change at least five business days before doing so.

[11] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[12] As set forth in the Exchange's original filing proposing the Pilot Program, if the Exchange were to propose an extension, an expansion, or permanent approval of the Pilot Program, the Exchange would submit, along with any filing proposing such amendments to the program, a report that would provide an analysis of the Pilot Program covering the entire period during which the Pilot Program was in effect. The report would include, at a minimum: (1) Data and written analysis on the open interest and trading volume in the classes for which Short Term Option Series were opened; (2) an assessment of the appropriateness of the option classes selected for the Pilot Program; (3) an assessment of the impact of the Pilot Program on the capacity of the Exchange, OPRA, and market data vendors (to the extent data from market data vendors is available); (4) any capacity problems or other problems that arose during the operation of the Pilot Program and how the Exchange addressed such problems; (5) any complaints that the Exchange received during the operation of the Pilot Program and how the Exchange addressed them; and (6) any additional information that would assist in assessing the operation of the Pilot Program. The report must be submitted to the Commission at least sixty (60) days prior to the expiration date of the Pilot Program. *See* Form 19b–4 for File No. SR–Amex–2005–35, filed March 23, 2005.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate the rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File No. SR–Amex–2007–62 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Amex–2007–62. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commissions Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Amex–2007–62 and should be submitted on or before August 7, 2007.[13]

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. E7–13809 Filed 7–16–07; 8:45 am]

BILLING CODE 8010–01–P

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56047; File No. SR–ISE–2007–54]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Short Term Option Series Pilot Program

July 11, 2007.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 27, 2007, the International Securities Exchange, LLC (''Exchange'' or ''ISE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the Exchange. The Exchange has designated this proposal as non-controversial under section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend its rules to extend the Short Term Option Series Pilot Program (''Pilot Program'') for an additional year. The text of the proposed rule change is

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

available on the Exchange's Web site (*http://www.ise.com*), at the Exchange's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On July 12, 2005, the Commission approved the Pilot Program, which allows ISE to list and trade Short Term Option Series.[5] Under the terms of the Pilot Program, the Exchange can select up to five options classes on which Short Term Option Series may be opened on any Short Term Option Opening Date, as that term is defined in ISE Rules 504 and 2009. The Exchange is also allowed to list Short Term Option Series on any option class that is selected by other securities exchanges that employ a similar Pilot Program under their respective rules.

The Pilot Program is currently set to expire on July 12, 2007.[6] The purpose of this proposed rule change is to extend the Pilot Program for an additional year, through July 12, 2008. The Exchange believes that Short Term Option Series provides investors with a flexible and valuable tool to manage risk exposure, minimize capital outlays, and be more responsive to the timing of events affecting the securities that underlie option contracts. While ISE has not listed any Short Term Option Series during the Pilot Program, there has been investor interest in trading short-term options at the Chicago Board Options Exchange. For competitive reasons and in order to have the ability to respond to customer interest in Short Term Option Series, the Exchange proposes the continuation of the Pilot Program at ISE.

In the original proposal to establish the Pilot Program, the Exchange stated that if it were to propose an extension or an expansion of the Pilot Program, the Exchange would submit, along with any filing proposing such amendments to the Pilot Program, a report (''Pilot Program Report'') that would provide an analysis of the Pilot Program covering the entire period during which the Pilot Program was in effect. Since the Exchange did not list any Short Term Option Series during the preceding year of the Pilot Program, there is no data available to compile such a report at this time. Therefore, the Exchange is not submitting a Pilot Program Report with this proposal.

Finally, the Exchange represents that it has the necessary systems capacity to support the listing of Short Term Option Series, should it determine to do so in the future.

2. Statutory Basis

The Exchange believes that Short Term Option Series increase the variety of listed options available to investors and provide investors with a valuable tool to manage risk exposure, minimize capital outlays, and be more responsive to the timing of events affecting the securities that underlie options contracts. For these reasons, the Exchange believes the proposed rule change is consistent with section 6(b) of the Act.[7] Specifically, the Exchange believes the proposed rule change is consistent with the requirements of section 6(b)(5) of the Act[8] that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has designated the proposed rule change as one that: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for 30 days from the date of filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. Therefore, the foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act[9] and subparagraph (f)(6) of Rule 19b–4 thereunder.[10] The Exchange has asked the Commission to waive the operative delay to permit the Pilot Program extension to become operative prior to the 30th day after filing.[11]

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the benefits of the Pilot Program to continue without interruption.[12] Therefore, the Commission designates the proposal operative upon filing.[13]

[5] *See* Securities Exchange Act Release No. 52012 (July 12, 2005), 70 FR 41246 (July 18, 2005) (File No. SR–ISE–2005–17).

[6] *See* Securities Exchange Act Release No. 54117 (July 10, 2006), 71 FR 40564 (July 17, 2006) (File No. SR–ISE–2006–37).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change at least five business before doing so.

[12] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

[13] As set forth in the Exchange's original filing proposing the Pilot Program, if the Exchange were to propose an extension, an expansion, or permanent approval of the Pilot Program, the Exchange would submit, along with any filing proposing such amendments to the program, a report that would provide an analysis of the Pilot Program covering the entire period during which the Pilot Program was in effect. The report would include, at a minimum: (1) Data and written analysis on the open interest and trading volume in the classes for which Short Term Option Series were opened; (2) an assessment of the appropriateness of the option classes selected for the Pilot Program; (3) an assessment of the impact of the Pilot Program on the capacity of the Exchange, OPRA, and market data vendors (to the extent data from market data vendors is available); (4) any capacity problems or other problems that arose during the operation of the Pilot Program and how the Exchange addressed such problems; (5) any complaints that the Exchange received during the operation of the Pilot Program and how the Exchange addressed them; and (6) any additional information that would assist in assessing the operation of the Pilot Program. The report must be submitted to the Commission at least sixty (60) days prior to the expiration date of the Pilot Program. *See* Form 19b–4 for File No. SR–ISE–2005–17, filed March 7, 2005.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate the rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

• Send an e-mail to *rule-comments@sec.gov*. Please include File No. SR–ISE–2007–54 on the subject line.

Paper Comments

• Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2007–54. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commissions Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2007–54 and should besubmitted on or before August 7, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. E7–13810 Filed 7–16–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56044; File No. SR–NASDAQ–2007–024]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto To Provide Additional Transparency To How Nasdaq Applies Its Public Interest Authority

July 11, 2007.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 16, 2007, The NASDAQ Stock Market LLC (''Nasdaq'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by Nasdaq. On June 26, 2007, Nasdaq filed Amendment No. 1 to the proposed rule change. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

Nasdaq proposes to modify Nasdaq IM–4300 to provide additional transparency to how Nasdaq applies its public interest authority. Nasdaq will implement the proposed rule upon approval. The text of the proposed rule change is below. Proposed new language is in italics; proposed deletions are in brackets.[3]

* * * * *

IM–4300. Use of Discretionary Authority

In order to further issuers' understanding of Rule 4300, Nasdaq is adopting this Interpretive Material as a non-exclusive description of the circumstances in which the Rule is generally invoked.

Nasdaq may use its authority under Rule 4300 to deny initial or continued listing to an issuer when an individual with a history of regulatory misconduct is associated with the issuer. Such individuals are typically an officer, director, substantial security holder (as defined in Rule 4350(i)(5)), or consultant to the issuer. In making this determination, Nasdaq [shall] *will* consider a variety of factors, including: [the severity of the violation; whether it involved fraud or dishonesty; whether it was securities-related; whether the investing public was involved; when the violation occurred; how the individual has been employed since the violation; whether there are continuing sanctions against the individual; whether the individual made restitution; whether the issuer has taken effective remedial action; and the totality of the individual's relationship to the issuer.]

• *The nature and severity of the conduct, taken in conjunction with the length of time since the conduct occurred;*

• *whether the conduct involved fraud or dishonesty;*

• *whether the conduct was securities-related;*

• *whether the investing public was involved;*

• *how the individual has been employed since the violative conduct;*

• *whether there are continuing sanctions (either criminal or civil) against the individual;*

• *whether the individual made restitution;*

• *whether the issuer has taken effective remedial action; and*

• *the totality of the individual's relationship to the issuer, giving consideration to:*

○ the individual's current or proposed position;

○ o the individual's current or proposed scope of authority;

○ the extent to which the individual has responsibility for financial accounting or reporting; and

○ the individual's equity interest.

Based on this review, Nasdaq may determine that the regulatory history rises to the level of a public interest concern, but may also consider whether remedial measures proposed by the issuer, if taken, would allay that concern. Examples of such remedial measures could include any or all of the following, as appropriate:

• The individual's resignation from officer and director positions, and/or other employment with the company;

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Changes are marked to the rule text that appears in the electronic manual of Nasdaq found at *http://www.complinet.com/nasdaq*.

• divestiture of stock holdings;
• terminations of contractual arrangements between the issuer and the individual; or
• the establishment of a voting trust surrounding the individual's shares.

Nasdaq staff is willing to discuss with issuers, on a case-by-case basis, what remedial measures may be appropriate to address public interest concerns, and for how long such remedial measures would be required. Alternatively, Nasdaq may conclude that a public interest concern is so serious that no remedial measure would be sufficient to alleviate it. In the event that Nasdaq staff [makes such a determination] denies initial or continued listing based on such public interest considerations, the issuer may seek review of that determination through the procedures set forth in the Rule 4800 Series. On consideration of such appeal, a listing qualifications panel comprised of persons independent of Nasdaq may accept, reject or modify the staff's recommendations by imposing conditions.

Nasdaq may also use its discretionary authority, for example, when an issuer files for protection under any provision of the federal bankruptcy laws or comparable foreign laws, when an issuer's independent accountants issue a disclaimer opinion on financial statements required to be audited, or when financial statements do not contain a required certification.

In addition, pursuant to its discretionary authority, Nasdaq [shall] *will* review the issuer's past corporate governance activities. This review may include activities taking place while the issuer is listed on Nasdaq or an exchange that imposes corporate governance requirements, as well as activities taking place after a formerly listed issuer is no longer listed on Nasdaq or such an exchange. Based on such review, and in accordance with the Rule 4800 Series, Nasdaq may take any appropriate action, including placing restrictions on or additional requirements for listing, or denying listing of a security, if Nasdaq determines that there have been violations or evasions of such corporate governance standards. Such determinations [shall] *will* be made on a case-by-case basis as necessary to protect investors and the public interest.

Although Nasdaq has broad discretion under Rule 4300 to impose additional or more stringent criteria, the Rule does not provide a basis for Nasdaq to grant exemptions or exceptions from the enumerated criteria for initial or continued listing, which may be granted solely pursuant to rules explicitly providing such authority.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq proposes to modify Nasdaq IM–4300 to provide additional transparency to how Nasdaq applies its public interest authority. Specifically, Nasdaq proposes to clarify certain of the factors contained in this interpretive material to better guide companies. Nasdaq also proposes to change the formatting of portions of the text to enhance their readability and to add new language highlighting Nasdaq staff's willingness to discuss these concerns, and possible remedial measures, with companies. Nasdaq does not consider these changes to be substantive in nature.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of section 6 of the Act,[4] in general, and with section 6(b)(5) of the Act,[5] in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The proposed rule change clarifies how Nasdaq applies its public interest authority.

[4] 15 U.S.C. 78f.
[5] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
• Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2007–024 on the subject line.

Paper Comments

• Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2007–024. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent

amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–NASDAQ–2007–024 and should be submitted on or before August 7, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. E7–13808 Filed 7–16–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56039; File No. SR–NASD–2007–021]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc., Notice of Filing of Proposed Rule Change To Amend the Definition of Public Arbitrator

July 10, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 12, 2007, the National Association of Securities Dealers, Inc. (''NASD''), through its wholly owned subsidiary, NASD Dispute Resolution, Inc. (''NASD Dispute Resolution'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASD Dispute Resolution proposes to amend the Code of Arbitration Procedure for Customer Disputes (''Customer Code''), and the Code of Arbitration Procedure for Industry Disputes (''Industry Code'') to amend the definition of public arbitrator to add an annual revenue limitation. The text of the proposed rule change is available at NASD, *http://www.nasd.com,* and the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASD has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NASD has taken numerous steps in recent years to ensure the integrity and neutrality of its arbitrator roster by addressing classification of arbitrators. For example, in August 2003, NASD proposed changes to Rules 10308 and 10312 of the Code of Arbitration Procedure (''Code'') to modify the definitions of public and non-public arbitrators to further prevent individuals with significant ties to the securities industry from serving as public arbitrators.[3] The 2003 proposal:

- Increased from three years to five years the period for transitioning from a non-public to public arbitrator after leaving the securities industry.
- Clarified that the term ''retired'' from the industry includes anyone who spent a substantial part of his or her career in the industry.
- Prohibited anyone who has been associated with the industry for at least 20 years from ever becoming a public arbitrator, regardless of how long ago the association ended.
- Excluded from the public arbitrator roster attorneys, accountants, or other professionals whose firms have derived 10 percent or more of their annual revenue in the previous two years from clients involved in securities-related activities.

The proposal was approved by the SEC on April 16, 2004, and became effective on July 19, 2004.[4]

On July 22, 2005, NASD proposed a further amendment to Rule 10308 of the Code relating to arbitrator classification to prevent individuals with certain indirect ties to the securities industry from serving as public arbitrators. Specifically, NASD proposed to amend the definition of public arbitrator to exclude individuals who work for, or are officers or directors of, an entity that controls, is controlled by, or is under common control with, a broker/dealer, or who have a spouse or immediate family member who works for, or is an officer or director of, an entity that is in such a control relationship with a broker/dealer. NASD also proposed to amend Rule 10308 to clarify that individuals registered through broker-dealers may not be public arbitrators, even if they are employed by a non-broker-dealer (such as a bank). This rule filing was approved by the SEC on October 16, 2006, and became effective on January 15, 2007.[5]

Finally, during the time that the above changes were being made, NASD also had pending at the Commission a 2003 proposal to amend the Code to reorganize the rules into the Customer Code, the Industry Code, and a separate code for mediation. The final provisions of this proposal were approved by the Commission on January 24, 2007, and became effective on April 16, 2007.[6]

[6] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In July 2002, the SEC retained Professor Michael Perino to assess the adequacy of arbitrator disclosure requirements at NASD and at the New York Stock Exchange (NYSE). Professor Perino's report (Perino Report) concluded that undisclosed conflicts of interest were not a significant problem in arbitrations sponsored by self-regulatory organizations (SROs), such as NASD and the NYSE. However, the Perino Report recommended several amendments to SRO arbitrator classification and disclosure rules that might ''provide additional assurance to investors that arbitrations are in fact neutral and fair.'' This proposal implemented the recommendations of the Perino Report and made several other related changes to the definitions of public and non-public arbitrators that were consistent with the Perino Report recommendations. The Perino Report is available at *http://www.sec.gov/pdf/arbconflict.pdf.*

[4] *See* Securities Exchange Act Rel. No. 49573 (April 16, 2004), 69 FR 21871 (April 22, 2004) (SR–NASD–2003–95) (approval order). The changes were announced in Notice to Members 04–49 (June 2004).

[5] *See* Securities Exchange Act Rel. No. 54607 (Oct. 16, 2006), 71 FR 62026 (Oct. 20, 2006) (SR–NASD–2005–094) (approval order). The changes were announced in Notice to Members 06–64 (November 2006).

[6] *See* Securities Exchange Act Rel. No. 51856 (June 15, 2005), 70 FR 36442 (June 23, 2005) (SR–

Several of the substantive changes to the Customer and Industry Codes will affect the classification of arbitrators[7] and how they are selected for panels.[8]

Despite these many initiatives amending the arbitrator classification rules, some users of the forum continue to voice concerns about individuals serving as public arbitrators when they have business relationships with entities that derive income from broker-dealers. The concern is that, for example, an arbitrator classified as public might work for a very large law firm that derived less than 10% of its annual revenue from broker-dealer clients, but still receives a large dollar amount of such revenue. The concern focused primarily on the law firm's defense of action (in arbitration or litigation) by customers of broker-dealers, and not on representing broker-dealers in underwriting or other activities. Therefore, those concerned with the amount of annual revenue recommended that there be an annual dollar limitation of $50,000 on revenue from broker-dealers relating to customer disputes with a brokerage firm or associated person concerning an investment account.

NASD supports these recommendations and is, therefore, proposing to amend the definition of public arbitrator in Rule 12100(u) of the Customer Code and Rule 13100(u) of the Industry Code to add a provision that would prevent an attorney, accountant, or other professional from being classified as a public arbitrator, if the person's firm derived $50,000 or more in annual revenue in the past two years from professional services rendered to any persons or entities listed in Rule 12100(p)(1) of the Customer Code or Rule 13100(p)(1) of the Industry Code relating to any customer disputes concerning an investment account or transaction, including but not limited to, law firm fees, accounting firm fees, and consulting fees.[9]

NASD believes the proposed amendment, in conjunction with the existing 10 percent revenue limitation,[10] will further improve NASD's public arbitrator roster by ensuring that arbitrators whose firms receive a significant amount of compensation from any persons or entities associated with or engaged in the securities, commodities, or futures business are removed from the public roster.[11]

2. Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act, which requires, among other things, that the Association's rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. NASD believes that the proposed rule change will enhance investor confidence in the fairness and neutrality of NASD's arbitration forum, by providing further assurance to parties that persons who have a relationship with those who receive a significant amount of compensation from the securities industry are not able to serve as public arbitrators in NASD arbitrations.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASD–2007–021 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASD–2007–021. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than

NASD–2003–158) (notice); See Securities Exchange Act Rel. No. 51857 (June 15, 2005), 70 FR 36430 (June 23, 2005) (SR–NASD–2004–011) (notice); and *See* Securities Exchange Act Rel. No. 51855 (June 15, 2005), 70 FR 36440 (June 23, 2005) (SR–NASD–2004–013) (notice). The changes were announced in Notice to Members 07–07 (February 2007).

[7] NASD believes the new Codes have improved the arbitrator selection process by creating and maintaining a new roster of arbitrators who are qualified to serve as chairpersons. The chair roster will consist of more experienced arbitrators available on NASD's public arbitrator roster for all investor cases and for certain intra-industry cases. For other industry cases, the Code also creates a chair roster of experienced non-public arbitrators. *See* Rules 12400(b) and (c) of the Customer Code and Rules 13400(b) and (c) of Industry Code.

[8] The new Codes also change how arbitrator lists are generated and how arbitrators are selected for a panel. *See* Rules 12403 and 12404 of the Customer Code and Rules 13403 and 13404 of the Industry Code.

[9] Rule 12100(p) defines ''non-public arbitrator.'' Paragraph (1) of the rule states, in relevant part, that the term ''non-public arbitrator'' means a person who is otherwise qualified to serve as an arbitrator and is or, within the past five years, was: (A) Associated with, including registered through, a broker or a dealer (including a government securities broker or dealer or a municipal securities dealer); (B) registered under the Commodity Exchange Act; (C) a member of a commodities exchange or a registered futures association; or (D) associated with a person or firm registered under the Commodity Exchange Act. Rule 13100(p) is the same as Rule 12100(p).

[10] *See* supra note 4. Under the July 2004 amendments, a public arbitrator cannot be ''an attorney, accountant, or other professional whose firm derived 10 percent or more of its annual revenue in the past 2 years from any persons or entities listed in Rules 12100(p)(1) and 13100(p)(1) of the new Codes.''

[11] NASD will survey its public arbitrators to determine which arbitrators will be removed from the roster for appointment to new cases upon the effective date of the proposed rule.

those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of NASD. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASD–2007–021 and should be submitted on or before August 7, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–13747 Filed 7–16–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56040; File No. SR–NYSEArca–2007–67]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Quarterly Options Series Pilot Program for a Two-Week Period

July 10, 2007.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 10, 2007, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the Exchange. The Exchange has designated this proposal as non-controversial under section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to extend the Quarterly Options Series pilot program (''Pilot Program'') for an additional two-week period, through July 24, 2007, and to amend Rule 5.19(a) regarding the restriction on the number of strike prices for Quarterly Options Series based on an underlying index. The text of the proposed rule change is available on the Exchange's Web site (*http://www.nysearca.com*), at the Exchange's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On July 12, 2006, the Exchange filed with the Commission a proposed rule change that allowed it to establish the Pilot Program, pursuant to which the Exchange lists and trades Quarterly Options Series.[5] The rule change was effective upon filing. The Exchange hereby proposes to extend the Pilot Program for an additional two-week period, so that it will expire on July 24, 2007.[6]

In the Pilot Program Release, the Exchange stated that it would submit, in connection with any proposed extension of the Pilot Program, a Pilot Program Report (''Report'') that would provide an analysis of the Pilot Program covering the entire period which the program was in effect. The Report will include: (1) Data and written analysis on the open interest and trading volume in the classes for which Quarterly Options Series were opened; (2) an assessment of the appropriateness of the option classes selected for the Pilot Program; (3) an assessment of the impact of the Pilot Program on the capacity on the Exchange, OPRA, and market data vendors (to the extent data from market data vendors is available); (4) any capacity problems or other problems that arose during the operation of the Pilot Program and how the Exchange addressed such problems; (5) any complaints that the Exchange received during the operation of the Pilot Program and how the Exchange addressed them; and (6) any additional information that would assist the Commission in assessing the operation of the Pilot Program. The Exchange plans to submit the Report in connection with a proposal that will extend the Pilot Program until July 10, 2008. This proposal and Report will be filed with the Commission at the conclusion of the proposed two-week extension.

The Exchange also proposes at this time to add a provision to Rule 5.19(a) regarding the limitations on the number of strikes the Exchange may list for Quarterly Options Series based on an underlying index. These changes mirror provisions previously submitted by the Chicago Board Options Exchange (''CBOE'') and approved by the Commission.[7] The Exchange proposes to: (1) Limit the number of strike prices that the Exchange may initially open for Quarterly Options Series to five strike prices above and five below the value of the underlying index; (2) clarify that the Exchange may open for trading additional Quarterly Options Series of the same class when the Exchange deems such action necessary to maintain an orderly market or meet customer demand, provided that the additional series priced above (below) the value of the underlying index do not cause there to be more than five strike process above (below) the value of the underlying index; and (3) clarify that the opening of any new Quarterly Options Series will not affect the previously opened series of the same class. These changes are based on CBOE Rule 24.9 and are shown in Exhibit 5 to the proposed rule change on Form 19b–4 filed with the Commission.

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities Exchange Act Release No. 54166 (July 18, 2006), 71 FR 42151 (July 25, 2006) (File No. SR–NYSEArca–2006–45) (''Pilot Program Release'').

[6] At the end of this proposed two-week extension, NYSE Arca will submit a subsequent proposal to the Commission, in conjunction with a report on the Pilot Program, requesting that the Pilot Program be extended until July 10, 2008.

[7] *See* Securities Exchange Act Release No. 54762 (November 16, 2006), 71 FR 67663 (November 22, 2006) (File No. SR–CBOE–2006–93).

Finally, NYSE Arca represents that the Exchange has the necessary system capacity to support any additional series listed as part of the Pilot Program.

2. Statutory Basis

The Exchange believes that the continuation of the Quarterly Options Series Pilot Program will stimulate customer interest in options by creating greater trading opportunities and flexibility in investment choices. The Exchange further believes that continuation of the Pilot Program will provide the ability to more closely tailor investment strategies and provide a valuable hedging tool for investors. For these reasons, the Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder and, in particular, the requirements of section 6(b) of the Act.[8] Specifically, the Exchange believes the proposed rule change is consistent with of section 6(b)(5) of the Act,[9] which requires that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has designated the proposed rule change as one that: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for 30 days from the date of filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. Therefore, the foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act[10] and subparagraph (f)(6) of Rule 19b–4 thereunder.[11] The Exchange has asked the Commission to waive the operative delay to permit the Pilot Program extension to become operative prior to the 30th day after filing.[12]

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the benefits of the Pilot Program to continue without interruption.[13] Therefore, the Commission designates the proposal operative upon filing. The Commission, in deciding to waive the operative delay in order to allow the Pilot Program to continue uninterrupted for the proposed two-week extension, has relied on the Exchange's representation that it will submit the Report as required by the Pilot Program on or before the expiration of the extension period (*i.e.*, July 24, 2007).[14]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate the rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to: *rule-comments@sec.gov*. Please include File No. SR–NYSEArca–2007–67 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2007–67. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commissions Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2007–67 and should be submitted on or August 7, 2007.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change at least five business before doing so.

[13] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] As set forth in the Exchange's original filing proposing the Pilot Program, if the Exchange were to propose an extension, an expansion, or permanent approval of the Pilot Program, the Exchange would submit, along with any filing proposing such amendments to the program, a report that would provide an analysis of the Pilot Program covering the entire period during which the Pilot Program was in effect. The report would include, at a minimum: (1) Data and written analysis on the open interest and trading volume in the classes for which Quarterly Options Series were opened; (2) an assessment of the appropriateness of the option classes selected for the Pilot Program; (3) an assessment of the impact of the Pilot Program on the capacity of the Exchange, OPRA, and market data vendors (to the extent data from market data vendors is available); (4) any capacity problems or other problems that arose during the operation of the Pilot Program and how the Exchange addressed such problems; (5) any complaints that the Exchange received during the operation of the Pilot Program and how the Exchange addressed them; and (6) any additional information that would assist in assessing the operation of the Pilot Program. The report must be submitted to the Commission at least sixty (60) days prior to the expiration date of the Pilot Program. *See* Form 19b–4 for File No. SR–PCX–2005–32, filed March 16, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–13748 Filed 7–16–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56041; File No. SR–NYSEArca–2007–43]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change To List and Trade Shares of the iShares COMEX Gold Trust

July 11, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 11, 2007, NYSE Arca, Inc. (the ''Exchange''), through its wholly-owned subsidiary, NYSE Arca Equities, Inc. (''NYSE Arca Equities''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the Exchange. This order provides notice of the proposed rule change and approves the proposed rule change on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade shares (''Shares'') of the iShares ® [3] COMEX ® [4] Gold Trust (''Trust'') pursuant to NYSE Arca Equities Rule 8.201. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com*.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Pursuant to NYSE Arca Equities Rule 8.201, which permits the trading of Commodity-Based Trust Shares [5] either by listing or pursuant to unlisted trading privileges (''UTP''), the Exchange proposes to list and trade the Shares. The Shares are currently listed on the American Stock Exchange LLC (''Amex''),[6] and the Exchange currently trades the Shares pursuant to UTP.[7] The Exchange represents that the Shares satisfy the requirements of NYSE Arca Equities Rule 8.201 and thereby qualify for listing on the Exchange.

The Shares represent beneficial ownership interests in the net assets of the Trust, which holds gold bullion. The objective of the Trust is for the value of the Shares to reflect, at any given time, the price of gold owned by the Trust at that time, less the Trust's expenses and liabilities. The Trust is not actively managed and does not engage in any activities designed to obtain a profit from, or to ameliorate losses caused by, changes in the price of gold. The Trust is neither an investment company registered under the Investment Company Act of 1940 nor a commodity pool for purposes of the Commodity Exchange Act.[8] Barclays Global Investors International Inc., a Delaware corporation and a subsidiary of Barclays Bank PLC, is the sponsor of the Trust (''Sponsor''). The Shares are not obligations of, and are not guaranteed by, the Sponsor or any of its respective subsidiaries or affiliates.

A detailed discussion of the gold market, including the over-the-counter gold market and the gold futures exchanges, gold market regulation, COMEX gold futures contracts, the process for creations and redemptions of the Shares, certificates evidencing the Shares, and Trust distributions, among others, can be found in the Amex Notice and in the Trust Prospectus.[9]

The Web site for the Trust at *http://www.ishares.com*, which is publicly accessible at no charge, contains the following information about the Shares: (a) The prior business day's net asset value (''NAV'') per Share; [10] (b) Basket Gold Amount; [11] (c) the reported Share closing price; (d) the present day's Indicative Basket Gold Amount; [12] (e) the mid-point of the bid-ask price in relation to the NAV as of the time the

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[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ''iShares'' is a registered trademark of Barclays Global Investors, N.A.

[4] ''COMEX'' is a registered service mark of Commodity Exchange, Inc., a subsidiary of the New York Mercantile Exchange, Inc. (''NYMEX''). COMEX is operated by Commodity Exchange, Inc. and the Tokyo Commodity Exchange. Open outcry trading of gold futures on COMEX is conducted from 8:20 a.m. Eastern Time (''ET'') until 1:30 p.m. ET, and electronic trading of such gold futures is conducted from 6 p.m. ET until 5:15 p.m. ET via the CME Globex ® trading platform, Sunday through Friday. Thus, except for brief breaks (45 minutes) to switch between open outcry and electronic trading in the evening and the morning, gold futures trade almost 24 hours per day, five business days per week.

[5] As defined in NYSE Arca Equities Rule 8.201(c)(1), ''Commodity-Based Trust Shares'' are securities that: (1) Are issued by a trust that holds a specified commodity deposited with the trust; (2) are issued by such trust in a specified aggregate minimum number in return for a deposit of a quantity of the underlying commodity; and (3) when aggregated in the same specified minimum number, may be redeemed at a holder's request by such trust which would deliver to the redeeming holder the quantity of the underlying commodity.

[6] *See* Securities Exchange Act Release No. 51058 (January 19, 2005), 70 FR 3749 (January 26, 2005) (SR–Amex–2004–38) (granting approval to list and trade the Shares on Amex). *See also* Securities Exchange Act Release No. 50792 (December 3, 2004), 69 FR 71446 (December 9, 2004) (SR–Amex–2004–38) (providing notice of Amex's proposal to list and trade the Shares) (''Amex Notice'').

[7] *See* Securities Exchange Act Release No. 51067 (January 21, 2005), 70 FR 3952 (January 27, 2005) (SR–PCX–2004–132) (approving NYSE Arca Equities Rule 8.201 and the trading of the Shares pursuant to UTP) (''UTP Order'').

[8] The Exchange states that the Trust does not trade in gold futures contracts. The Trust takes delivery of physical gold that complies with certain gold delivery rules. Because the Trust does not trade in gold futures contracts on any futures exchange, the Trust is not regulated as a commodity pool, and is not operated by a commodity pool operator.

[9] *See supra* note 6; *see also* iShares COMEX Gold Trust Prospectus dated March 1, 2007 (Registration Statement No. 333–140874) (''Prospectus''). E-mail from Timothy J. Malinowski, Director, NYSE Group, Inc., to Edward Cho, Special Counsel, Division of Market Regulation, Commission, dated July 11, 2007 (confirming that additional information on the gold markets, the Trust, and the Shares can be found in the Amex Notice and the Prospectus, as supplemented).

[10] The Exchange states that it would obtain a representation from the Trust, prior to listing, that the NAV per Share would be calculated daily and made available to all market participants at the same time.

[11] The ''Basket Gold Amount'' is the corresponding amount of gold, measured in fine ounces, to be exchanged for an issuance of a basket of 50,000 Shares (each such basket, a ''Basket''), for the purpose of creating and redeeming the Shares.

[12] The ''Indicative Basket Gold Amount'' is the indicative amount of gold to be deposited for issuance of the Shares that Authorized Participants can use. Because the creation/redemption process is based entirely on the physical delivery of gold (and does not contemplate a cash component), the actual number of fine ounces required for the Indicative Basket Gold Amount would not change intra-day, even though the value of the Indicative Basket Gold Amount may change based on the market price of gold.

NAV is calculated (''Bid-Ask Price''); [13] (f) calculation of the premium or discount of such price against such NAV; (g) data in chart form displaying the frequency distribution of discounts and premiums of the Bid-Ask Price against the NAV, within appropriate ranges for each of the four previous calendar quarters; (h) the Prospectus; and (i) other applicable quantitative information, such as expense ratios, trading volumes, and the total return of the Shares. The Exchange also provides a hyperlink on its Web site to the Trust's Web site.

The Exchange would make available, through the facilities of the Consolidated Tape Association (''CTA''), quotation information including the last sale price for the Shares, the daily trading volume, closing prices, and the NAV for the Shares from the previous day. In addition, the Exchange or a major market data vendor would disseminate each day through the facilities of the CTA the number of Shares outstanding and the Indicative Trust Value (''ITV'') on a per-Share basis at least every 15 seconds [14] from 9:30 a.m. to 4:15 p.m. ET.[15] The ITV is calculated based on the estimated amount of gold required for creations and redemptions on any particular day (*e.g.*, the Indicative Basket Gold Amount) and a price of gold derived from the most recently reported trade price in the active gold futures contract. The prices reported for the active contract month are adjusted based on the prior day's spread differential between settlement values for that contract and the spot month contract. In the event that the spot month contract is also the active contract, the last sale price for the active contract is not adjusted.[16]

Shortly after 4 p.m. ET each business day, the Trustee,[17] the Exchange, and the Sponsor would disseminate the NAV for the Shares, the Basket Gold Amount (for orders placed during the day), and the Indicative Basket Gold Amount (for use by Authorized Participants [18] contemplating placing orders the following business day). The Basket Gold Amount, the Indicative Basket Gold Amount, and the NAV are communicated by the Trustee to all Authorized Participants via facsimile or e-mail and are available on the Trust's Web site.

The Exchange states that information on gold prices and gold markets is available on public Internet Web sites and through professional and subscription services. In most instances, real-time information is available only for a fee, and information available free-of-charge is subject to delay (typically 20 minutes). The Exchange also states that investors may obtain on a 24-hour basis gold pricing information based on the spot price for a troy ounce of gold from various financial information service providers, such as Reuters and Bloomberg. Reuters and Bloomberg provide at no charge on their Web sites delayed information regarding the spot price of gold and last sale prices of gold futures, as well as information about news and developments in the gold market. Reuters and Bloomberg also offer a professional service to subscribers for a fee that provides information on gold prices directly from market participants. In addition, an organization named EBS provides an electronic trading platform to institutions such as bullion banks and dealers for the trading of spot gold, as well as a feed of live streaming prices to Reuters and Moneyline Telerate subscribers.

The Exchange further represents that complete real-time data for gold futures and options prices traded on COMEX is available by subscription from Reuters and Bloomberg. The closing price and settlement prices of the COMEX gold futures contracts are publicly available from NYMEX at *http://www.nymex.com*, automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters. NYMEX also provides delayed futures and options information on current and past trading sessions and market news free of charge on its Web site.

The Exchange states that the Shares are subject to the criteria for initial and continued listing of Commodity-Based Trust Shares under NYSE Arca Equities Rule 8.201. As indicated above, the Shares are currently trading on the Exchange pursuant to UTP. A minimum of 100,000 Shares would be required to be outstanding when the Shares are listed. This minimum number of Shares required to be outstanding is comparable to requirements that have been applied to previously listed series of exchange-traded funds. The Exchange believes that the proposed minimum number of Shares outstanding at the start of trading is sufficient to provide market liquidity. In addition, the Exchange represents that the Trust is required to comply with Rule 10A–3 under the Act [19] for the initial and continued listing of the Shares.

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. The trading hours for the Shares on the Exchange are the same as those set forth in NYSE Arca Equities Rule 7.34 (Opening, Core, and Late Trading Sessions, 4 a.m. ET to 8 p.m. ET).[20]

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These reasons may include (1) the extent to which trading is not occurring in the underlying COMEX gold futures contract, or (2) whether other unusual conditions or circumstances detrimental

[13] The Bid-Ask Price of Shares is determined using the highest bid and lowest offer as of the time of calculation of the NAV.

[14] E-mail from Timothy J. Malinowski, Director, NYSE Group, Inc., to Edward Cho, Special Counsel, Division of Market Regulation, Commission, dated July 9, 2007 (confirming the updated ITV would be disseminated at least every 15 seconds).

[15] The Exchange states that the ITV will not reflect changes to the price of gold between the close of trading at COMEX, which is typically 1:30 p.m. ET, and the open of trading on the NYMEX ACCESS market at 2 p.m. ET. While the market for the gold futures is open for trading, the ITV can be expected to closely approximate the value per Share of the Indicative Basket Gold Amount. The ITV on a per-Share basis disseminated during the hours from 9:30 a.m. to 4:15 p.m. ET should not be viewed as a real-time update of the NAV, which is calculated only once a day. E-mail from Timothy J. Malinowski, Director, NYSE Group, Inc., to Edward Cho, Special Counsel, Division of Market Regulation, Commission, dated July 9, 2007. *See also* UTP Order, 70 FR at 3956.

[16] E-mail from Timothy J. Malinowski, Director, NYSE Group, Inc., to Edward Cho, Special Counsel, Division of Market Regulation, Commission, dated July 9, 2007 (confirming the ITV calculation methodology). *See also* UTP Order, 70 FR at 3956 n.33.

[17] The Bank of New York serves as the Trustee and is responsible for the day-to-day administration of the Trust, including processing orders for the creation and redemption of Shares, coordinating the receipt and delivery of gold transferred to, or by, the Trust in connection with each creation and redemption of Shares, calculating the NAV and the adjusted NAV of the Trust on each business day, and selling the Trust's gold as needed to cover the Trust's expenses.

[18] An ''Authorized Participant'' is a person who, at the time of submitting to the Trustee an order to create or redeem one of more Baskets, (1) is a registered broker-dealer, (2) is a Depository Trust Company participant or an indirect participant, and (3) has in effect a valid authorized participant agreement.

[19] 17 CFR 240.10A–3.

[20] The Exchange states that, while the Shares would trade on the Exchange until 8 p.m. ET, liquidity in the over-the-counter market for gold generally decreases after 1:30 p.m. ET when daily trading at COMEX and other world gold trading centers ends. Trading spreads and the resulting premium or discount on the Shares may widen as a result of reduced liquidity in the over-the-counter gold market. The Exchange does not believe that the Shares would trade at a material discount or premium to the value of the underlying gold held by the Trust because of arbitrage opportunities.

to the maintenance of a fair and orderly market are present. In addition, trading in the Shares could be halted pursuant to the Exchange's ''circuit breaker'' rule [21] or by the halt or suspension of trading of the underlying gold. The Exchange further notes that, if the ITV or the value of the underlying gold is not being calculated or widely disseminated as required, the Exchange may halt trading during the day in which the interruption to the calculation or wide dissemination of the ITV or the value of the underlying gold occurs. If the interruption to the calculation or wide dissemination of the ITV or the value of the underlying gold persists past the trading day in which it occurred, the Exchange would halt trading no later than the beginning of the trading day following the interruption.

The Exchange intends to utilize its existing surveillance procedures applicable to derivative products to monitor trading in the Shares. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules. The Exchange may also obtain information via the Intermarket Surveillance Group (''ISG'') from other exchanges that are members or affiliate members of ISG. In addition, the Exchange has an information sharing agreement in place with NYMEX for the purpose of providing information in connection with trading in or related to gold futures contracts traded on COMEX. Furthermore, the Exchange states that the Shares are subject to NYSE Arca Equities Rule 8.201(g)–(i), which set forth certain restrictions on ETP Holders [22] acting as registered market makers in the Shares to facilitate surveillance. The Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

Prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin (''Bulletin'') of the special characteristics and risks associated with trading the Shares. Specifically, the Bulletin will discuss the following: (a) Description of the Shares; (b) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated ITV will not be calculated or publicly disseminated; [23] (c) the procedures for purchases and redemptions of Shares in Baskets (and that Shares are not individually redeemable); (d) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (e) how information regarding the ITV is disseminated; (f) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (g) other relevant trading information. In addition, the Bulletin will reference that the Trust is subject to various fees and expenses, the number of ounces of gold required to create a Basket or to be delivered upon redemption of a Basket would gradually decrease over time because the Shares comprising a Basket would represent a decreasing amount of gold due to the sale of the Trust's gold to pay Trust expenses, and that there is no regulated source of last-sale information regarding physical gold. The Bulletin will also disclose that the NAV for the Shares will be calculated after 4 p.m. ET each trading day, based on the COMEX daily settlement value, which is disseminated shortly after 1:30 p.m. ET each trading day and discuss any exemptive, no-action, and/or interpretive relief granted by the Commission from any rules under the Act.[24]

2. Statutory Basis

The proposal is consistent with Section 6(b) of the Act,[25] in general, and Section 6(b)(5) of the Act,[26] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2007–43 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2007–43. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington,

[21] *See* NYSE Arca Equities Rule 7.12 (Trading Halts Due to Extraordinary Market Volatility).

[22] An ETP Holder is a registered broker or dealer that has been issued an Equity Trading Permit (ETP) by NYSE Arca Equities.

[23] E-mail from Timothy J. Malinowski, Director, NYSE Group, Inc., to Edward Cho, Special Counsel, Division of Market Regulation, Commission, dated July 9, 2007 (confirming that such risks will be disclosed in the Bulletin).

[24] The Exchange represents that the Commission has granted exemptions from, or interpretive or no-action advice regarding, Section 11(d)(1) of the Act (15 U.S.C. 78k(d)(1)), Rules 10a–1 (17 CFR 240.10a–1) and 11d1–2 (17 CFR 240.11d1–2), Rule 200(g) of Regulation SHO (17 CFR 242.200(g)), and Rules 101 and 102 of Regulation M (17 CFR 242.101 and 17 CFR 242.102) under the Act, in respect of trading of the Shares. *See* Letter from James A. Brigagliano, Assistant Director, Office of Trading Practices, Division of Market Regulation, Commission, to David Yeres, Esq., Clifford Chance U.S. LLP, dated January 27, 2005. *See also* Letter from Brian A. Bussey, Assistant Chief Counsel, Division of Market Regulation, Commission, to David Yeres, Esq., Clifford Chance U.S. LLP, dated December 12, 2005.

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2007–43 and should be submitted on or before August 7, 2007.

IV. Commission's Findings and Order Granting Accelerated Approval of the Proposed Rule Change

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[27] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[28] which requires that an exchange have rules designed, among other things, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission notes that it previously approved the original listing and trading of the Shares on Amex, and the instant proposal is substantively identical to the previous Amex proposal.[29]

The Commission further believes that the proposal is consistent with Section 11A(a)(1)(C)(iii) of the Act,[30] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. The Exchange would make available, through the facilities of the CTA, quotation and last sale price information for the Shares, the daily trading volume, closing prices, and the NAV for the Shares from the previous day. In addition, the Exchange or a major market data vendor would disseminate each day through the facilities of the CTA the number of Shares outstanding and the ITV on a per-Share basis at least every 15 seconds from 9:30 a.m. to 4:15 p.m. ET. The Web site for the Trust contains information related to the NAV, including the Bid-Ask Price, the Basket Gold Amount, the Indicative Basket Gold Amount, calculation information and data related to the premium or discount of the Bid-Ask Price against the NAV, the Prospectus, and other applicable quantitative information, including trading volume data, total return of the Shares, expense ratios, and reported Share closing prices. Shortly after 4 p.m. ET each business day, the Trustee, the Exchange, and the Sponsor would disseminate the NAV for the Shares, the Basket Gold Amount, and the Indicative Basket Gold Amount. Information on gold prices and gold markets is available on public Web sites and through professional subscription services, and investors may obtain on a 24-hour basis gold pricing information based on the spot price for a troy ounce of gold from various financial information service providers. Closing and settlement prices of gold futures contracts traded on COMEX are publicly available from NYMEX's Web site, automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters. NYMEX also provides delayed futures and options information on current and past trading sessions and market news free of charge.

Furthermore, the Commission believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately. The Commission notes that the Exchange will obtain a representation from the Trust, prior to listing, that the NAV per Share would be calculated daily and made available to all market participants at the same time.[31] In addition, NYSE Arca Equities Rule 8.201(i) provides that, in connection with trading in an underlying physical commodity, related commodity futures or options on commodity futures, or any other related commodity derivative, including Commodity-Based Trust Shares, an ETP Holder acting as a Market Maker (as defined in NYSE Arca Equities Rule 1.1(u)) in the Shares is restricted from using any material non-public information received from any person associated with such ETP Holder who is trading such underlying physical commodity, related commodity futures or options on commodity futures, or other related commodity derivatives.

The Commission also believes that the Exchange's trading halt rules are reasonably designed to prevent trading in the Shares when transparency is impaired. NYSE Arca Equities Rule 8.201(e)(2) provides that, when the Exchange is the listing market, if the value of the underlying commodity or ITV is no longer calculated or available on at least a 15-second delayed basis, the Exchange would consider suspending trading in the Shares. The Exchange further represents that if the interruption to the calculation or wide dissemination of the value of the underlying gold or ITV persists past the trading day in which it occurred, the Exchange would halt trading no later than the beginning of the trading day following the interruption. NYSE Arca Equities Rule 8.201(e)(2) also provides that the Exchange may seek to delist the Shares in the event the value of the underlying gold or ITV is no longer calculated or available as required.

The Commission further believes that the trading rules and procedures to which the Shares will be subject pursuant to this proposal are consistent with the Act. The Exchange has represented that any securities listed pursuant to this proposal will be deemed equity securities, and subject to existing Exchange rules governing the trading of equity securities.

In support of this proposal, the Exchange has made the following representations:

(1) The Exchange's surveillance procedures are adequate to address any concerns associated with the trading of the Shares.

(2) The Exchange would inform its members in an Information Bulletin of the special characteristics and risks associated with trading the Shares, including risks inherent with trading the Shares during the Opening and Late Trading Sessions when the updated ITV is not calculated and disseminated and suitability recommendation requirements.

(3) The Exchange would require its members to deliver a prospectus or product description to investors purchasing Shares prior to or concurrently with a transaction in such Shares and will note this prospectus delivery requirement in the Information Bulletin.

This approval order is conditioned on the Exchange's adherence to these representations.

The Commission finds good cause for approving this proposal before the thirtieth day after the publication of notice thereof in the **Federal Register**. As noted above, the Commission

[27] In approving this rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[28] 15 U.S.C. 78f(b)(5).

[29] *See supra* note 6.

[30] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[31] *See supra* note 10.

previously approved the original listing and trading of the Shares on Amex and the trading of the Shares pursuant to UTP on the Exchange.[32] The Commission presently is not aware of any regulatory issue that should cause it to revisit those findings or would preclude the listing and trading of the Shares on the Exchange. Accelerating approval of this proposed rule change would allow the Shares to be listed on the Exchange without undue delay and continuously traded without interruption, to the benefit of investors.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[33] that the proposed rule change (SR–NYSEArca–2007–43) be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[34]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–13749 Filed 7–16–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56042; File No. SR–NYSEArca–2007–45]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change To Trade Units of the United States Natural Gas Fund, LP Pursuant to Unlisted Trading Privileges

July 11, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 15, 2007, NYSE Arca, Inc. (the ''Exchange''), through its wholly-owned subsidiary, NYSE Arca Equities, Inc. (''NYSE Arca Equities''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the Exchange. This order provides notice of the proposed rule change and approves the proposed rule change on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange, through NYSE Arca Equities, proposes to trade partnership units (''Units'') of the United States Natural Gas Fund, LP (''USNG'' or ''Partnership'') pursuant to unlisted trading privileges (''UTP''). The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Under NYSE Arca Equities Rule 8.300, which permits the trading of Partnership Units either by listing or pursuant to UTP,[3] the Exchange proposes to trade pursuant to UTP the Units of the Partnership. Each Unit represents ownership of a fractional undivided beneficial interest in the net assets of USNG.[4] The Commission has approved the listing and trading of the Units on the American Stock Exchange LLC (''Amex'').[5]

The net assets of USNG consist of investments in futures contracts based on natural gas, crude oil, heating oil, gasoline, and other petroleum-based fuels traded on the New York Mercantile Exchange (''NYMEX''), Intercontinental Exchange (''ICE Futures''), or other U.S. and foreign exchanges (such futures contracts collectively referred to herein as ''Futures Contracts''). USNG may also invest in other natural-gas-related investments such as cash-settled options on Futures Contracts; forward contracts for natural gas; over-the-counter instruments that are based on the price of natural gas, oil, and other petroleum-based fuels; Futures Contracts; and indices based on the foregoing (collectively referred to herein as ''Other Natural Gas Related Investments,'' and together with Futures Contracts, ''Natural Gas Interests''). A detailed discussion of the natural gas, crude oil, heating oil, and gasoline markets; futures regulation and the regulation of USNG; investment strategy; creations and redemptions of baskets of Units; and calculation methodology of the net asset value (''NAV'') for the Units, among others, can be found in the Amex Notice.[6]

The Web site for Amex at *http://www.amex.com,* which is publicly accessible at no charge, contains the following information: (1) The prior business day's NAV and the reported closing price; (2) the mid-point of the bid-ask price in relation to the NAV as of the time the NAV is calculated (''Bid-Ask Price'');[7] (3) calculation of the premium or discount of such price against such NAV; (4) data in chart form displaying the frequency distribution of discounts and premiums of the Bid-Ask Price against the NAV, within appropriate ranges for each of the four previous calendar quarters; (5) the prospectus and the most recent periodic reports filed with the Commission or required by the Commodity Futures Trading Commission; and (6) other applicable quantitative information.

The NAV for USNG is calculated and disseminated daily.[8] Amex disseminates for USNG on a daily basis through the facilities of the Consolidated Tape Association (CTA/CQ High Speed Lines) information with respect to the Indicative Partnership Value (as discussed below), recent NAV, Units outstanding, the Basket Amount,[9] and

[32] *See supra* notes 6 and 7.

[33] 15 U.S.C. 78s(b)(2).

[34] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 53875 (May 25, 2006), 71 FR 32164 (June 2, 2006) (SR–NYSEArca–2006–11) (approving NYSE Arca Equities Rule 8.300 and the trading of Partnership Units of the United States Oil Fund, LP pursuant to UTP).

[4] USNG is a commodity pool that issues Units that would be purchased and sold on the Exchange.

[5] *See* Securities Exchange Act Release No. 55632 (April 13, 2007), 72 FR 19987 (April 20, 2007) (SR–Amex–2006–112) (granting approval to list and trade the Units on Amex); Securities Exchange Act Release No. 55372 (February 28, 2007), 72 FR 10267 (March 7, 2007) (SR–Amex–2006–112) (providing notice of Amex's proposal to list and trade the Units) (''Amex Notice'').

[6] *See id.*

[7] The Bid-Ask Price of Units is determined using the highest bid and lowest offer as of the time of calculation of the NAV.

[8] *See* Amex Notice, 72 FR at 10273 n.18 (confirming that a representation would be obtained from USNG that its NAV per Unit will be calculated daily and made available to all market participants at the same time).

[9] A ''Basket Amount'' is the amount equal to the NAV per Unit, times 100,000 Units (each such aggregation of Units, a ''Basket'') calculated for the purpose of issuing Baskets to Authorized Purchasers. *See* Amex Notice, 72 FR at 10271. An

the Deposit Amount.[10] Amex also makes available on its Web site daily Unit trading volume and closing prices.

To provide updated information relating to USNG for use by investors, professionals, and persons wishing to create or redeem the Units, Amex disseminates through the facilities of the Consolidated Tape Association an updated Indicative Partnership Value (''Indicative Partnership Value''). The Indicative Partnership Value is disseminated on a per-Unit basis at least every 15 seconds during the regular trading hours of 9:30 a.m. to 4:15 p.m. Eastern Time (''ET''). The Indicative Partnership Value is calculated based on the Cash [11] required for creations and redemptions (*i.e.*, NAV per limit × 100,000 Units) and adjusted to reflect the price changes of the Benchmark Futures Contract.[12]

The Indicative Partnership Value does not reflect price changes to the price of the Benchmark Futures Contract between the close of open-outcry trading of such contract on NYMEX at 2:30 p.m. ET and the open of trading on the NYMEX ACCESS market at 3:15 p.m. ET.[13] The Indicative Partnership Value after 3:15 p.m. ET will reflect changes to the Benchmark Futures Contract as provided for through NYMEX ACCESS. The value of a Unit may accordingly be influenced by non-concurrent trading hours between the NYSE Arca Marketplace and NYMEX. While the Units will trade on the NYSE Arca Marketplace in accordance with NYSE Arca Equities Rule 7.34 (4 a.m. to 8 p.m. ET), the Benchmark Futures Contract will trade, in open-outcry, on NYMEX from 10 a.m. to 2:30 pm ET and NYMEX ACCESS from 3:15 p.m. through the following morning 9:30 a.m. ET.

While NYMEX is open for trading, the Indicative Partnership Value can be expected to closely approximate the value per Unit of the Basket Amount. However, during trading hours when the Futures Contracts have ceased trading, spreads and resulting premiums or discounts may widen, and therefore, increase the difference between the price of the Units and the NAV of the Units. The Indicative Partnership Value on a per-Unit basis disseminated from 9:30 a.m. to 4:15 p.m. ET should not be viewed as a real-time update of the NAV, which is calculated only once a day.

The Exchange represents that it will cease trading the Units of USNG if: (1) The original listing market stops trading the Units; or (b) the original listing market delists the Units. Additionally, the Exchange may cease trading the Units if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.[14] UTP trading in the Units is also governed by the trading halts provisions of NYSE Arca Equities Rule 7.34 relating to temporary interruptions in the calculation or wide dissemination of the Indicative Partnership Value or the value of the Benchmark Futures Contract.[15]

The Exchange deems the Units to be equity securities, thus rendering trading in the Units subject to the Exchange's existing rules governing the trading of equity securities. Units will trade on the NYSE Arca Marketplace from 4 a.m. ET until 8 p.m. ET in accordance with NYSE Arca Equities Rule 7.34 (Opening, Core, and Late Trading Sessions). The Exchange states that it has appropriate rules to facilitate transactions in the Units during all trading sessions.

The Exchange intends to utilize its existing surveillance procedures applicable to derivative products to monitor trading in the Units. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Units in all trading sessions and to deter and detect violations of Exchange rules. The Exchange may also obtain information via the Intermarket Surveillance Group (''ISG'') from other exchanges who are members or affiliate members of ISG. In addition, the Exchange has information sharing agreements in place with NYMEX and ICE Futures for the purpose of providing information in connection with trading in or related to futures contracts traded on NYMEX and ICE Futures, respectively. To the extent that USNG invests in Natural Gas Interests traded on other exchanges, the Exchange will seek to enter into information sharing agreements with those particular exchanges. In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

Prior to the commencement of trading, the Exchange will inform its ETP Holders [16] in an Information Bulletin (''Bulletin'') of the special characteristics and risks associated with trading the Units. Specifically, the Bulletin will discuss the following: (1) The risks involved in trading the Units during the Opening and Late Trading Sessions when an updated Indicative Partnership Value will not be calculated or publicly disseminated; [17] (2) the procedures for purchases and redemptions of Units in Baskets (and that Units are not individually redeemable); (3) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Units; (4) how and when information regarding the Indicative Partnership Value and NAV is disseminated; (5) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Units prior to or concurrently with the confirmation of a transaction; and (6) other relevant

''Authorized Purchaser'' is a person, who, at the time of submitting an order to create or redeem Units, is (1) A registered broker-dealer or other market participant, such as a bank or other financial institution, that is exempt from broker-dealer registration, (2) a Depository Trust Company participant, and (3) a party to a valid Authorized Purchaser agreement. *See id.*

[10] The ''Deposit Amount'' is the amount transferred from a purchaser to the Administrator for the purpose of purchasing a Basket of Units. *See* Amex Notice, 72 FR at 10272. The ''Administrator'' is Brown Brothers Harriman & Co., performing or supervising the performance of services necessary for the operation and administration of USNG. *See* Amex Notice, 72 FR at 10269.

[11] ''Cash'' includes short-term obligations of the United States, cash equivalents, and cash.

[12] The ''Benchmark Futures Contract,'' which is used to measure changes in percentage terms of a Unit's NAV, is the natural gas futures contract traded on NYMEX reflecting the price and change in price of natural gas delivered at the Henry Hub, Louisiana.

[13] NYMEX ACCESS®, an electronic trading system, is open for price discovery on the Benchmark Futures Contract each Monday through Thursday at 3:15 p.m. ET through the following morning at 9:30 a.m. ET, and from 7 p.m. Sunday night until Monday morning 9:30 a.m. ET.

[14] With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Units. These may include (1) the extent to which trading is not occurring in the underlying Futures Contracts, or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. In addition, trading in the Units could be halted pursuant to the Exchange's ''circuit breaker'' rule or by the halt or suspension of trading of the underlying securities. *See* NYSE Arca Equities Rule 7.12 (Trading Halts Due to Extraordinary Market Volatility).

[15] The Exchange states that NYSE Arca Equities Rule 7.34(a) literally addresses temporary interruptions in the calculation or wide dissemination of the Indicative Intra-Day Value and the value of an underlying index. The Units, however, do not have an underlying index, but have an underlying Benchmark Futures Contract. Therefore, the Exchange represents that the provisions in NYSE Arca Equities Rule 7.34(a) that address interruptions in the calculation or wide dissemination of the value of an underlying index shall also apply, in this case, to interruptions in the calculation or wide dissemination of the value of the underlying Benchmark Futures Contract. *See infra*

[16] 16 An ETP Holder is a registered broker or dealer that has been issued an Equity Trading Permit (ETP) by NYSE Arca Equities.

[17] E-mail from Timothy J. Malinowski, Director, NYSE Group, Inc., to Edward Cho, Special Counsel, Division of Market Regulation, Commission, dated July 9, 2007 (confirming that such risks will be disclosed in the Bulletin).

trading information. In addition, the Bulletin will reference that the Partnership is subject to various fees and expenses and that there is no regulated source of last-sale information regarding physical commodities. The Bulletin will also discuss any exemptive, no-action, and/or interpretive relief granted by the Commission from any rules under the Act.

2. Statutory Basis

The proposal is consistent with Section 6(b) of the Act,[18] in general, and Section 6(b)(5) of the Act,[19] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. In addition, the proposal is consistent with Rule 12f–5 under the Act [20] because the Exchange deems the Units to be equity securities, thus rendering trading in the Units subject to the Exchange's existing rules governing the trading of equity securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2007–45 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2007–45. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2007–45 and should be submitted on or before August 7, 2007.

IV. Commission's Findings and Order Granting Accelerated Approval of the Proposed Rule Change

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[21] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[22] which requires that an exchange have rules designed, among other things, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission believes that this proposal should benefit investors by increasing competition among markets that trade the Units.

In addition, the Commission finds that the proposal is consistent with Section 12(f) of the Act,[23] which permits an exchange to trade, pursuant to UTP, a security that is listed and registered on another exchange.[24] The Commission notes that it previously approved the original listing and trading of the Units on Amex.[25] The Commission finds that the proposal is consistent with Rule 12f–5 under the Act,[26] which provides that an exchange shall not extend UTP to a security unless the exchange has in effect a rule or rules providing for transactions in the class or type of security to which the exchange extends UTP. The Exchange has represented that it meets this requirement because it deems the Units to be equity securities, thus rendering trading in the Units subject to the Exchange's existing rules governing the trading of equity securities. The Commission notes that it previously approved for trading on the Exchange pursuant to UTP Partnership Units issued by the United States Oil Fund, LP, which are similar to the Units issued by USNG.[27]

The Commission further believes that the proposal is consistent with Section 11A(a)(1)(C)(iii) of the Act,[28] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Quotations for and last-sale information regarding the Units will be disseminated through the Consolidated Quotation System and the Consolidated Tape Association,

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(5).

[20] 17 CFR 240.12f–5.

[21] In approving this rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78*l*(f).

[24] Section 12(a) of the Act, 15 U.S.C. 78*l*(a), generally prohibits a broker-dealer from trading a security on a national securities exchange unless the security is registered on that exchange pursuant to Section 12 of the Act. Section 12(f) of the Act excludes from this restriction trading in any security to which an exchange ''extends UTP.'' When an exchange extends UTP to a security, it allows its members to trade the security as if it were listed and registered on the exchange even though it is not so listed and registered.

[25] *See supra* note 5.

[26] 17 CFR 240.12f–5.

[27] *See supra* note 3.

[28] 15 U.S.C. 78k–1(a)(1)(C)(iii).

respectively.[29] In addition, Amex disseminates a variety of information through the facilities of the Consolidated Tape Association including the Indicative Partnership Value on a per-Unit basis at least every 15 seconds during regular Amex trading hours, the number of Units outstanding, the Basket Amount, and the Deposit Amount. Daily closing and settlement prices for the NYMEX-traded Futures Contracts held by USNG, delayed futures information on current and past trading sessions, and market news are publicly available on the NYMEX Web site. Quotations and last-sale information for the Futures Contracts are widely disseminated through a variety of market data vendors worldwide, including Bloomberg and Reuters. Amex's Web site contains information related to the NAV, including the Bid-Ask Price, calculation information and other data of the premium or discount of the Bid-Ask Price against the NAV, the prospectus and other periodically-filed reports, trading volume data, Unit closing prices, and other applicable quantitative information. Finally, USNG's Web site discloses on each business day that Amex is open for trading the total portfolio composition of USNG, including the name, value, type, and characteristics of the Natural Gas Interests and Cash held.

The Commission also believes that the Exchange's trading halt rules are reasonably designed to prevent trading in the Shares when transparency is impaired. Existing NYSE Arca Equities Rule 7.34(a)(4), which will apply to the trading of the Units, provides that, if the Benchmark Futures Contract or Indicative Partnership Value is no longer calculated or disseminated as required (a) during the Opening Session (4 a.m. to 9:30 a.m. ET), the Exchange may continue to trade the Units for the remainder of the Opening Session; (b) during the Core Trading Session (9:30 a.m. to 4 p.m. ET), the Exchange must halt trading in the Units; and (c) during the Late Trading Session (4 p.m. to 8 p.m. ET), the Exchange may continue trading in the Units only if the original listing market traded such Units until the close of its regular trading session without halt.[30] If the Benchmark Futures Contract or Indicative Partnership Value continues not to be calculated or disseminated as of the next business day's Opening Session, the Exchange will not commence trading in the Units in such Opening Session.[31]

The Commission notes that, if the Units should be delisted by the listing exchange, the Exchange would no longer have authority to trade the Units pursuant to this order.

In support of this proposal, the Exchange has made the following representations:

(1) The Exchange's surveillance procedures are adequate to address any concerns associated with the trading of the Units on a UTP basis.

(2) The Exchange would inform its members in an Information Bulletin of the special characteristics and risks associated with trading the Units, including risks inherent with trading the Units during the Opening and Late Trading Sessions when the updated Indicative Partnership Value is not calculated and disseminated and suitability recommendation requirements.

(3) The Exchange would require its members to deliver a prospectus or product description to investors purchasing Units prior to or concurrently with a transaction in such Units and will note this prospectus delivery requirement in the Information Bulletin.

This approval order is conditioned on the Exchange's adherence to these representations.

The Commission finds good cause for approving this proposal before the thirtieth day after the publication of notice thereof in the **Federal Register**. As noted above, the Commission previously approved the original listing and trading of the Units on Amex and the trading of Partnership Units issued by the United States Oil Fund, LP, which are similar to the Partnership Units issued by the Partnership, pursuant to UTP on the Exchange. The Commission presently is not aware of any regulatory issue that should cause it to revisit those findings or would preclude the trading of the Units on the Exchange pursuant to UTP. Accelerating approval of this proposal should benefit investors by creating, without undue delay, additional competition in the market for such Units.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[32] that the proposed rule change (SR–NYSEArca–2007–45) be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[33]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–13750 Filed 7–16–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56049; File No. SR–Phlx–2007–20]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change as Modified by Amendment No. 1 Thereto Adopting Generic Listing Standards for Exchange-Traded Funds Based on International or Global Indexes or Indexes Described in Exchange Rules Previously Approved by the Commission as Underlying Benchmarks for Derivative Securities

July 11, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 9, 2007, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by Phlx. On June 18, 2007, Phlx filed Amendment No. 1 to the proposal. This order provides notice of the proposal, as amended, and approves the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Phlx proposes to revise its listing standards, adopted pursuant to Rule 19b–4(e),[3] in Phlx Rule 803 to include generic listing standards for Trust Shares and Index Fund Shares (''IFSs'') (which together with Trust Shares are referred to as ''exchange-traded funds'' or ''ETFs'') that are based on

[29] E-mail from Timothy J. Malinowski, Director, NYSE Group, Inc., to Edward Cho, Special Counsel, Division of Market Regulation, Commission, dated July 9, 2007 (confirming the method of dissemination of quotations and last-sale information regarding the Units).

[30] *See supra* note 15 and accompanying text.

[31] The Exchange may resume trading in the Units only if the calculation and dissemination of the Benchmark Futures Contract or Indicative Partnership Value resumes, or trading in the Units resumes in the original listing market. *See* NYSE Arca Equities Rule 7.34(a)(4)(C)(2).

[32] 15 U.S.C. 78s(b)(2).

[33] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(e).

international or global indexes, or on indexes described in exchange rules that have been previously approved by the Commission for the trading of ETFs or other specified index-based securities.

The text of the proposed rule change is available at Phlx, from the Commission's Public Reference Room, and on Phlx's Web site (*http://www.Phlx.com*).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Phlx included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. Phlx has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to provide for the more efficient and timely listing and trading of ETFs. This proposal would enable the Exchange to list and trade ETFs pursuant to Rule 19b–4(e) under the Act[4] if each of the conditions set forth in Phlx Rules 803(i) and (*l*) is satisfied. Rule 19b–4(e) provides that the listing and trading of a new derivative securities product by a self-regulatory organization (''SRO'') shall not be deemed a proposed rule change, pursuant to paragraph (c)(1) of Rule 19b–4,[5] if the Commission has approved, pursuant to Section 19(b) of the Act, the trading rules, procedures, and listing standards for the product class that would include the new derivatives securities product, and the SRO has a surveillance program for the product class.[6]

Background

Currently, Phlx Rule 803(i) provides standards for listing Trust Shares on Phlx. A Trust Share is a security based on a unit investment trust registered under the Investment Company Act of 1940 (''1940 Act''),[7] which holds the securities that comprise an index or portfolio underlying a series of Trust Shares. Phlx Rule 803(*l*) provides standards for listing IFSs, which are securities issued by an open-end management investment company registered under the 1940 Act (*i.e.*, an open-end mutual fund) based on a portfolio of stocks that seeks to provide investment results that correspond generally to the price and yield performance of a specified foreign or domestic stock index.

Pursuant to Phlx Rule 803(i), Trust Shares that are eligible for listing on the Exchange must be issued in a specified aggregate minimum number in return for a deposit of specified securities and/or a cash amount. When aggregated in the same specified minimum number, the Trust Shares must be redeemable from the Trust for the securities and/or cash. Pursuant to Phlx Rule 803(*l*), IFSs that are eligible for listing on the Exchange must be issued in a specified aggregate minimum number in return for a deposit of specified securities and/or a cash amount, with a value equal to the next determined net asset value (''NAV''). When aggregated in the same specified minimum number, IFSs must be redeemable by the issuer for the securities and/or cash, with a value equal to the next determined NAV. The NAV is calculated once a day after the close of the regular trading day.[8]

To meet the investment objective of providing investment returns that correspond to the price and the dividend and yield performance of the underlying index, an ETF may use a ''replication'' strategy or a ''representative sampling'' strategy with respect to the ETF portfolio.[9] An ETF using a replication strategy will invest in each stock of the underlying index in about the same proportion as that stock is represented in the index itself. An ETF using a representative sampling strategy will generally invest in a significant number but not all of the component securities of the underlying index, and will hold stocks that, in the aggregate, are intended to approximate the full index in terms of key characteristics, such as price/earnings ratio, earnings growth, and dividend yield.

In addition, an ETF portfolio may be adjusted in accordance with changes in the composition of the underlying index or to maintain compliance with requirements applicable to a regulated investment company under the Internal Revenue Code (''IRC'').

Generic Listing Standards for Exchange-Traded Funds

The Commission has previously approved generic listing standards for ETFs based on indexes that consist of stocks listed on U.S. exchanges.[10] In general, the proposed criteria for the underlying component securities in the international and global indexes are similar to those for the domestic indexes, but with modifications for the issues and risks associated with non-U.S. securities.

In addition, the Commission has previously approved generic listing standards of exchanges governing the listing and trading of ETFs based on indexes composed of non-U.S. Component Stocks as well as indexes based on both non-U.S. Component Stocks and U.S. Component Stocks.[11] The Commission has also approved generic listing standards for index-based derivative securities products based on indexes described in exchange rules that have been previously approved by the Commission under Section 19(b)(2) of the Act for the trading of ETFs or other index-based securities, on the condition that all of the standards set forth in those orders, including surveillance sharing agreements, continue to be satisfied.[12]

The Exchange believes that adopting generic listing standards and applying Rule 19b–4(e) should fulfill the intended objective of that rule by allowing those ETFs that satisfy the

[4] 17 CFR 240.19b–4(e).

[5] 17 CFR 240.19b–4(c)(1).

[6] When relying on Rule 19b–4(e), the SRO must submit Form 19b–4(e) to the Commission within five business days after it begins trading the new derivative securities products. *See* 17 CFR 240.19b–4(e)(2)(ii).

[7] 15 U.S.C. 80a.

[8] *See* e-mail from John Dayton, Director and Counsel, Phlx, to Natasha Cowen, Special Counsel, Division of Market Regulation (''Division''), Commission, dated July 6, 2007.

[9] In either case, an ETF, by its terms, may be considered invested in the securities of the underlying index to the extent the ETF invests in sponsored American Depositary Receipts (''ADRs''), Global Depositary Receipts (''GDRs''), or European Depositary Receipts (''EDRs'') that trade on exchanges with last-sale reporting representing securities in the underlying index.

[10] *See* Securities Exchange Act Release No. 43717 (December 13, 2000), 65 FR 80976 (December 22, 2000) (SR–Phlx–00–54) (approving Phlx Rule 803(i), which sets forth the rules related to the listing and trading of Trust Shares); Securities Exchange Act Release No. 43912 (January 31, 2001), 66 FR 9401 (February 7, 2001) (SR–Phlx–00–91) (approving Phlx Rule 803(*l*), which sets forth the rules including generic listing standards for the listing and trading of Index Fund Shares under Phlx Rule 803(*l*)).

[11] *See* Securities Exchange Act Release No. 55621 (April 12, 2007), 72 FR 19571 (April 18, 2007) (SR–NYSEArca–2006–86); Securities Exchange Act Release No. 55269 (February 9, 2007), 72 FR 7490 (February 15, 2007) (SR–NASDAQ–2006–50); Securities Exchange Act Release No. 55113 (January 17, 2007), 72 FR 3179 (January 24, 2007) (SR–NYSE–2006–101).

[12] *See, e.g.* Securities Exchange Act Release No. 51563 (April 15, 2005) 70 FR 21257 (April 25, 2005) (SR–Amex–2005–001); Securities Exchange Act Release No. 52204 (August 3, 2005), 70 FR 46559 (August 10, 2005) (SR–PCX–2005–63).

proposed generic listing standards to commence trading, without the need for a public comment period and Commission approval. The proposed rules have the potential to reduce the time frame for bringing ETFs to market, thereby reducing the burdens on issuers and other market participants. The failure of a particular ETF to comply with the proposed generic listing standards under Rule 19b–4(e) would not, however, preclude the Exchange from submitting a separate filing pursuant to Section 19(b)(2) requesting Commission approval to list and trade a particular ETF.

Proposed Listing and Trading Requirements

ETFs that are listed pursuant to the proposed generic listing standards or that are traded pursuant to UTP would be traded, in all other respects, under the Exchange's existing trading rules and procedures that apply to ETFs and would be covered under Exchange's surveillance program for ETFs.[13]

To list a Trust Share or IFS pursuant to the proposed generic listing standards for international and global indexes, the index underlying the Trust Share or IFS must satisfy all the conditions contained in proposed Phlx Rules 803(i)(11)(b) or (*l*)(6)(B). As with the existing generic standards for ETFs based on domestic indexes, these generic listing standards are intended to ensure that stocks with substantial market capitalization and trading volume account for a substantial portion of the weight of an index or portfolio. While the standards in this proposal are based on the standards contained in the current generic listing standards for ETFs based on domestic indexes, they have been adapted as appropriate to apply to international and global indexes.

As proposed, Phlx Rule 803(i)(1)(iii) and (iv) and Phlx Rule 803(*l*)(2)(C) and (D) would be revised to include definitions of ''U.S. Component Stock'' and ''Non-U.S. Component Stock.'' These new definitions would provide the basis for the standards for indexes with either domestic or international stocks, or a combination of both. A ''Non-U.S. Component Stock'' would mean an equity security that is not registered under Section 12(b) or 12(g) of the Act,[14] and that is issued by an entity that (1) is not organized, domiciled, or incorporated in the United States; and (2) is an operating company (including a real estate investment trust (REIT) or income trust, but excluding an investment trust, unit trust, mutual fund, or derivative). This definition is designed to create a category of component stocks that are issued by companies that are not based in the United States, are not subject to oversight through Commission registration, and would include sponsored GDRs and EDRs. A ''U.S. Component Stock'' would mean an equity security that is registered under Section 12(b) or 12(g) of the Act or an ADR the underlying equity security of which is registered under Section 12(b) or 12(g) of the Act. An ADR with an underlying equity security that is registered pursuant to the Act is considered a U.S. Component Stock because the issuer of that security is subject to Commission jurisdiction and must comply with Commission rules.

The Exchange proposes that, to list a Trust Share or an IFS based on an international or global index or portfolio pursuant to the generic listing standards, such index or portfolio must meet the following criteria:

- Component stocks that in the aggregate account for at least 90% of the weight of the index or portfolio each must have a minimum market value of at least $100 million (Phlx Rules 803(i)(11)(b)(i) and (*l*)(6)(B)(I));
- Component stocks representing at least 90% of the weight of the index or portfolio each must have a minimum worldwide monthly trading volume during each of the last six months of at least 250,000 shares (Phlx Rules 803(i)(11)(b)(ii) and (*l*)(6)(B)(II));
- The most heavily weighted component stock may not exceed 25% of the weight of the index or portfolio and the five most heavily weighted component stocks may not exceed 60% of the weight of the index or portfolio (Phlx Rules 803(i)(11)(b)(iii) and (*l*)(6)(B)(III));
- The index or portfolio shall include a minimum of 20 component stocks (Phlx Rules 803(i)(11)(b)(iv) and (*l*)(6)(B)(IV)); and
- Each U.S. Component Stock must be listed on a national securities exchange and be an NMS stock as defined in Rule 600 of Regulation NMS under the Act, and each Non-U.S. Component Stock must be listed on an exchange that has last-sale reporting (Phlx Rules 803(i)(11)(b)(v) and (*l*)(6)(B)(V)).

The Exchange believes that these proposed standards are reasonable for international and global indexes, and, when applied in conjunction with the other listing requirements, would result in the listing and trading on the Exchange of ETFs that are sufficiently broad-based in scope and not readily susceptible to manipulation. The Exchange also believes that the proposed standards would result in ETFs that are adequately diversified in weighting for any single security or small group of securities to significantly reduce concerns that trading in an ETF based on an international or global index could become a surrogate for the trading of securities not registered in the United States.

The Exchange further notes that, while these standards are similar to those for indexes that include only U.S. Component Stocks, they differ in certain important respects and are generally more restrictive, reflecting greater concerns over portfolio diversification with respect to ETFs investing in components that are not individually registered with the Commission. First, in the proposed standards, component stocks that in the aggregate account for at least 90% of the weight of the index or portfolio each shall have a minimum market value of at least $100 million, compared to a minimum market value of at least $75 million for indexes with only U.S. Component Stocks. (Market value is calculated by multiplying the total shares outstanding by the price per share of the component stock.) Second, in the proposed standards, the most heavily weighted component stock cannot exceed 25% of the weight of the index or portfolio, in contrast to a 30% standard for an index or portfolio comprised of only U.S. Component Stocks. Third, in the proposed standards, the five most heavily weighted component stocks shall not exceed 60% of the weight of the index or portfolio, compared to a 65% standard for indexes comprised of only U.S. Component Stocks. Fourth, the minimum number of stocks in the proposed standards is 20, in contrast to a minimum of 13 in the standards for an index or portfolio with only U.S. Component Stocks. Finally, the proposed standards require that each Non-U.S. Component Stock included in the index or portfolio be listed and traded on an exchange that has last-sale reporting.

The Exchange also proposes new Phlx Rules 803(i)(11)(e) and (*l*)(6)(E) to require that the index value for an ETF listed pursuant to the proposed standards for international and global indexes be widely disseminated by one or more major market data vendors at least every 60 seconds during the time when the ETF shares trade on the Exchange. If the index value does not change during some or all of the period when trading is occurring on the Exchange, the last official calculated index value must remain available throughout Exchange trading hours. In

[13] *See* Phlx Rule 803(i)(11)(i) and (*l*)(6)(I).

[14] 15 U.S.C. 78*l*(b) or (g).

contrast, the index value for an ETF listed pursuant to the existing standards for domestic indexes must be disseminated at least every 15 seconds during the trading day. This modification reflects limitations, in some instances, on the frequency of intra-day trading information with respect to Non-U.S. Component Stocks and that, in many cases, trading hours for overseas markets overlap only in part, or not at all, with Exchange trading hours.

In addition, proposed Phlx Rules 803(i)(11)(e) and (*l*)(6)(E) would define the term ''Intraday Indicative Value'' (''IIV'') as the estimate of the value of a share of each ETF that is updated at least every 15 seconds during the Core Session [15] and during any Pre Market Session [16] for the ETF. Phlx also proposes to clarify in these rules that the IIV would be updated at least every 15 seconds during the Core Session on Phlx's XLE equities trading platform and during any Pre Market Session on XLE for the ETF to reflect changes in the exchange rate between the U.S. dollar and the currency in which any component stock is denominated. If the IIV does not change during some or all of the period when trading is occurring on XLE because the underlying components of an index or portfolio are not trading, then the last official calculated IIV must remain available throughout XLE's trading hours.

As set forth in proposed Phlx Rules 803(i)(11)(l) and (*l*)(6)(H), Phlx may designate an ETF for trading during XLE's Pre Market Session and/or the Post Market Session [17] as long as the index value and IIV dissemination requirements of proposed Phlx Rules 803(i)(11)(e) and (*l*)(6)(E) are met. If there is no overlap with the trading hours of the primary market trading the underlying components of an ETF, Phlx may designate the ETF for the Pre Market Session as long as the last official calculated IIV remains available.[18] Although the IIV does not need to be calculated during XLE's current Post Market Session, the last official calculated IIV must also remain available during such post-market trading session.

The Exchange is also proposing to add provisions, proposed Phlx Rules 803(i)(11)(k) and (*l*)(6)(K), regarding the creation and redemption process for ETFs and compliance with federal securities laws for ETFs listed pursuant to the new generic listing standards. These new provisions would require that the statutory prospectus or the application for exemption from provisions of the 1940 Act for the ETF state that the ETF must comply with the federal securities laws in accepting securities for deposits and satisfying redemptions with redemption securities, including that the securities accepted for deposits and the securities used to satisfy redemption requests are sold in transactions that would be exempt from registration under the Securities Act of 1933.[19]

The Commission has approved generic listing standards providing for the listing, pursuant to Rule 19b–4(e), of derivative securities products based on indexes described in rules previously approved by the Commission under Section 19(b)(2) of the Act.[20] The Exchange would include in its proposed generic listing standards indexes described in exchange rules that have been approved by the Commission in connection with the listing of options, ETFs, index-linked exchangeable notes, or index-linked securities. The Exchange believes that the application of this standard to ETFs is appropriate because the underlying index would have been subject to detailed and specific Commission review in the context of the approval of listing of those other derivatives. This new generic standard would be limited to stock indexes and would require that each component stock be either: (1) A U.S. Component Stock that is listed on a national securities exchange and is an NMS Stock as defined in Rule 600 of Regulation NMS; or (2) a Non-U.S. Component Stock that is listed and traded on an exchange that has last-sale reporting.

The Exchange also proposes to include additional continued listing standards relating to ETFs. The Exchange proposes to adopt Phlx Rules 803(i)(5)(D) and (*l*)(5)(D) to formalize in the rules existing best practices for providing equal access to material information about the value of ETFs. Prior to approving an ETF for listing, the Exchange would obtain a representation from the ETF issuer that the NAV per share would be calculated daily and made available to all market participants at the same time. The Exchange would commence delisting proceedings for an ETF if the value of the index or portfolio of securities on which the ETF is based is no longer calculated or disseminated.

Phlx's proposed amendments to Phlx Rule 136 would expand the application of the trading halt provisions of Rule 136(c) and (d) from index-linked securities to a broader range of derivative securities products listed or traded on Phlx on a UTP basis. Current Phlx Rule 136, among other things, sets out the trading halt rules for a Derivative Securities Product [21] in the event that there is a temporary interruption in the calculation and dissemination of the index value or the IIV. Phlx Rule 136(c) sets forth the trading halt requirement when Phlx is the primary listing market while Phlx Rule 136(d) sets forth the trading halt requirement when Phlx is trading an ETF pursuant to UTP. The proposed amendments to Phlx Rule 136(e) would expand the definition of a Derivative Securities Product to include Trust Shares, IFSs, and other derivative securities, thus applying Phlx trading halt rules to such securities if there is a temporary interruption in the calculation and dissemination of the index value or the IIV. Phlx is also proposing to clarify and expand the definition of ''Required Value'' to include the Indicative Optimized Portfolio Value, which is used in connection with certain derivative securities products, and other comparable values.[22]

The Exchange proposes to amend Phlx Rule 803 to stipulate that, as provided by Commission Rule 12f–5,[23] the Exchange may extend UTP to any security, such as an ETF, for which the Exchange has in effect rules providing for transactions in such class or type of security. Provisions of Phlx Rule 803 that govern trading hours and surveillance procedures, and that relate to information circulars and prospectus delivery, also would apply to securities traded on a UTP basis (as do applicable proposed trading halt provision of Phlx Rule 136). The Exchange would not, however, apply quantitative listing standards to securities traded on a UTP basis. Accordingly, introductory

[15] The Core Session on XLE shall take place for each security from 9:30 a.m. until 4 p.m., except for specified ETFs, for which it shall last until 4:15 p.m. *See* Phlx Rule 101 Supplementary Material .02(2).

[16] The Pre Market Session on XLE begins at 8 a.m. and concludes at the commencement of the Core Session. *See* Phlx Rule 101 Supplementary Material .02(1).

[17] The Post Market Session on XLE shall begin following the conclusion of the Core Session and conclude at 6 p.m. *See* Phlx Rule 101 Supplementary Material .02(3).

[18] *See* Phlx Rule 803(i)(11)(l) and (*l*)(6)(H).

[19] 15 U.S.C. 77a *et seq.*

[20] *See supra* note 12.

[21] Current Phlx Rule 136 defines a ''Derivative Securities Product'' as ''a series of Index-Linked Securities.''

[22] Phone conversation between John Dayton, Director and Counsel, Phlx, with Natasha Cowen, Special Counsel, Division, Commission, on July 10, 2007 (clarifying the implications of proposed changes to Rule 136).

[23] 17 CFR 240.12f–5.

language in Phlx Rules 803(i)(11) and (*l*)(6) that could be read to require unlisted securities to meet Phlx's quantitative listing standards for Trust Shares or IFSs in order to trade on a UTP basis is being deleted.

The Exchange is proposing other minor and clarifying changes to Phlx Rules 803(i) and (*l*). Phlx proposed to amend Rules 803(i)(11)(d)(ii)–(iii) and (*l*)(6)(D)(II)–(III) to make sure that an entity that advises an index provider or calculator and related entities has in place procedures designed to prevent the use and dissemination of material non-public information regarding the index underlying the ETF. Phlx Rules 803(i)(11)(g) and (*l*)(6)(G) would be amended to clarify that the trading increments for ETFs are set in Phlx Rule 125. Phlx Rule 803(*l*)(6)(H) would be amended and Phlx Rule 803(i)(11)(l) would be added to, among other things, clarify that the trading hours for ETFs are set in Phlx Rule 101. Phlx Rule 803(*l*)(6)(A)(III), which sets forth one of the listing requirements for a series of IFSs that are based on U.S. Component Stocks, would be amended to change the maximum weighting requirement for the most heavily weighted component stock of the underlying index from 25% to 30%.[24] Phlx Rule 803(*l*)(3) would be amended to harmonize its provisions with those in Phlx Rule 803(*l*)(7).

The Exchange represents that its surveillance procedures are adequate to properly monitor the trading of Trust Shares and IFSs that would be listed pursuant to the proposed listing standards or traded on a UTP basis. Specifically, Phlx will rely on its existing surveillance procedures governing equities, options, and ETFs. The Exchange states that it will closely monitor activity in ETFs to identify and deter any potential improper trading activity in ETFs. In addition, the Exchange has a general policy prohibiting the dissemination of material, non-public information by its employees.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[25] in general, and with Section 6(b)(5) of the Act,[26] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2007–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2007–20. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of Phlx. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2007–20 and should be submitted on or before August 7, 2007.

IV. Commission's Findings and Order Granting Accelerated Approval of the Proposed Rule Change

After careful review, the Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[27] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act[28] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

Currently, the Exchange must file a proposed rule change with the Commission pursuant to Section 19(b)(1) of the Act[29] and Rule 19b–4 thereunder[30] to list and trade any ETF based on an index comprised of foreign securities. The Exchange also must file a proposed rule change to list and trade ETFs based on indexes or portfolios described in rule changes that have previously been approved by the Commission as underlying benchmarks for derivative securities. However, Rule 19b–4(e) provides that the listing and trading of a new derivative securities product by an SRO will not be deemed a proposed rule change pursuant to Rule 19b–4(c)(1) if the Commission has approved, pursuant to Section 19(b) of the Act, the SRO's trading rules, procedures, and listing standards for the product class that would include the new derivative securities product, and the SRO has a surveillance program for the product class. Phlx's proposed rules

[24] *See* Securities Exchange Act Release Nos. 44532 (July 10, 2001), 66 FR 37078 (July 16, 2001) (SR–Amex–2001–25).

[25] 15 U.S.C. 78f.

[26] 15 U.S.C. 78f(b)(5).

[27] In approving this rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[28] 15 U.S.C. 78f(b)(5).

[29] 15 U.S.C. 78s(b)(1).

[30] 17 CFR 240.19b–4.

for the listing and trading of ETFs pursuant to Rule 19b–4(e) based on (1) certain indexes with components that include foreign securities or (2) indexes or portfolios described in exchange rules that have been previously approved by the Commission as underlying benchmarks for derivative securities, fulfill these requirements. Use of Rule 19b–4(e) by the Exchange to list and trade such ETFs should promote competition, reduce burdens on issuers and other market participants, and make such ETFs available to investors more quickly.[31]

The Commission previously has approved generic listing standards for other exchanges that are substantially similar to those proposed here by the Exchange.[32] This proposal does not appear to raise any novel regulatory issues. Therefore, the Commission finds that Phlx's proposal is consistent with the Act on the same basis that it approved the other exchange's generic listing standards for ETFs based on international or global indexes or on indexes or portfolios described in exchange rules that have been previously approved by the Commission as underlying benchmarks for derivative securities.

Proposed Phlx Rules 803(i)(11)(b) and (*l*)(6)(B) establish standards for the composition of indexes and portfolios underlying ETFs. These requirements are designed, among other things, to require that components of an index or portfolio underlying an ETF are adequately capitalized and sufficiently liquid, and that no one security dominates the index. The Commission believes that, taken together, these standards are reasonably designed to ensure that securities with substantial market capitalization and trading volume account for a substantial portion of any underlying index or portfolio, and that when applied in conjunction with the other applicable listing requirements will permit the listing and trading of only ETFs that are sufficiently broad-based in scope to minimize potential manipulation. The Commission further believes that the proposed listing standards are reasonably designed to preclude Phlx from listing and trading ETFs that might be used as surrogate for trading in unregistered securities. The requirement that each component security underlying an ETF be an NMS Stock (in the case of a U.S. Component Stock) or listed on an exchange and subject to last-sale reporting (in the case of a Non-U.S. Component Stock) also should contribute to the transparency of the market for these ETFs.

The proposed generic listing standards will permit the Exchange to list and trade an ETF if the Commission has previously approved an SRO rule change that contemplates listing and trading a derivative product based on the same underlying index. Phlx would be able to rely on that earlier approval order, provided that: (1) The securities comprising the underlying index consist of U.S. Component Stocks or Non-U.S. Component Stocks; and (2) Phlx complies with the commitments undertaken by the other SRO set forth in the prior order, including any surveillance-sharing arrangements with a foreign market.

The Commission believes that Phlx's proposal is consistent with Section 11A(a)(1)(C)(iii) of the Act,[33] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Phlx's proposal requires the value of the index or portfolio underlying an ETF based on a global or international index to be disseminated at least once every 60 seconds during the time when the ETF shares trade on the Exchange.[34] Phlx has represented that, if an underlying index or portfolio value is no longer calculated or available, it would commence delisting proceedings for the associated ETF.

In addition, an IIV, which represents an estimate of the value of a share of each ETF, must be updated and disseminated at least once every 15 seconds during Phlx XLE's Core Session. If the underlying components are trading during the same hours as the XLE's Pre Market Session, Phlx may not trade the ETF unless an updated IIV is being calculated and disseminated. The IIV must reflect changes in the exchange rate between the U.S. dollar and the currency in which any index or portfolio component stock is denominated. When there is no overlap with the trading hours of the primary market or markets trading the underlying components of an ETF, Phlx may trade such ETF during the Pre Market Session, as long as the last official calculated IIV remains available.[35] In those instances, the IIV will not reflect changes associated with the exchange rate. Although the IIV is not calculated during XLE's current Post Market Session, the last official calculated IIV must also remain available during such post-market trading session.

The Commission believes the proposal is reasonably designed to preclude trading of ETFs when transparency is impaired. Existing Phlx Rule 136 sets out the trading halt rules for Derivative Securities Products in the event that there is a temporary interruption in the calculation and dissemination of the index value or the IIV. In the proposed rule change, Phlx would amend its definition of a ''Derivative Securities Product'' and thereby extend Rule 136 to a broader range of derivative securities products that currently trade on the Exchange, including Trust Shares and IFSs. This proposed rule change is designed to ensure that similar derivative securities products are treated consistently and that the same trading halt rules apply when there is a temporary disruption in the dissemination of the IIV and index value.

In addition, in the proposed rule change, Phlx would clarify that the trading halt rules apply when values that are comparable to the IIV, such as the Indicative Optimized Portfolio Value, are not disseminated as required. The Commission believes that it is reasonable and consistent with the Act for Phlx to apply consistent trading halt rules to similar derivative securities products.

The Commission believes that the proposed rules are reasonably designed to promote fair disclosure of information that may be necessary to price an ETF appropriately. These generic listing standards provide that the issuer of an ETF must represent that it will calculate the NAV and make it available daily to all market participants at the same time.[36] Phlx proposed to amend Rules 803(i)(11)(d)(ii)–(iii) and

[31] The Commission notes, however, that the failure of a particular ETF to meet these generic listing standards would not preclude the Exchange from submitting a separate proposed rule change to list and trade the ETF.

[32] *See, e.g.*, Securities Exchange Act Release No. 55269 (February 9, 2007), 72 FR 19571 (February 15, 2007) (SR–NASDAQ–2006–50); Securities Exchange Act Release No. 55621 (April 12, 2007), 72 FR 19571 (April 18, 2007) (SR–NYSEArca–2006–86); Securities Exchange Act Release No. 55113 (January 17, 2007), 72 FR 3179 (January 24, 2007) (SR–NYSE–2006–101); Securities Exchange Act Release No. 54739 (November 9, 2006), 71 FR 66993 (November 17, 2007) (SR–Amex–2006–78).

[33] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[34] *See* Phlx Rules 803(i)(11)(e) and (*l*)(6)(E). In the underlying components of an index or portfolio are not trading and the index or portfolio value is therefore static, the last official calculated index or portfolio value must continue to be disseminated during the time that the ETF trades on the Exchange.

[35] *See* Phlx Rule 803(i)(11)(l) and (*l*)(6)(H).

[36] *See* proposed Phlx Rules 803(i)(5)(D) and (*l*)(5)(D).

(*I*)(6)(D)(II)–(III) to make sure that an entity that advises an index provider or calculator and related entities has in place procedures designed to prevent the use and dissemination of material non-public information regarding the index underlying the ETF.

In approving this proposal, the Commission relied on Phlx's representation that its surveillance procedures are adequate to properly monitor the trading of the Trust Shares and IFSs listed pursuant to the proposed new listing standards or traded on a UTP basis. This approval is conditioned on the continuing accuracy of that representation.

Acceleration

The Commission finds good cause for approving the proposed rule change, as amended, prior to the 30th day after the date of publication of the notice of filing thereof in the **Federal Register**. The Commission notes that Phlx's proposal is substantially similar to other proposals that have been approved by the Commission.[37] The Commission does not believe that Phlx's proposal raises any novel regulatory issues and, therefore, that good cause exists for approving the filing before the conclusion of a notice-and-comment period. Accelerated approval of the proposal will expedite the listing and trading of additional ETFs by Phlx, subject to consistent and reasonable standards. Therefore, the Commission finds good cause, consistent with Section 19(b)(2) of the Act,[38] to approve the proposed rule change, as amended, on an accelerated basis.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[39] that the proposed rule change (SR–Phlx–2007–20), as amended, be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[40]

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. E7–13807 Filed 7–16–07; 8:45 am]

BILLING CODE 8010–01–P

[37] *See supra* note 32.

[38] 15 U.S.C. 78s(b)(2).

[39] *Id.*

[40] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #10919 and #10920]

Texas Disaster Number TX–00254

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Texas (FEMA–1709–DR), dated 06/29/2007.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 06/16/2007 and continuing.

Effective Date: 07/06/2007.

Physical Loan Application Deadline Date: 08/28/2007.

EIDL Loan Application Deadline Date: 03/31/2008.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Texas, dated 06/29/2007 is hereby amended to re-establish the incident period for this disaster as beginning 06/16/2007 and continuing.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E7–13768 Filed 7–16–07; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 10919 and # 10920]

Texas Disaster Number TX–00254

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Texas (FEMA–1709–DR), dated 06/29/2007.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 06/16/2007 and continuing.

Effective Date: 07/10/2007.

Physical Loan Application Deadline Date: 08/28/2007.

EIDL Loan Application Deadline Date: 03/31/2008.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the Presidential disaster declaration for the State of Texas, dated 06/29/2007 is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties:

Archer, Bell, Burnet, Eastland, Hood, Parker, Starr, Victoria, Webb, Wichita, Williamson.

Contiguous Counties:

Texas: Bastrop, Baylor, Blanco, Brooks, Brown, Calhoun, Callahan, Clay, Comanche, Dewitt, Dimmit, Duval, Erath, Falls, Goliad, Hidalgo, Jack, Jackson, Jim Hogg, La Salle, Lavaca, Lee, Llano, Maverick, Mcmullen, Milam, Palo Pinto, Refugio, Shackelford, Somervell, Stephens, Throckmorton, Travis, Wilbarger, Young, Zapata.

Oklahoma: Cotton, Tillman.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E7–13799 Filed 7–16–07; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 5868]

Notice of Declaration of Foreign Countries as Reciprocating Countries for the Enforcement of Family Support (Maintenance) Obligations

This notice amends and supplements Department of State Public Notice 4819, 69 FR 59980–81 (October 6, 2004).

Section 459A of the Social Security Act (42 U.S.C. 659A) authorizes the Secretary of State with the concurrence of the Secretary of Health and Human Services to declare foreign countries or their political subdivisions to be reciprocating countries for the purpose of the enforcement of family support

obligations if the country has established or has undertaken to establish procedures for the establishment and enforcement of duties of support for residents of the United States. These procedures must be in substantial conformity with the standards set forth in the statute. The statutory standards are: Establishment of child support orders, including the establishment of paternity if necessary to establish the order; enforcement of child support orders, including collection and distribution of payments under such orders; cost-free services (including administrative and legal services), as well as paternity testing; and the designation of an agency as Central Authority to facilitate enforcement.

Once such a declaration is made, support agencies in jurisdictions of the United States participating in the program established by Title IV–D of the Social Security Act (the IV–D program) must provide enforcement services under that program to such reciprocating countries as if the request for service came from a U.S. State.

The declaration authorized by the statute may be made ''in the form of an international agreement, in connection with an international agreement or corresponding foreign declaration, or on a unilateral basis.'' The Secretary of State has authorized either the Legal Adviser or the Assistant Secretary for Consular Affairs to make such a declaration after consultation with the other.

As of this date, the following countries (or Canadian provinces or territories) have been designated foreign reciprocating countries:

Country	Effective date
Australia	May 21, 2001.
El Salvador	June 21, 2007.
Czech Republic	May 3, 2000.
Hungary	Jan. 22, 2007.
Ireland	Sept. 10, 1997.
Netherlands	May 1, 2002.
Norway	June 10, 2002.
Poland	June 14, 1999.
Portugal	Mar. 17, 2001.
Slovak Republic	Feb. 1, 1998.
Switzerland	Sept. 30, 2004.
Canadian Provinces or Territories:	
Alberta	Sept. 4, 2002.
British Columbia	Dec. 15, 1999.
Manitoba	July 11, 2000.
New Brunswick	Feb. 1, 2004.
Northwest Territories	Feb. 7, 2004.
Nunavut	Jan. 20, 2004.
Newfoundland/Labrador	Aug. 7, 2002.
Nova Scotia	Dec. 18, 1998.
Ontario	Aug. 7, 2002.
Saskatchewan	Jan. 24, 2007.
Yukon	May 22, 2007.

Information

Each of these countries (or Canadian provinces or territories) has designated a Central Authority to facilitate enforcement and ensure compliance with the standards of the statute. Information relating to the designated Central Authorities, and the procedures for processing requests may be obtained by contacting the United States Central Authority for International Child Support, Department of Health and Human Services, Office of Child Support Enforcement (OCSE), 370 L'Enfant Promenade, SW., 4–East, Washington, DC 20447; phone (202) 401–5566, fax (202) 401–5539, e-mail: *ocseinternational@acf.hhs.gov.*

As of this date, reciprocity agreements have been signed, but are not yet in effect, with Costa Rica and Finland.

Questions regarding this notice, the status of negotiations, declarations and agreements may be obtained by contacting Mary Helen Carlson at the Office of the Assistant Legal Adviser for Private International Law, Suite 203 South Building, 2430 E Street, NW., Washington, DC 20037–2851; phone (202) 776–8420, fax (202) 776–8482, e-mail: *carlsonmh@state.gov.*

The law also permits individual states of the United States to establish or continue existing reciprocating arrangements with foreign countries when there has been no Federal declaration. Many states have such arrangements with additional countries not yet the subject of a Federal declaration. Information as to these arrangements may be obtained from the individual State IV–D Agency.

Dated: July 11, 2007.

Mary Helen Carlson,

Attorney-Adviser, Office of the Legal Adviser for Private International Law, Department of State.

[FR Doc. E7–13815 Filed 7–16–07; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Public Notice for Waiver of Aeronautical Land-Use Assurance; North Vernon Municipal Airport; North Vernon, IN

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of intent of waiver with respect to land.

SUMMARY: The Federal Aviation Administration (FAA) is considering a proposal to change a portion of the airport from aeronautical use to non-aeronautical use and to authorize the lease of the airport property. The area is a 224-acre parcel of vacant land located west of the airport. The land is presently subject to a farm lease. The land was acquired via quitclaim deed dated February 13, 1948, recorded February 27, 1948, in Jennings County, Deed Record No. 78, Page No. 634–636. There are no impacts to the airport by allowing the airport to lease the property. The land is not needed for aeronautical use, and will be sub-let to various future developers as an industrial airpark. Approval does not constitute a commitment by the FAA to financially assist in the disposal of the subject airport property nor a determination of eligibility for grant-in-aid funding from the FAA. The disposition of the proceeds from the lease of the airport property will be in accordance with FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in the **Federal Register** on February 16, 1999.

In accordance with Section 47107(h) of Title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

DATES: Comments must be received on or before August 16, 2007.

ADDRESSES: Documents reflecting this FAA action may be reviewed at 2300 East Devon Avenue, Des Plaines, IL, 60018, or at North Vernon Municipal Airport, North Vernon, Indiana.

FOR FURTHER INFORMATION CONTACT: Bobb Beauchamp, Environmental Program Manager, 2300 East Devon Avenue, Des Plaines, IL, 60018. Telephone Number 847–294–7364/FAX Number 847–294–7046.

SUPPLEMENTARY INFORMATION: Following is a legal description of the property: A parcel of land situated in Sections 15 and 22, Township 7 North, Range 8 East, Center Township, Jennings County, Indiana, being more particularly described as follows: Beginning at the point of the intersection of the east right-of-way line of the C.C.C. and St. L. Railroad and east and west centerline of said Section 15 also being the point of beginning of the Quitclaim Deed in the Jennings County Deed Record 78 page 634 to 636; thence North 89 degrees, 26 minutes, 06 seconds East, 2134.3 feet to a point on the centerline of Jennings County Road 20 West to a point on the south line of said Quitclaim Deed; thence westerly on and along said south line of said Quitclaim Deed to the west line of said

Quitclaim Deed; thence north 11 degrees, 27 minutes, 46 seconds east, 5496.27 feet to the point of beginning containing 282 acres more or less.

Except: A part of Section 15 Township 7 North, Range 8 East, Center Township, Jennings County, Indiana, and more particularly described as follows: Commencing at the point of the intersection of the east right-of-way line of the C.C.C. & St. L. Railroad and east and west centerline of said Section 15 also being the point of beginning of the Quitclaim Deed in the Jennings County Deed Record 78 page 634 to 636; thence north 89 degrees, 26 minutes, 06 seconds east, 2134.3 feet to the point of beginning on the centerline of Jennings County Road 20 West; thence southerly on and along the centerline of Jennings County Road 20 West to a point being 700 feet abeam the extended centerline of Runway 15–33 at the North Vernon Municipal Airport; thence northwesterly on and along a line parallel to and 700 feet abeam the extended centerline of Runway 15–33 at the North Vernon Municipal Airport to a point on the east and west centerline of said Section 15; thence on and along said east and west centerline of said Section 15 to the point of beginning containing 13 acres more or less.

Except: A part of Section 22, Township 7 North, Range 8 East, Center Township, Jennings County, Indiana, and more particularly described as follows: Commencing at the point of the intersection of the east right-of-way line of the C.C.C. & St. L. Railroad and east and west centerline of said Section 15 also being the point of beginning of the Quitclaim Deed in the Jennings County Deed Record 78 page 634 to 636, thence north 89 degrees, 26 minutes, 06 seconds East, 2134.3 feet to a point on the centerline of Jennings County Road 20 West; thence southerly on and along the centerline of Jennings County Road 20 West to the point of beginning being 1000 feet abeam of the extended centerline of Runway 5–23 at the North Vernon Municipal Airport; thence continuing southerly on and along the centerline of Jennings County Road 20 West to a point on the south line of said Quitclaim Deed; thence westerly on and along said south line of said Quitclaim Deed to a point also being 1000 feet abeam the extended centerline of Runway 5–23 at the North Vernon Municipal Airport; thence northeasterly on and along a line parallel to and 1000 feet abeam the extended centerline of Runway 5–23 at the North Vernon Municipal Airport to the point of beginning containing 45 acres more or less.

Together containing 224 acres more or less, subject to all liens, encumbrances, easements, limitations, and restrictions of record.

Issued in Des Plaines, Illinois, on May 1, 2007.

James G. Keefer

Manager, Chicago Airports District Office, FAA, Great Lakes Region.

[FR Doc. 07–3462 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement, Canyon and Ada Counties, ID I–84, Karcher Interchange to Five Mile Road Environmental Study

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Letter of Project Initiation; Notice of Intent to prepare an Environmental Impact Statement (EIS); and initiation of public and agency scoping for the addition of traffic lanes, interchange configuration improvements, structure widening, structure replacements and pavement reconstruction to Interstate 84 (I–84) from the Karcher Interchange in Canyon County to the Five Mile Road overpass in Ada County, Idaho.

SUMMARY: The FHWA hereby gives notice that it intends to prepare an EIS for the proposed addition of lanes and other reconstruction improvements to approximately 16 miles of I–84 between the Karcher Interchange in Canyon County and Five Mile Road in Ada County, Idaho. The environmental study will evaluate the potential impacts of design alternatives for future construction of the additional lanes and several associated staged improvement projects of this highway segment. This EIS is being prepared and considered in accordance with the National Environmental Policy Act (NEPA) of 1969, regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and FWHA regulations, guidance and policy.

Anticipated Federal approvals/actions needed for this project to be constructed include permits for Sections 401 and 404 of the Clean Water Act (U.S. Army Corps of Engineers) and compliance with Section 106 of the National Historic Preservation Act.

Cooperating Agencies: There are no cooperating agencies identified for this project.

DATES: Public comments and questions are welcome anytime during the NEPA process and should be directed to the addresses listed below. Additional formal opportunities for public participation after the Public Scoping are tentatively scheduled as follows:

Review and comment of Draft EIS (including a public hearing): Early 2009.

Review of Final EIS: Summer of 2009.

Notices of availability for the Draft EIS, Final EIS and Record of Decision will be provided through direct mail, the **Federal Register** and other media. Notification also will be sent to Federal, State, local agencies, persons, and organizations that submit comments or questions. Precise schedules and locations for public meetings will be announced in the local news media. Interested individuals and organizations may request to be included on the mailing list for the distribution of meeting announcements and associated information.

FOR FURTHER INFORMATION CONTACT: Edwin Johnson, Field Operations Engineer; Federal Highway Administration, 3050 Lake Harbor Lane, Suite 126, Boise, Idaho 83703, Telephone: (208) 334–9180; or Gwen Smith, GARVEE Public Involvement Coordinator, Idaho Transportation Department, P.O. Box 7129, Boise, Idaho 83707–1129, Telephone: (208) 334–4444.

SUPPLEMENTARY INFORMATION:

Electronic access

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the Office of the Federal Register's home page at *http://nara.gov/fedreg* and the Government Printing Office's database at: *http://access.gpo.gov.nara.*

Background

The FHWA in cooperation with the Idaho Transportation Department (ITD) will prepare an EIS for the proposed addition of lanes and other staged associated reconstruction improvement projects to approximately 16 miles of I–84 between the Karcher Interchange in Canyon County (Mile Post 33) and Five Mile Road (Mile Post 49) in Ada County, Idaho. These associated projects could include reconstructing existing lanes, reconstructing interchanges at Meridian Road and Garrity Boulevard; replacing seven overpass structures at Five Mile Road, Cloverdale Road, Ten Mile Road, 11th Avenue, Franklin Boulevard, Northwest Boulevard and Karcher Boulevard; ramp modifications at the

Eagle Road Interchange, Franklin Boulevard, Meridian Road Interchange, and Karcher Interchange; two railroad structures; and six irrigation/canal structures. Three of these associated projects are currently identified in the Idaho State Transportation Improvement Program (STIP) for District 3, as projects funded through Connecting Idaho GARVEE. These projects are:

- The reconstruction and widening of the existing Garrity overpass to accommodate additional lanes on I–84.
- The reconstruction and widening of I–84 mainline from Franklin Boulevard to the Garrity Road Interchange.
- The reconstruction and widening of the Garrity Interchange to Meridian Interchange.

Another associated project that is anticipated to be added to the 2008 STIP is:

- The reconstruction of the east half of the Franklin Boulevard Interchange.

Additional associated projects have been identified through previous studies, the Community Planning Association of Southwest Idaho (COMPASS) MPO plan and other long range planning documents. These projects have been presented to the public through public meetings, workshops, and publicly distributed documents. These projects are not in the current STIP or may not be programmed for funding at this time, but have been identified as a needed improvement through these studies. These projects are:

- The rehabilitation of the bridge on the eastbound lane of the Karcher Boulevard Interchange.
- The rehabilitation of the I–84, UPRR overpass, westbound lanes.
- Widening I–84 mainline from Eagle Road to the Five Mile Overcrossing at Mile Post 49.
- Widening I–84 mainline from Ten Mile Road to Eagle Road.
- Widening I–84 mainline from Garrity Boulevard to Ten Mile Road.
- The Meridian Road Interchange improvement project.
- Reconstruction of the Garrity Boulevard Interchange.

Notice is hereby given that the public scoping process has been initiated to prepare an EIS that will address the impacts of and alternatives to the proposal. The purpose of the scoping process is to solicit public comment regarding the full spectrum of issues and concerns, including a suitable range of alternatives, and the nature and extent of potential environmental impacts and appropriate mitigation measures that should be addressed in the EIS process. The EIS will examine the short and long-term impacts of a reasonable range of alternatives, including the no action alternative, on the natural, physical, and human environments. The impacts assessment will include, but not be limited to, impacts on wetlands, wildlife; social environment; changes in land use; noise, aesthetics; changes in traffic; and economic impacts. Environmental Justice (as outlined in Executive Order 12898) will also be addressed as part of the impact assessment. The EIS will also examine measures to mitigate adverse impacts resulting from the proposed action.

Comments are being solicited from Federal, State, and local agencies and from private organizations and citizens who have interest in this proposal. Public information meetings, including scoping meetings, will be held in the project area to discuss the potential alignments and alternatives. The draft EIS will be available for public and agency review, and a public hearing will be held to receive comments. Public notice will be given of the time and place of all meetings and hearings.

Comments and/or suggestions from all interested parties are requested, to ensure that the purpose and need for the project, the full range of all issues, and significant environmental issues in particular, are identified and reviewed. Comments or questions concerning this proposed action and/or its EIS should be directed to the FHWA, or ITD at the addresses listed previously.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this proposed action)

Authority: 23 U.S.C. 315; 23 CFR 771.123; 49 CFR 1.48.

Peter Hartman,

Idaho Division Administrator, FHWA.

[FR Doc. 07–3464 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) has received a request for a waiver of compliance from certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Union Pacific Railroad Company

[Waiver Petition Docket Number FRA–2007–28454]

The Union Pacific Railroad Company (UP) seeks a waiver of compliance from certain provisions of 49 CFR Part 232, *Brake System Safety Standards for Freight and Other Non-Passenger Trains and Equipment.* Specifically, UP is seeking relief from the requirements for performing the single car air brake test as prescribed in § 232.305(b)(2), which states in part: ''A car is on a shop or repair track, as defined in § 232.303(a), for any reason and has not received a single car air brake test within the previous 12-month period.''

UP states that they are performing repairs and wheel change-outs to cars in-train on selected trains in their yards across their system, in order to reduce the number of impact wheels and satisfy the demands of their customers to move commodities. UP claims that the in-train repairs also greatly reduce the number of switching events that would otherwise be required to effect the repairs, further reducing the risk of injury and derailment. UP believes that reducing the number of impact wheels has helped reduce the number of derailments due to broken rails, joint bars, wheels and bearings. The majority of these trains are in coal service and the cars are privately owned. UP contends that these cars receive regular periodic maintenance, so they seldom approach the 5-year limit in which a single car air brake test would normally be required. In addition, UP states that their system automatically flags cars in the yard when they are listed on the Association of American Railroad's MA–63, which is a list that identifies cars within 90 days of the 5-year limit. UP states that they will continue to perform a single car air brake test in compliance with § 232.305 (b)(4–5), (c), (d), and (e). UP believes that this request will not have an adverse effect on safety.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA in writing before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (*e.g.*, Waiver

Petition Docket Number FRA–2007–28454) and must be submitted to the Docket Clerk, DOT Docket Management Facility, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590. Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://dms.dot.gov*.

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or you may visit *http://dms.dot.gov*.

Issued in Washington, DC on July 11, 2007.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E7–13741 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2007–28424]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System or Relief From the Requirements of Title 49 Code of Federal Regulations Part 236

Pursuant to Title 49 Code of Federal Regulations (CFR) Part 235 and 49 U.S.C. 20502(a), the following railroad has petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of the signal system or relief from the requirements of 49 CFR Part 236, as detailed below.

Applicant: Union Pacific Railroad, Mr. Thomas T. Ogee, AVP Engineering Design, 1400 Douglas Street, Stop 0910, Omaha, Nebraska 68179.

The Union Pacific Railroad Company (UP) seeks approval of the proposed discontinuance and removal of the automatic block signal system (ABS) on the UP Albert Lea Subdivision between Milepost 193.1 and Milepost 194.2 in or near Mason City, Iowa. Train movements on the affected portion of track will be governed by Rule 6.13 of the General Code of Operating Rules, *Yard Limits.*

The reason given for the proposed changes is that the ABS system is no longer needed for safe train operation.

Any interested party desiring to protest the granting of an application shall set forth specifically the grounds upon which the protest is made, and include a concise statement of the interest of the party in the proceeding. Additionally, one copy of the protest shall be furnished to the applicant at the address listed above.

FRA expects to be able to determine these matters without an oral hearing. However, if a specific request for an oral hearing is accompanied by a showing that the party is unable to adequately present his or her position by written statements, an application may be set for public hearing.

All communications concerning this proceeding should be identified by Docket Number FRA–2007–28424 and may be submitted by one of the following methods:

Web site: http://dms.dot.gov. Follow the instructions for submitting comments on the DOT electronic site;

Fax: 202–493–2251;

Mail: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590; or

Hand Delivery: Room W12–140 of the U.S. Department of Transportation West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://dms.dot.gov.*

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Issued in Washington, DC on July 11, 2007.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E7–13737 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Early Scoping Notice

AGENCY: Federal Transit Administration, U.S. Department of Transportation, and the Detroit Department of Transportation.

ACTION: Early Scoping Notice for the Detroit Transit Options for Growth Study.

SUMMARY: The Federal Transit Administration (FTA) and the Detroit Department of Transportation (DDOT) are issuing this early scoping notice to advise agencies and the public that they intend to explore, in the context of the Council on Environmental Quality's early scoping process, alternative means of implementing rapid transit improvements in the Detroit area in Wayne County, Michigan. Three alignments, described below, will be examined, largely to explore their potential for implementation of a major transit capital investment (New Start). Public scoping meetings have been planned and are announced below. This process may result in selection of a locally preferred alternative (proposed action). If preparation of an environmental impact statement is warranted, this early scoping process is intended to satisfy standard National Environmental Policy Act scoping requirements, except that comments on the purpose and need for the proposed action, the range of alternatives to be considered, and potentially significant impacts, as described in a forthcoming notice of intent, will be invited and considered.

DATES: One interagency scoping meeting and four public scoping meetings will be conducted on the following dates and times at the locations indicated:

Interagency Scoping Meeting

Friday, July 27, 2007, 1 p.m. to 3 p.m., Detroit Department of Transportation, 1301 East Warren, Detroit, Michigan 48207.

Public Scoping Meetings

Wednesday, July 25, 2007, 11 a.m. to 2 p.m., The Guardian Building, Mezzanine Lobby, 500 Griswold, Detroit, Michigan 48226.

Wednesday, July 25, 2007, 5 p.m. to 8 p.m., Wayne State University, Welcome Center, 42 West Warren Avenue, Detroit, Michigan 48202.

Thursday, July 26, 2007, 5 p.m. to 8 p.m., Wayne County Community College, Cooper Community Center, 5901 Conner, Detroit, MI 48213.

Saturday, July 28, 2007, 10 a.m. to 1 p.m., Ford Community and Performing Arts Center, Studio A, 15801 Michigan Avenue, Dearborn, MI 48126.

The public scoping meetings will begin with an hour-long open house allowing the public to discuss the scoping process and study options with project staff. Handouts describing alignments, study options, and other aspects of contemplated rapid transit improvements will be available at the meetings. The meetings will be facilitated and a court reporter will be present to record oral comments which are welcomed. The scoping information will also be available on the project Web site at *http://www.dtogs.com.* American Sign Language, Arabic, and Spanish interpreters will be present at the public scoping meetings. The buildings are accessible to persons with disabilities.

ADDRESSES: Written comments on this notice should be submitted by August 29, 2007 to: Mr. Tim Roseboom, Project Manager, Detroit Department of Transportation, 1301 East Warren, Detroit, Michigan 48207, Telephone: (313) 833–7973, Fax: (313) 833–5493, E-mail: *TimRos@detroitmi.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Bill Wheeler, Community Planner, Federal Transit Administration (FTA), Region V, 200 West Adams Street, Suite 320, Chicago, Illinois 60606–5232, Telephone: (312) 353–2789.

SUPPLEMENTARY INFORMATION: Early scoping is a National Environmental Policy Act (NEPA) process that is particularly useful in situations where, as here, a proposed action (the locally preferred alternative) has not been identified and multiple broad alternatives are under consideration in several corridors. While scoping normally follows issuance of a notice of intent, which must describe the proposed action, it ''may be initiated earlier, as long as there is appropriate public notice and enough information available on the proposal so that the public and relevant agencies can participate effectively.'' Council on Environmental Quality, ''Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations,'' 46 FR 18026, 18030 (1981) (Answer to Question 13). Available information is more than adequate to permit the public and relevant agencies to participate effectively in early scoping.

The Detroit Transit Options for Growth Study and Subsequent Developments

The Detroit Transit Options for Growth (DTOG) Study identifies 14 corridors in the study area that includes the cities of Dearborn, Detroit, Hamtramck, and Highland Park and encompasses approximately 160 square miles. The study-area population is over 1 million and estimated employment stands at nearly 500,000 jobs. Transit service in the study area is provided by buses, which have strong ridership and serve many people who depend on transit for their trips. The Detroit People Mover, a 2.9 mile elevated rail circulator in downtown Detroit, also provides transit service, but no rapid transit service is available within the study area. The DTOG Study represents a major step to promote regional and local rapid transit improvements in Southeast Michigan for the purposes of addressing existing, as well as projected congestion, and improving air quality, or at least not degrading it any further.

In the summer of 2006, DDOT initiated State and local planning required for anticipated New Starts transit projects to be eligible for Federal funding assistance under 49 U.S.C. 5309. The objective of beginning early planning efforts was to advance the realization of regional and local rapid transit improvements to serve current and future population and employment centers and destinations by narrowing options developed in the DTOG Study. Following a multi-phase screening process that included public participation, it was determined that three priority corridors (of the 14 identified in the DTOG Study) would be advanced for further study. The three alignments include: (1) The Woodward Avenue Corridor from downtown Detroit to Eight Mile Road; (2) a combined Woodward and Michigan Avenues Corridor from downtown Detroit to Grand Boulevard near the New Center area and on Michigan Avenue from downtown Detroit to the City of Dearborn near Fairlane Mall and University of Michigan Dearborn; and (3) a combined Woodward and Gratiot Avenues Corridor from downtown Detroit to Grand Boulevard near the New Center area and the Gratiot Avenue Corridor from downtown Detroit to Eight Mile Road. It was further determined that potential rapid transit modes that would meet the objectives of the DTOG Study included Bus Rapid Transit (BRT), Light Rail Transit (LRT), and modern streetcar. A public participation program has been developed and initiated with a Web site, newsletter, and public meetings and stakeholder meetings. A technical committee has been established and meets monthly.

State and Local Planning and Early Scoping

Public planning for an anticipated New Starts transit project in the Detroit area continues. The public planning process resembles in some respects alternatives analysis required by the NEPA process, except that the former evaluates alternatives broadly by examining several modal and alignment options for addressing defined mobility needs in a particular corridor. Essentially, State and local planning produces a clearly defined project problem statement for use in New Starts in alternative analysis whereas consideration of project alternatives under NEPA calls for a concise statement of purpose and need. Nevertheless, to the extent that State and local planning efforts can lead toward a well-defined purpose and need statement and satisfy requirements of the NEPA process, including scoping, it should not have to be duplicated subsequently in that process. See 40 CFR 1506.2(b) (''Agencies shall cooperate with State and local agencies to the fullest extent possible to reduce duplication between NEPA and State and local requirements.''). Early scoping provides a means through which duplication, waste, and delay that could otherwise be experienced in situations such as this may be avoided.

Future New Starts planning alternatives analysis will examine alignments, technologies, station locations, costs, funding, ridership, economic development, land use, engineering feasibility, and environmental factors in a selected corridor. During alternatives analysis, DDOT will also evaluate options for transportation improvements in the study area that do not involve significant capital investment (e.g., enhanced bus service). At the conclusion of this early scoping and alternatives analysis process, a locally preferred alternative—the ''proposed action''—will be determined, as well as the appropriate NEPA process—environmental assessment or environmental impact statement—to be undertaken for the proposed action. If preparation of an environmental impact statement is warranted, a notice of

intent will be published in the **Federal Register** and comments on the purpose and need for the proposed action, the range of alternatives to be considered, and potentially significant environmental impacts will be invited and considered.

In conjunction with issuance of this notice, and consistent with provisions of 23 U.S.C. 139, invitations will be extended to other Federal and non-Federal agencies that may have an interest in this matter to be participating agencies. A plan for coordinating public and agency participation in and comment on the environmental review process for issues and alternatives under consideration here and at subsequent phases of the process will be prepared.

Issued this 10th day of July, 2007.

Marisol R. Simon,

Regional Administrator, Region 5.

[FR Doc. E7–13766 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD 2007 28708]

Information Collection Available for Public Comments and Recommendations

ACTION: Notice of intention to request extension of OMB approval and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Maritime Administration's (MARAD's) intention to request extension of approval (with modifications) for three years of a currently approved information collection.

DATES: Comments should be submitted on or before September 17, 2007.

FOR FURTHER INFORMATION CONTACT: Mitch Hudson, Maritime Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone: 202–366–9373; or E-Mail: *mitch.hudson@dot.gov.* Copies of this collection also can be obtained from that office.

SUPPLEMENTARY INFORMATION:

Title of Collection: Requirements for Establishing U.S. Citizenship—46 CFR Parts 355 and 356.

Type of Request: Extension with modifications of currently approved information collection.

OMB Control Number: 2133–0012.

Form Numbers: None.

Expiration Date of Approval: Three years from date of approval by the Office of Management and Budget.

Summary of Collection of Information: Maritime Administration implementing regulations at 46 CFR parts 355 and 356 set forth requirements for establishing U.S. citizenship in accordance with MARAD statutory authority. Those receiving benefits under 46 U.S.C. Chapters 531, 535, and 537 (formerly the Merchant Marine Act, 1936, as amended), or applicants seeking a fishery endorsement eligibility approval pursuant to the American Fisheries Act must be citizens of the United States within the meaning of 46 U.S.C. 50501, (formerly Section 2 of the Shipping Act, 1916, as amended). In either case, whether seeking program benefits or fishery endorsement eligibility, Section 50501 sets forth the statutory requirements for determining whether an applicant, be it a corporation, partnership, or association is a U.S. citizen. 46 CFR part 356 is distinguished from 46 CFR part 355 in that part 356 establishes requirements for U.S. citizenship exclusively in accordance with the AFA while part 355 is applied for purposes of establishing citizenship across multiple MARAD programs arising under other statutory authority. Most program participants are required to submit to MARAD on an annual basis the form of affidavit prescribed by part 355 or part 356.

Need and Use of the Information: MARAD will review the Affidavits of U.S. Citizenship to determine if the applicants are eligible to participate in the programs offered by the agency or to receive a MARAD fishery endorsement eligibility approval.

Description of Respondents: The Affidavits of U.S. Citizenship are filed with MARAD by shipowners, trustees, ship mortgagees, charterers, equity owners, ship managers, etc.

Annual Responses: 500 responses.

Annual Burden: 2,500 hours.

Comments: Comments should refer to the docket number that appears at the top of this document. Written comments may be submitted to the Docket Clerk, U.S. DOT Dockets, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. Comments also may be submitted by electronic means via the Internet at *http://dms.dot.gov/submit.* Specifically address whether this information collection is necessary for proper performance of the functions of the agency and will have practical utility, accuracy of the burden estimates, ways to minimize this burden, and ways to enhance the quality, utility, and clarity of the information to be collected. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m. EDT (or EST), Monday through Friday, except Federal Holidays. An electronic version of this document is available on the World Wide Web at *http://dms.dot.gov.*

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Authority: 49 CFR 1.66.

Dated: July 10, 2007.

By Order of the Maritime Administrator,

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–13769 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2007–28702]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel MANAWALE'A.

SUMMARY: As authorized by Public Law 105–383 and Public Law 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2007–28702 at *http://dms.dot.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Public Law 105–383 and MARAD's regulations at 46 CFR Part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a

waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

DATES: Submit comments on or before August 16, 2007.

ADDRESSES: Comments should refer to docket number MARAD–2007–28702. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://dmses.dot.gov/submit/.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MANAWALE'A is:

Intended Use: ''Recreational diving, sightseeing, snorkeling, whalewatching, exploring, and expedition charters and member LLC.''

Geographic Region: ''Hawaiian Waters.''

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Dated: July 6, 2007.

By order of the Maritime Administrator.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–13771 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2007–28703]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel REDWINGS.

SUMMARY: As authorized by Public Law 105–383 and Public Law 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2007–28703 at *http://dms.dot.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Public Law 105–383 and MARAD's regulations at 46 CFR Part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

DATES: Submit comments on or before August 16, 2007.

ADDRESSES: Comments should refer to docket number MARAD–2007–28703. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://dmses.dot.gov/submit/.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel REDWINGS is:

Intended Use: ''Captained sailing cruises.''

Geographic Region: ''ME, NH, MA, RI, CT, NY, NJ, DE, MD, VA, NC, SC, GA, FL, AL, MS, LA, TX, CA, OR, WA, AK (excluding SE Alaska), HI, MI, WI, OH, MN''

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Dated: July 6, 2007.

By order of the Maritime Administrator.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–13773 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket Number: PHMSA–04–18938]

Request for Public Comments and Office of Management and Budget Approval of a Change to an Existing Information Collection (2137–0604, 2137–0605, and 2137–0610)

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), U.S. Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that PHMSA forwarded an Information Collection Request to the Office of Management and Budget (OMB) for a change to an existing information collection for pipeline integrity management (IM). The purpose of this notice is to allow the public an additional 30 days to submit comments.

DATES: Submit comments on or before August 16, 2007.

ADDRESSES: Send comments directly to the Office Management and Budget, Office of Regulatory Affairs, Attn: Desk Officer for the Department of Transportation, 726 Jackson Place, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Mike Israni by phone at (202) 366–4571 or by e-mail at: *mike.israni@dot.gov.*

SUPPLEMENTARY INFORMATION: PHMSA's IM regulations require operators of hazardous liquid and gas transmission pipelines to assess, evaluate, repair, and validate through comprehensive analyses the integrity of pipeline segments in high consequence areas where a leak or failure would do the most damage to populated, unusually sensitive environmental areas, and other populated areas. These regulations also require operators who cannot meet their evaluation schedules to notify PHMSA when temporarily reducing operating pressure or shutting down their pipelines. This change adds a requirement for operators to also notify PHMSA if pressure reductions exceed 365 days.

PHMSA published a notice of proposed rulemaking (NPRM) on December 15, 2005 (70 FR 74265) requesting comments on a change to these existing information collections.

PHMSA received comments from 12 parties: American Petroleum Institute and Association of Oil Pipe Lines; the American Gas Association; Texas Pipeline Association; Kinder Morgan Energy Partners, L.P.; Southwest Gas Corporation; Paiute Pipeline Company; Orange and Rockland Utilities, Inc.; Duke Energy Gas Transmission Corporation; Magellan Midstream Partners, L.P.; Panhandle Energy; Puget Sound Energy; and Enbridge Energy Company, Inc.—Liquids Transportation Segment.

Pursuant to 44 U.S.C. 3506(c)(2)(A) of the PRA, PHMSA will include the comments in the request for OMB's clearance of this information collection. PHMSA is now forwarding the collection of information request to OMB and providing an additional 30 days for comments. PHMSA is inviting comments on whether the proposed information collection is necessary for the proper performance of the functions of DOT. The term ''information collection'' includes all work related to preparing and disseminating information in accordance with recordkeeping requirements. The comments should address (1) whether the information will have practical utility; (2) the accuracy of the Department's estimate of the burden of the proposed information collection; (3) ways to enhance the quality, utility, and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, including the use of automated collection techniques or other forms of information technology.

OMB control No.	Regulation title	Number of operators	Number of responses (percent)	Total annual burden hours
2137–0604	Pipeline Integrity Management in High Consequence Areas Operators with more than 500 miles of Hazardous Liquid Pipeline.	71	0.85	3
2137–0605	Pipeline Integrity Management in High Consequence Areas Operators with less than 500 miles of Hazardous Liquid Pipeline.	192	0.85	9
2137–0610	Pipeline Integrity Management in High Consequence Areas Gas Transmission Pipeline Operators.	721	0.85	34
Totals	.....	1,166	N/A	46

Issued in Washington, DC, on July 6, 2007.

Florence L. Hamn,

Director of Regulations, Office of Pipeline Safety.

[FR Doc. E7–13764 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket: PHMSA–98–4957]

Request for Public Comments and Office of Management and Budget Approval of Existing Information Collection Requirement

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), U.S. Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that PHMSA forwarded an Information Collection Request to the Office of Management and Budget (OMB) for an extension of the currently approved collection of information ''Incorporation by Reference of Industry Standard on Leak Detection'' (2137–0598). The purpose of this notice is to invite the public to submit comments on the request to OMB.

DATES: Submit comments on or before August 16, 2007.

ADDRESSES: Send comments directly to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attn: Desk Office for the Department of Transportation, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: L.E. Herrick at (202) 366–5523, or by e-mail at: *le.herrick@dot.gov.*

SUPPLEMENTARY INFORMATION: The hazardous liquid pipeline safety regulations require operators that elect to use software-based Computer Monitoring System (CPM) leak detection systems to comply with the American Petroleum Institute's (API) 1130 standard (49 CFR 195.134). API 1130 provides guidance for operating, maintaining, and testing software-based CPM systems. Hazardous liquid operators, with software-based CPM systems, must maintain records documenting the operation, maintenance, and testing of those systems. PHMSA, through the incorporation of this industry standard, will be able to continue to ensure that appropriate technology is used to

maximize safety in the pipeline industry.

Pursuant to 44 U.S.C. 3506(c)(2)(A) of the PRA, PHMSA is required to obtain OMB approval for all information collections. The term ''information collection'' includes all work related to the preparing and disseminating of information in accordance with the recordkeeping requirements. PHMSA published a notice providing a 60 day period for comments on these information collection renewals in the **Federal Register** on May 29, 2007 (72 FR 29578), and received no comments. PHMSA is now forwarding the information collection request to OMB and providing an additional 30 days for comments. PHMSA invites comments on whether the proposed information collection is necessary for the proper performance of the functions of DOT. The comments should address (1) whether the information will have practical utility; (2) the accuracy of DOT's estimate about the information collection burden; (3) ways to enhance the quality, utility, and clarity of the information collection; and (4) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. PHMSA estimates the burden of these requirements as follows:

Type of Information Collection Request: Renewal of existing collection.

Title of Information Collection: Incorporation by Reference of Industry Standard on Leak Detection.

Respondents: 50.

Estimated Total Annual Burden Hours on Respondents: 100.

Estimated Cost: $6,475.

Issued in Washington, DC, on July 9, 2007.

Florence L. Hamn,

Director of Regulations, Office of Pipeline Safety.

[FR Doc. E7–13767 Filed 7–16–07; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–6 (Sub–No. 454X)]

BNSF Railway Company—Abandonment Exemption—in Multnomah County, OR

BNSF Railway Company (BNSF) has filed a notice of exemption under 49 CFR Part 1152 Subpart F—*Exempt Abandonments* to abandon a 0.48-mile line of railroad between milepost 1.88 and milepost 2.36, near Portland, in Multnomah County, OR (the line). The line traverses United States Postal Service Zip Code 97210.

BNSF has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) overhead traffic handled on the line will be rerouted; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements of 49 CFR 1105.7 (environmental report), 49 CFR 1105.8 (historic report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on August 11, 2007, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by July 23, 2007. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by August 1, 2007, with: Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to BNSF's representative: Sidney L. Strickland, Jr., Sidney Strickland and Associates, PLLC, 3050 K Street, NW., Suite 101, Washington, DC 20007.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

BNSF has filed environmental and historic reports which address the effects, if any, of the abandonment on the environment and historic resources. SEA will issue an environmental assessment (EA) by July 17, 2007. Interested persons may obtain a copy of the EA by writing to SEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling SEA, at (202) 245–0305. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.] Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), BNSF shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by BNSF's filing of a notice of consummation by July 12, 2008, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: July 3, 2007.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E7–13758 Filed 7–16–07; 8:45 am]

BILLING CODE 4915–01–P

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which currently is set at $1,300. *See* 49 CFR 1002.2(f)(25).

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

July 10, 2007.

The Department of the Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the

Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before August 16, 2007 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–0137.

Type of Review: Revision.

Title: Contract Coverage Under Title II of the Social Security Act.

Form: 2032.

Description: U.S. citizens and resident aliens employed abroad by foreign affiliates of American employers are exempt from social security taxes. Under Internal Revenue Code section 3121(1), American employers may file an agreement on Form 2032 to waive this exemption and obtain social security coverage for U.S. citizens and resident aliens employed abroad by their foreign affiliates. The American employers can later file Form 2032 to cover additional foreign affiliates as an amendment to their original agreement.

Respondents: Individuals or households.

Estimated Total Burden Hours: 973 hours.

OMB Number: 1545–0122.

Type of Review: Extension.

Title: Foreign Tax Credit Corporations.

Form: 1118, Schedules I & J.

Description: Form 1118 and separate Schedules I and J are used by domestic and foreign corporations to claim a credit for taxes paid to foreign countries. The IRS uses Form 1118 and related schedules to determine if the corporation has computed the foreign tax credit correctly.

Respondents: Businesses or other for-profit institutions.

Estimated Total Burden Hours: 4,031,736 hours.

OMB Number: 1545–0575.

Type of Review: Revision.

Title: Return of Excise Taxes Related to Employee Benefit Plans.

Form: 5330.

Description: U.S. Code sections 4971, 4972, 4973(a)(3), 4975, 4976, 4977, 4978, 4978A, 4978B, 4979, 4979A and 4980 impose various excise taxes in connection with employee benefit plans. Form 5330 is used to compute and collect these taxes.

Respondents: Businesses or other for-profit institutions.

Estimated Total Burden Hours: 478,215 hours.

OMB Number: 1545–1596.

Type of Review: Extension.

Title: Request for Innocent Spouse Relief.

Form: 8857.

Description: Section 6103(e) of the Internal Revenue Code allows taxpayers to request, and IRS to grant, ''innocent spouse'' relief when: taxpayer filed a joint return with tax substantially understated; taxpayer establishes no knowledge of or benefit from, the understatement; and it would be inequitable to hold the taxpayer liable. GAO Report GAO/GGD–97–34 recommended that IRS develop a form to make relief easier for the public to request.

Respondents: Businesses and other for-profit institutions.

Estimated Total Burden Hours: 2,070 hours.

OMB Number: 1545–0800.

Type of Review: Revision.

Title: Reg. 601.601 Rules and Regulations.

Description: Persons wishing to speak at a public hearing on a proposed rule must submit written comments and an outline within prescribed time limits, for use in preparing agendas and allocating time. Persons interested in the issuance, amendment, of repeal of a rule may submit a petition for this. IRS considers the petitions in its deliberations.

Respondents: Individuals or households.

Estimated Total Burden Hours: 240,500 hours.

OMB Number: 1545–1881.

Type of Review: Extension.

Title: Election To Treat a Qualified Revocable Trust as Party of an Estate.

Form: 8855.

Description: Form 8855 is used to make a section 645 election that allows a qualified revocable trust to be treated and taxed (for income tax purposes) as part of its related estate during the election period.

Respondents: Businesses and other for-profit institutions.

Estimated Total Burden Hours: 28,200 hours.

OMB Number: 1545–1155.

Type of Review: Extension.

Title: PS–74–89 (TD 8282) Final Election of Reduced Research Credit Estate Tax (TD 8686).

Description: These regulations prescribe the procedure for making the election described in section 280C(c)(3) of the Internal Revenue Code. Taxpayers making this election must reduce their section 41(a) research credit, but are not required to reduce their deductions for qualified research expenses, as required in paragraphs (1) and (2) of section 280C(c).

Respondents: Businesses and other for-profit institutions.

Estimated Total Burden Hours: 50 hours.

OMB Number: 1545–0806.

Type of Review: Extension.

Title: EE–12–78 (Final) Non-Bank Trustees.

Description: Section 408(a)(2) permits an institution other than a bank to be the trustee of an individual retirement account. Section 1.408–2(e)(1) of the Income Tax Regulations provides that such an institution must file a written application with the IRS demonstrating its ability to act as trustee. Section 1.408–2(e)(2) requires an applicant to demonstrate in detail in his written application the ability to act within the accepted rules of fiduciary conduct. Certain reporting and recordkeeping requirements must be demonstrated by an applicant in his written application and are imposed in connection with the ongoing activities of a non-bank trustee.

Respondents: Businesses or other for-profit institutions.

Estimated Total Burden Hours: 13 hours.

Clearance Officer: Glenn P. Kirkland, (202) 622–3428, Internal Revenue Service, Room 6516, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt, (202) 395–7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Robert Dahl,

Treasury PRA Clearance Officer.

[FR Doc. E7–13743 Filed 7–16–07; 8:45 am]

BILLING CODE 4830–01–P

Corrections

Federal Register
Vol. 72, No. 136
Tuesday, July 17, 2007

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8331–6]

Protection of Stratospheric Ozone: Notice of Data Availability—Changes in HCFC Consumption and Emissions from the U.S. Proposed Adjustments for Accelerating the HCFC Phaseout

Correction

In notice document E7–12446 beginning on page 35230 in the issue of Wednesday, June 27, 2007, make the following correction:

On page 35232, the table appearing under the heading ''**4. How is this action related to the U.S. phaseout of ozone-depleting substances?**'' should read as follows:

HCFC PHASEOUT SCHEDULE

Comparison of the current Montreal Protocol schedule for Non-Article 5 Parties and United States phaseout schedules

Montreal Protocol		United States	
Year to be implemented	Percent reduction in consumption, using the cap as a baseline	Year to be implemented	Implementation of HCFC phaseout through Clean Air Act regulations
2004	35.0	2003	No production and no importing of HCFC–141b.
2010	65.0	2010	No production and no importing of HCFC–142b and HCFC–22, except for use in equipment manufactured before 1/1/2010.
2015	90.0	2015	No production and no importing of any HCFCs, except for use as refrigerants in equipment manufactured before 1/1/2020.
2020	99.5	2020	No production and no importing of HCFC–142b and HCFC–22.
2030	100.0	2030	No production and no importing of any HCFCs.

[FR Doc. Z7–12446 Filed 7–16–07; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF JUSTICE

Amended Notice of Lodging of Settlement Agreement Under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (''CERCLA'')

Correction

In notice document 07–3270 beginning on page 37054 in the issue of Friday, July 6, 2007, make the following correction:

On page 37054, in the third column, in the first paragraph of the document, in the third line ''2001'' should read ''2007''.

[FR Doc. C7–3270 Filed 7–16–07; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9329]

RIN 1545–BF26

Guidance Necessary to Facilitate Business Electronic Filing and Burden Reduction

Correction

In rule document E7–11148 beginning on page 32794 in the issue of Thursday, June 14, 2007, make the following correction:

PART 1—[CORRECTED]

On page 32807, in the third column, in the four lines above amendatory instruction **Par. 46.**, the section heading is corrected to read as follows:

§§ 1.302–4, 1.338(h)(10)–1, 1.382–2T, 1.382–6, 1.382–8, 1.1502–13, 1.1502–32, 1.1502–92, 1.1502–94, 1.1502–95, 1.1563–3, and 1.6043–2

[FR Doc. Z7–11148 Filed 7–16–07; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG–143797–06]

RIN 1545-BF97

Employer Comparable Contributions to Health Savings Accounts Under Section 4980G

Correction

In proposed rule document E7–10529 beginning on page 30501 in the issue of Friday, June 1, 2007, make the following corrections:

PART 54—[CORRECTED]

1. On page 30503, in the second column, in amendatory instruction **Par. 2.**, in the first line, ''§ 54.4980g–0'' should read ''§ 54.4980G–0''.

2. On the same page, in the same column, in the same paragraph, in the third line, ''§ 54.4980g–4'' should read ''§ 54.4980G–4''.

§ 54.4980G–0 [Corrected]

3. On the same page, in the third column, in § 54.4980G–0, in the first line, ''§ 54.4980g–0'' should read ''§ 54.4980G–0''.

4. On the same page, in the same column, in the same section, in the third line, ''§ 54.4980g–4'' should read ''§ 54.4980G–4''.

5. On the same page, in the same column, in § 54.4880G–4, in amendatory instruction **Par. 3.**, in the first line, ''§ 54.4980g–4'' should read ''§ 54.4980G–4''.

[FR Doc. Z7–10529 Filed 7–16–07; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Tuesday,
July 17, 2007

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 447

Medicaid Program; Prescription Drugs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2238–FC]

RIN 0938–AO20

Medicaid Program; Prescription Drugs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period will implement the provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid Program. The DRA requires the Secretary of HHS to promulgate a final regulation no later than July 1, 2007. In addition, we are adding to existing regulations certain established Medicaid rebate policies that are currently set forth in CMS guidance. This rule will bring together existing and new regulatory requirements in one, cohesive subpart.

Finally, this final rule with comment period allows for further public comment on the Average Manufacturer Price and Federal upper limit (FUL) outlier section of the rule.

DATES: *Effective Date:* These regulations are effective on October 1, 2007.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 2, 2008.

ADDRESSES: In commenting, please refer to file code CMS–2238–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2238–FC, P.O. Box 8012, Baltimore, MD 21244–8012.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2238–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–8012.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or

7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Kimberly Howell, (410) 786–6762 (for issues related to the determination of average manufacturer price (AMP)).

Joseph Fine, (410) 786–2128 (for issues related to the determination of best price).

Yolanda Reese, (410) 786–9898 (for issues related to authorized generics).

Madlyn Kruh, (410) 786–3239 (for issues related to nominal prices).

Marge Watchorn, (410) 786–4361 (for issues related to manufacturer reporting requirements).

Gail Sexton, (410) 786–4583 (for issues related to FULs).

Christina Lyon, (410) 786–3332 (for issues related to physician-administered drugs).

Bernadette Leeds, (410) 786–9463 (for issues related to the regulatory impact analysis (RIA)).

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on the AMP and FUL outlier provisions as set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–2238–FC.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Introduction

Under the Medicaid Program, States may provide coverage of outpatient drugs as an optional service under section 1905(a)(12) of the Social Security Act (the Act). Section 1903(a) of the Act provides for Federal financial participation (FFP) in State expenditures for these drugs. In order for payment to be made available under section 1903 for certain drugs, manufacturers must enter into the national rebate agreement as set forth in section 1927(a) of the Act. Section 1927 of the Act provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formula for calculating rebate payments, and requirements for States with respect to covered outpatient drugs.

This final rule implements sections 6001(a)–(d), 6002, and 6003 of the DRA, Pub. L. 109–171 (Feb. 8, 2006). It also codifies those parts of section 1927 of

the Act that pertain to requirements for drug manufacturers' calculation and reporting of AMP and best price, and it revises existing regulations that set upper payment limits for certain covered outpatient drugs. This final rule also implements section 1903(i)(10) of the Act, as revised by the DRA, with regard to the denial of FFP in expenditures for certain physician-administered drugs. Finally, the rule addresses other provisions of the Medicaid Drug Rebate Program, to the extent those provisions are affected by the DRA.

The Medicaid Drug Rebate Program was established by section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), Pub. L. 101–508 (Nov. 5, 1990) and subsequently modified by the Veterans Health Care Act of 1992 (VHCA), Pub. L. 102–585 (Nov. 4, 1992) and the Omnibus Budget Reconciliation Act of 1993, Pub. L. 103–66 (Aug. 10, 1993). These provisions were implemented primarily through the national rebate agreement (56 Fed. Reg. 7049 (Feb. 21, 1991)) and other informal program releases, which provide standards for manufacturer reporting and rebate calculations. The statutory changes that affect the provisions of this final rule are described below.

B. Changes Made by the Deficit Reduction Act of 2005

Section 6001(a) of the DRA amends section 1927(e) of the Act to revise the formula CMS uses to set FULs for multiple source drugs. Effective January 1, 2007, the upper limit for multiple source drugs shall be established at 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent.

Section 6001(b) of the DRA amends section 1927(b)(3) of the Act to create a requirement that manufacturers report certain prices to the Secretary monthly. It also requires the Secretary to provide AMP to States on a monthly basis beginning July 1, 2006 and post AMP on a Web site at least quarterly. We are aware of concerns that the AMPs released to the States beginning July 1, 2006, will not reflect changes to the definition of AMP made by the DRA and finalized in this rule. While we made the AMPs available to the States beginning July 1, 2006, States should keep these data confidential in accordance with section 1927(b)(3)(D) of the Act. Section 6001(b) of the DRA revises these confidentiality provisions, effective January 1, 2007, to permit States to use AMP to calculate payment rates.

Section 6001(c) of the DRA modifies the definition of AMP to remove customary prompt pay discounts extended to wholesalers from the AMP calculation and requires manufacturers to report these customary prompt pay discounts to the Secretary. It requires the Inspector General of the Department of Health and Human Services (IG) to review the requirements for, and the manner in which, AMP is determined and submit to the Secretary and Congress any recommendations for changes no later than June 1, 2006. Finally, it requires the Secretary to promulgate a regulation that clarifies the requirements for, and the manner in which, AMP is determined no later than July 1, 2007, taking into consideration any IG recommendations.

Section 6001(d) of the DRA requires manufacturers to report information on sales at nominal price to the Secretary for calendar quarters beginning on or after January 1, 2007. It also specifies the entities to which nominal price applies. It limits the merely nominal exclusion to sales at nominal prices to the following: a covered entity described in section 340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR), a State-owned or operated nursing facility, and any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate, based on certain factors such as type of facility or entity, services provided by the facility or entity, and patient population.

Section 6001(e) of the DRA amends section 1927 of the Act to provide for a survey of retail prices and State performance rankings. These provisions were not addressed in the proposed rule.

Section 6001(f) of the DRA makes minor amendments to section 1927(g) of the Act which are self-implementing.

Section 6001(g) of the DRA provides that the amendments in section 6001 are effective on January 1, 2007, unless otherwise noted.

Section 6002 of the DRA amends section 1903(i)(10) of the Act by prohibiting Medicaid FFP for physician-administered drugs unless States submit the utilization data described in section 1927(a) of the Act. It also amends section 1927 of the Act to require the submission of utilization data for physician-administered drugs.

Section 6003(a) of the DRA amends section 1927(b)(3)(A) of the Act to require manufacturers to include within AMP and best price all of its drugs that are sold under a new drug application (NDA) approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA) when they report AMP and best price to the Secretary.

Section 6003(b) of the DRA amends section 1927(c)(1)(C) of the Act to clarify that manufacturers must include the lowest price available to any entity for a drug sold under an NDA approved under section 505(c) of the FFDCA when determining best price. Section 6003(b) also amends section 1927(k) of the Act to require that in the case of a manufacturer that approves, allows, or otherwise permits any of its drugs to be sold under an NDA approved under section 505(c) of the FFDCA, the AMP shall be calculated to include the average price paid for such drugs by wholesalers for drugs distributed to the retail pharmacy class of trade. Section 6003(c) of the DRA provides that the amendments made by section 6003 are effective January 1, 2007.

C. Proposed Rule Published September 19, 1995

On September 19, 1995, CMS (then the Health Care Financing Administration) published a proposed rule in the **Federal Register** (60 FR 48442 (Sept. 19, 1995)). The purpose of the 1995 proposed rule was to propose regulations pertaining to the Medicaid Drug Rebate Program and to address the national rebate agreement (56 FR 7049 (Feb. 21, 1991)). On August 29, 2003, CMS finalized two of the provisions in the 1995 proposed rule through a final rule with comment period (68 FR 51912). These regulations require manufacturers to retain records for data used to calculate AMP and best price for three years from when AMP and best price are reported to CMS. We also provided that manufacturers should report revisions to AMP and best price for a period not to exceed twelve quarters from the quarter in which the data are due. On November 26, 2004, we published final regulations (69 FR 68815) that require a manufacturer to retain pricing data for 10 years from the date the manufacturer reports that data to CMS and for an additional time frame where the manufacturer is the subject of an audit or government investigation. Due to the time that has elapsed since publication of the 1995 proposed rule and changes in the prescription drug industry, we do not plan to finalize the other provisions of that proposed rule, and any comments on the 1995 proposed rule are outside the scope of this final rule with comment period. This final rule with comment period does not address the entire Medicaid Drug Rebate Program, but focuses primarily on the provisions of the DRA

that address the Medicaid Drug Rebate Program.

II. Provisions of the Proposed Regulations

Basis and Purpose of Subpart I (§ 447.500)

We proposed that this subpart would implement specified provisions of sections 1927, 1903(i)(10), and 1902(a)(54) of the Act related to implementation of the DRA. It would include requirements related to State plans, FFP for drugs, and the payment for covered outpatient drugs under Medicaid. In the proposed rule, we also proposed to move the existing Medicaid drug provisions in the Federal regulations from subpart F to subpart I of 42 CFR part 447.

Definitions (§ 447.502)

We proposed that the rule include definitions of key terms used in 42 CFR part 447, subpart I. We proposed to use definitions from several sources, including the Act, Federal regulations, program guidance, and the national rebate agreement. We invited the public to provide comments on the terms we chose to define as well as the definitions described below.

We proposed to define ''bona fide service fee'' as a fee paid by a manufacturer to an entity, that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that a manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

We proposed to define ''brand name drug'' as a single source or innovator multiple source drug.

We proposed to define ''bundled sale'' as an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts should be proportionately allocated across all the drugs in the bundle.

We proposed to define ''Consumer Price Index—Urban (CPI–U)'' as the same as it is defined in the national rebate agreement, except we would replace ''U.S. Department of Commerce'' with ''U.S. Department of Labor'' to reflect that the Department of Labor is now responsible for updating the CPI–U. Therefore, the term CPI–U would mean the index of consumer prices developed and updated by the U.S. Department of Labor. For purposes of this subpart, it would be the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

We proposed to define ''dispensing fee'' similarly to how it is defined for the Medicare Part D program in 42 CFR 423.100 in light of some of the parallels of Part D to Medicaid. We proposed to define this term in order to assist States in their evaluation of factors in establishing a reasonable dispensing fee to pharmacy providers. We note that while we proposed to define this term, we do not intend to mandate a specific formula or methodology which the States must use to determine the dispensing fee. The formula is consistent with our regulation that defines estimated acquisition costs which give States flexibility to determine EAC. However, consistent with a recommendation made by the Office of Inspector General (OIG) in its report, ''Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,'' (A–06–06–00063) May 2006, we encouraged States to analyze the relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid Program appropriately reimburses pharmacies for estimated acquisition costs.

We proposed to define ''dispensing fee'' as the fee which—

(1) is incurred at the point of sale and pays for costs other than the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

We proposed to define ''innovator multiple source drug'' based on the definition in section 1927(k)(7)(A)(ii) of the Act. We also proposed using the definition from the national rebate agreement. Innovator multiple source drug would mean a multiple source drug that was originally marketed under an original NDA approved by the Food and Drug Administration (FDA). It would include a drug product marketed by any cross-licensed producers or distributors operating under the NDA and a covered outpatient drug approved under an NDA, Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). We believe this definition is consistent with our understanding of the drug rebate statute and section 6003 of the DRA which includes within the definition those drugs which often receive a certain amount of patent protection and/or market exclusivity.

We proposed to define ''manufacturer'' based on the definition in section 1927(k)(5) of the Act and the national rebate agreement. It would also mirror the current definition of manufacturer used by Medicare in the regulations regarding manufacturer's average sales price (ASP) data. For purposes of the Medicaid Program, we proposed that manufacturer would be defined as any entity that possesses legal title to the NDC for a covered drug or biological product and—

(a) is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(b) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesaler of drugs or a retail pharmacy licensed under State law.

(c) With respect to authorized generic products, the term ''manufacturer'' will

also include the original holder of the NDA.

(d) With respect to drugs subject to private labeling arrangements, the term ''manufacturer'' will also include those entities that do not possess legal title to the NDC.

''Multiple source drug'' is currently defined in Federal regulations at section 42 CFR 447.301. We proposed to remove the definition from that section and revise the definition to reflect the DRA amendments to section 1927 of the Act. We proposed to define the term multiple source drug to mean, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent. For the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.fda.gov/cder/orange/default.htm* or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the United States during the rebate period.

We proposed to define ''national drug code (NDC)'' as it is used by the FDA and based on the definition used in the national rebate agreement. For purposes of this subpart, it would mean the 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in the regulation as being without respect to package size (9-digit numerical code).

''National rebate agreement'' is described in section 1927 of the Act. Section 1927(b) of the Act outlines the terms of the national rebate agreement, including reporting timeframes, manufacturer responsibilities, penalties, and confidentiality of pricing data. We proposed that the national rebate agreement would continue to be defined as the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his designee and a manufacturer to implement section 1927 of the Act.

We proposed to define ''nominal price'' as it is in the national rebate agreement. We proposed incorporating this definition in this rule because it is the standard presently used in the Medicaid Program and the Medicare Part B program, and is similar to that used by the Department of Veterans Affairs (DVA) in administering the Federal Supply Schedule (FSS). We proposed that nominal price would mean a price that is less than 10 percent of AMP in the same quarter for which the AMP is computed.

''Rebate period'' is defined in section 1927(k)(8) of the Act as a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under the national rebate agreement. The Medicaid Drug Rebate Program currently operates using a calendar quarter for the rebate period. While AMPs would be reported monthly for purposes of calculating FULs and for release to States, we can find no evidence in the legislative history of the DRA that Congress intended to change the definition of rebate period. Therefore, we proposed to define rebate period as a calendar quarter.

''Single source drug'' is defined in section 1927(k)(7)(A)(iv) of the Act as a covered outpatient drug which is produced or distributed under an original NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It is further defined in the national rebate agreement as a covered outpatient drug approved under a PLA, ELA, or ADA.

We proposed to define the term single source drug as it is defined in the statute and the national rebate agreement.

Determination of Average Manufacturer Price (§ 447.504)

Background

Prior to the DRA, section 1927(k)(1) of the Act specified that the AMP with respect to a covered outpatient drug of a manufacturer for a rebate period is the average unit price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade after deducting customary prompt pay discounts.

The national rebate agreement (56 FR 7049 (Feb. 21, 1991)) further specifies that:

- Direct sales to hospitals, health maintenance organizations (HMOs) and wholesalers, where the drug is relabeled under that distributor's NDC number, and FSS prices are not included in the calculation of AMP;
- AMP includes cash discounts and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid;
- AMP is calculated as net sales divided by the number of units sold, excluding free goods (that is, drugs or any other items given away, but not contingent on any purchase requirements), and
- Net sales means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid.

Consistent with these provisions, it has been our policy that in order to provide a reflection of market transactions, the AMP for a quarter should be adjusted by the manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

AMP should be adjusted for bundled sales (as defined above) by determining the total value of all the discounts on all drugs in the bundle and allocating those discounts proportionately to the respective AMP calculations. The aggregate discount is allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. Where discounts are offered on multiple products in a bundle, the aggregate value of all the discounts should be proportionately allocated across all the drugs in the bundle. The average unit price means a manufacturer's quarterly sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

Provisions of the DRA

Section 6001(c)(1) of the DRA amended section 1927(k)(1) of the Act to revise the definition of AMP to exclude customary prompt pay discounts to wholesalers, effective January 1, 2007. Section 6001(c)(3) of the DRA requires the OIG to review the requirements for and manner in which AMPs are determined and recommend changes to the Secretary by June 1, 2006. Section 6001(c)(3) of the DRA requires the Secretary to clarify the requirements for and the manner in which AMPs are determined by promulgating a regulation no later than July 1, 2007, taking into consideration the OIG's recommendations.

OIG Recommendations on AMP

In accordance with 6001(c)(3) of the DRA, the OIG issued its report, ''Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,'' (A–06–06–00063), in May 2006. In this report, the OIG recommended that CMS:

- Clarify the requirements in regard to the definition of retail pharmacy class of trade and treatment of pharmacy benefit manager (PBM) rebates and Medicaid sales and
- Consider addressing issues raised by industry groups, such as:

- Administrative and service fees,
- Lagged price concessions and returned goods,
- The frequency of AMP reporting,
- AMP restatements, and
- Base date AMP.

The OIG also recommended that the Secretary direct CMS to:

- Issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA and
- Encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid Program appropriately reimburses pharmacies for estimated acquisition costs.

We addressed these recommendations as we discussed provisions of the proposed rule in the section below.

Definition of Retail Pharmacy Class of Trade and Determination of AMP

We recognize that there have been concerns expressed regarding AMP because of inconsistencies in the way manufacturers determine AMP, changes in the drug marketplace, and the introduction of newer business practices such as payment of services fees. We also realize that in light of the DRA amendments, AMP will serve two distinct purposes: For drug rebate liability and for payments. For the purpose of determining drug rebate liability, drug manufacturers would generally benefit from a broad definition of retail pharmacy class of trade which would include entities that purchase drugs at lower prices and which would lower rebate liability. Including these lower prices would decrease the AMP, decreasing manufacturers' rebate liability. The retail pharmacy industry might benefit from a narrow definition of retail pharmacy prices that would be limited to certain higher priced sales given that, in light of the DRA amendments, States might use AMP to calculate pharmacy payment rates. Excluding low-priced sales would increase AMP, increasing, in all likelihood, manufacturers' rebate payments. The pharmacy industry believes that mail order pharmacies and nursing home pharmacies (long-term care pharmacies) pay less for drugs than retail pharmacies (for example, independents and chain pharmacies), and thus the inclusion of such prices would lower AMP below the price paid by such retail pharmacies.

The statute mandates that, effective January 1, 2007, the Secretary use AMP when computing FULs. For this purpose, we proposed excluding certain outlier payments (see our discussion in the FULs section for a more complete description of outlier exclusions). The statute also requires that AMP be provided to States monthly and be posted on a public Web site. While there is no requirement that States use AMPs to set payment amounts, we believe the Congress intended that States have drug pricing data based on actual prices, in contrast to previously available data that did not necessarily reflect actual manufacturer prices of sales to the retail pharmacy class of trade. We considered several options to define what prices should be included in AMP. We considered including only prices of sales to retail pharmacies that dispense drugs to the general public (for example, independent and chain pharmacies) in retail pharmacy class of trade and removing prices to mail order pharmacies, nursing home pharmacies (long-term care pharmacies), and PBMs. We proposed that this definition would address the retail pharmacy industry's contentions that an AMP used for reimbursement to retail pharmacies should only reflect prices of sales to those pharmacies which dispense drugs to the general public.

The exclusion of prices to mail order pharmacies, nursing home facilities (long-term care facilities), and PBMs would substantially reduce the number of transactions included in AMP. Removal of these prices would simplify AMP calculations for manufacturers because it is our understanding that certain data (for example, PBM pricing data) are difficult for manufacturers to capture. In addition, removal of these prices would address differing interpretations of CMS policy identified by the OIG and the Government Accountability Office (GAO) due to the lack of a clear definition of AMP or specific guidance regarding which retail prices should be included in AMP. However, such a removal would not be consistent with past policy, as specified in Manufacturer Releases 28 and 29 (*http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp#TopOfPage*), would likely result in a higher AMP, and would result in an increase in drug manufacturers' rebate liabilities.

We also considered not revising the entities included in the retail pharmacy class of trade. However, this would not address the issues identified by the OIG in its report, ''Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program,'' (A–06–91–00092), November 1992 and GAO in its report ''Medicaid Drug Rebate Program—Inadequate Oversight Raises Concerns about Rebates Paid to States,'' (GAO–05–102), February 2005.

We believe, based in part on the OIG and GAO reports, that retail pharmacy class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services. As such, we proposed excluding from AMP the prices of sales to nursing home pharmacies (long-term care pharmacies) because nursing home pharmacies do not dispense to the general public. We proposed including in AMP the prices of sales and discounts to mail order pharmacies. We considered limiting mail order pharmacy prices to only those prices that are offered to all pharmacies under similar terms and conditions. However, given our belief that such prices are simply another form of how drugs enter into the retail pharmacy class of trade, we proposed maintaining these prices in the definition. We noted that even were we to incorporate this change, retail pharmacies may not be able to meet the terms and conditions placed on mail order pharmacies to be eligible for some manufacturer price concessions. CMS sought public comment on the inclusion of all mail order pharmacy prices in our definition of retail pharmacy class of trade for purposes of inclusion in the determination of AMP.

We recognized that a major factor contributing to the determination of AMP is the treatment of PBMs. These entities have assumed a significant role in drug distribution since the enactment of the Medicaid Drug Rebate Program in 1990. We considered how PBM rebates, discounts, or other price concessions should be recognized for purposes of AMP calculations.

A GAO report, ''Medicaid Drug Rebate Program—Inadequate Oversight Raises Concerns about Rebates Paid to States,'' (GAO–05–102), in February 2005, indicated that the Medicaid Drug Rebate Program does not clearly address certain financial concessions negotiated by PBMs. The GAO recommended that we issue clear guidance on manufacturer price determination methods and the definitions of AMP and best price, and update such guidance as additional issues arise.

The issue regarding PBMs was also addressed in the OIG report, ''Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,'' (A–06–06–00063), in May 2006. In this report, the OIG recommended that we clarify the treatment of PBM rebates. This

report says that manufacturers treat rebates and fees paid to PBMs in the calculation of AMP in three different ways. Specifically they found that manufacturers (1) did not subtract rebates or fees paid to PBMs from the AMP calculation; (2) subtracted the rebates or fees paid to PBMs; or (3) subtracted a portion of the PBMs rebates or fees from the AMP calculation.

In developing the proposed rule, we considered including all rebates, discounts and other price concessions from PBMs in the determination of AMP. We also considered excluding rebates, discounts and other price concessions from PBMs in the determination of AMP.

One of the most difficult issues with PBM discounts, rebates, or other price concessions is that manufacturers contend that they do not know what part of these discounts, rebates, or other price concessions is kept by the PBM for the cost of its activities and profit, what part is passed on to the health insurer or other insurer or other entity with which the PBM contracts, and what part, if any, that entity passes on to pharmacies. Despite the difficulties of including certain PBM rebates, discounts or other price concessions in AMP, excluding all of these price concessions could result in an artificial inflation of AMP. For this reason, we proposed to include PBM rebates, discounts, or other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP; however, we invited comments on whether this proposal is operationally feasible.

As discussed more fully below, we proposed that PBM rebates and price concessions that adjust the amount received by the manufacturer for drugs distributed to the retail pharmacy class of trade should be included in the calculation of AMP. We acknowledged that manufacturers have a variety of arrangements with PBMs and thus invited comments on all aspects of our proposal as explained below.

The national rebate agreement defines AMP to include cash discounts and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid to the manufacturer for drugs distributed to the retail pharmacy class of trade. As noted in Manufacturer Release 28 and reiterated in Manufacturer Release 29, manufacturers have developed a myriad of arrangements whereby specific discounts, chargebacks, or rebates are provided to PBMs which, in turn, are passed on to the purchaser. Those releases recognize that certain prices provided by manufacturers to PBMs should be included within AMP calculations. In accordance with those releases, our position has been that PBMs have no effect on the AMP calculations unless the PBM is acting as a wholesaler as defined in the national rebate agreement. We are concerned, however, that this position may unduly exclude from AMP certain PBM prices and discounts which have an impact on prices paid to the manufacturer.

We believe that AMP should be calculated to reflect the net drug price recognized by the manufacturer, inclusive of any price adjustments or discounts provided directly or indirectly by the manufacturer. We were interested in comments on this proposal, including the comments on the operational difficulties of including such PBM arrangements within AMP calculations.

We recognize that the statute defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade; however, in light of our understanding of congressional intent, we believe that the definition is meant to capture discounts and other price adjustments, regardless of whether such discounts or adjustments are provided directly or indirectly by the manufacturer. We invited comments on this definition and whether AMP should be calculated to include all adjustments that affect net drug prices.

We acknowledged that there are many PBM/manufacturer arrangements. To the extent manufacturers are offering rebates, discounts, or other price concessions to the PBM that are not bona fide service fees, we proposed that these lower prices should be included in the AMP calculations. We requested comments on the operational difficulties of tracking these rebates, discounts, or chargebacks provided to a PBM for purposes of calculating AMP and on the inclusion of all such price concessions in AMP. Specifically, we solicited comments on the extent to which CMS should or should not define in regulation which rebates, discounts, or price concessions provided to PBMs should be included in AMP and how best to measure these. Also, we solicited public comment on how these PBM price concessions should be reported to CMS to assure that appropriate price adjustments are captured and included in the determination of AMP.

Finally, we requested comments on any other issues that we should take into account in making our final decisions. These included, but were not limited to, possible Federal and State budgetary impacts (our savings estimates assumed no budgetary impacts as generic drugs are rarely, if ever, subject to PBM price adjustments in this context); possible future evolution in industry pricing and management practices (for example, growth of ''preferred'' generic drugs); and possible impacts on reimbursement for brand name drugs under Medicaid. We were generally interested in comments on how and to what extent PBMs act as ''wholesalers.'' We proposed to incorporate the explicitly listed exclusions in section 1927 of the Act, and in the national rebate agreement, which are direct sales to hospitals, HMOs/managed care organizations (MCOs), wholesalers where the drug is relabeled under that distributor's NDC and FSS prices.

The specific terms we proposed to clarify and the proposed clarifications follow.

Retail Pharmacy Class of Trade: We proposed to include in the definition of retail pharmacy class of trade any entity that purchases prescription drugs from a manufacturer or wholesaler for dispensing to the general public (for example, retail, independent, chain and mail order pharmacies), except as otherwise specified by the statute or regulation (for example, HMOs, hospitals).

PBM Price Concessions: We proposed to include any rebates, discounts or other price adjustments provided by the manufacturer to the PBM that affect the net price recognized by the manufacturer for drugs provided to entities in the retail pharmacy class of trade.

Customary Prompt Pay Discounts: Prior to the DRA, neither the statute nor the national rebate agreement defined customary prompt pay discounts. The DRA revises the definition of AMP to exclude customary prompt pay discounts extended to wholesalers; however, it does not revise or define customary prompt pay discounts. We proposed to define customary prompt pay discounts as any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time of the payment due date.

Treatment of Medicaid Sales: The OIG recommended that we should address whether AMP should include Medicaid prices of sales; that is, prices of sales where the end payer for the drug is the Medicaid Program. In its May 2006 report, the OIG noted confusion on this issue and recommended that we clarify that these prices of sales are to be included in AMP. It is our position that these sales are included in AMP because they are not expressly excluded in the

statute. In the proposed rule, we also proposed clarifying that prices to State Children's Health Insurance Program (SCHIP) Title XIX through an expanded Medicaid Program are covered under the provisions of section 1927 of the Act and generally subsumed in Medicaid sales. As a general matter, Medicaid does not directly purchase drugs from manufacturers or wholesalers but instead reimburses pharmacies for these drugs. Therefore, Medicaid sales are determined by the entities that are actually in the sales chain and because Medicaid reimburses pharmacies for drugs for Medicaid beneficiaries, integrated into the chain of sales otherwise included in AMP.

In the proposed rule, we proposed clarifying that the units associated with Medicaid sales should be included as part of the total units in the AMP calculation. We proposed that AMP be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by the statute or regulation or is provided to an entity excluded by statute or regulation. Therefore, we proposed clarifying that rebates paid to States under the Medicaid Drug Rebate Program should be excluded from AMP calculations but that price concessions associated with the sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients should be included.

We also proposed to clarify how the prices of sales to SCHIP Title XXI non-Medicaid expansion programs should be treated. Like the Medicaid Program, SCHIP non-Medicaid expansion programs do not directly purchase drugs. Because such programs are not part of the Medicaid Program, they are not covered under the provisions of section 1927 of the Act. As with Medicaid sales, these sales are included in AMP to the extent they concern sales at the retail pharmacy class of trade. Therefore, these sales should not be backed out of the AMP calculation to the extent that such sales are included within sales provided to the retail pharmacy class of trade. Rebates and units associated with those sales should also be included in the calculation of AMP.

Treatment of Medicare Part D Sales: We proposed clarifying that the treatment of prices of sales through a Medicare Part D prescription drug plan (PDP), a Medicare Advantage prescription drug plan (MA–PD), or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals should be included in the AMP calculation. Like the Medicaid Program, PDPs and MA–PDs do not directly purchase drugs, but are usually third party payers. As with Medicaid sales, these sales are included in AMP to the extent they are sales to the retail pharmacy class of trade. Therefore, we believe these prices of sales should not be backed out of the AMP. Rebates paid by the manufacturer to the PDP or MA–PD should be included in the calculation of AMP.

SPAP Price Concessions: In the proposed rule, we also proposed to clarify how the prices to State pharmaceutical assistance programs (SPAPs) should be treated. Like the Medicaid Program, PDPs, and MA–PDs, SPAPs do not directly purchase drugs, but are generally third party payers. As with Medicaid sales, these sales are included in AMP to the extent the sales are to an entity included in the retail pharmacy class of trade. Therefore, we proposed that SPAP sales should not be backed out of the AMP calculation. Rebates paid by the manufacturer to the SPAP should be included in the calculation of AMP.

Prices to Other Federal Programs: We proposed that any prices on or after October 1, 1992, to the Indian Health Service (IHS), the DVA, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in subsection 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA); any prices charged under the FSS of the General Services Administration (GSA); and any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government are excluded from the calculation of AMP. We proposed that the prices to these entities should be excluded from AMP because the prices to these entities are not available to the retail pharmacy class of trade.

Administrative and Service Fees: Current Medicaid drug rebate policy is that administrative fees which include service fees and distribution fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid Drug Rebate Program, should be included in the calculation of AMP, if those sales are to an entity included in the calculation of AMP. The OIG has noted in its report, ''Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,'' (A–06–06–00063), May 2006, that confusion exists about the treatment of fees, such as service fees negotiated between a manufacturer and pharmaceutical distributor. Some believe that these fees should not be included in AMP because the manufacturer does not know if the fees act to reduce the price paid by the end purchasers. Others believe such fees should be included in the calculation, which would reduce AMP because they serve as a price concession. For the same reason as for sales to PBMs, we proposed that all fees except fees paid for bona fide services should be included in AMP. We proposed that bona fide service fees means fees paid by a manufacturer to an entity, which represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and which are not passed in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. Medicare Part B also adopted this definition in its final rule with comment period that was published on December 1, 2006 (71 FR 69623 through 70251) that implemented the ASP provisions enacted in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We did not propose to define fair market value. However, CMS invited comments from the public regarding an appropriate definition for fair market value.

Direct Patient Sales: In response to manufacturers' questions, CMS has stated previously that covered outpatient drugs sold to patients through direct programs should be included in the calculation of AMP. These sales are usually for specialty drugs through a direct distribution arrangement, where the manufacturer retains ownership of the drug and pays either an administrative or service fee to a third party for functions such as the storage, delivery and billing of the drug. Some manufacturers have contended that direct patient sales for covered outpatient drugs sold by a manufacturer through a direct distribution channel should not qualify for inclusion in the calculation of AMP because the Medicaid rebate statute and the national rebate agreement do not address covered outpatient drugs that are not sold to wholesalers and/or not distributed in the retail pharmacy class of trade. We believe that the distributor is acting as a wholesaler and these sales are to the retail pharmacy class of trade. In light

of this, we proposed that these sales and the rebates associated with these sales to patients through direct programs would be included in AMP. CMS invited comments from the public on this proposed policy.

Returned Goods: Current Medicaid Drug Rebate Program policy is that returned goods are credited back to the manufacturer in either the quarter of sale or quarter of receipt. This has caused difficulty for some manufacturers when these returns have substantially reduced AMP in a quarter or resulted in a negative AMP. In light of these concerns, we proposed to exclude returned goods from the calculation of AMP when returned in good faith. CMS considers that goods are being returned in good faith when they are being returned pursuant to manufacturer policies which are not designed to manipulate or artificially inflate or deflate AMP. The Medicare Part B program excludes returned goods from the calculation of ASP. The exclusion of returned goods will allow the manufacturer to calculate and report an AMP that is more reflective of its true pricing policies to the retail pharmacy class of trade in the reporting period. It lessens the administrative burden and problems associated with allocating the returned goods back to the reporting period in which they were sold, as well as eliminating artificially low, zero or negative AMPs that may result from these adjustments.

Manufacturer Coupons: In the proposed rule, we proposed to clarify how manufacturer coupons should be treated. The treatment of manufacturer coupons has been problematic for CMS as well as some manufacturers. We proposed to include coupons redeemed by any entity other than the consumer in the calculation of AMP. We believe that the redemption of coupons by the consumer directly to the manufacturer is not included in the retail pharmacy class of trade. In the proposed rule, we proposed to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of AMP. CMS invited comments from the public on the proposed policy.

Future Clarifications of AMP: Based on past comments from the GAO and the OIG and recommendations of the OIG in its May 2006 report on AMP, we believe that we need to have the ability to clarify the definition of AMP in an expedited manner in order to address the evolving marketplace for the sale of drugs. We proposed to address future clarifications of AMP through the issuance of program releases and by posting the clarifications on the CMS Web site as needed.

Requirements for Average Manufacturer Price

To implement the provisions set forth in sections 6001 and 6003 of the DRA related to AMP, we proposed a new §447.504. In §447.504(a), we proposed a revised definition of AMP and clarified that AMP is determined without regard to customary prompt pay discounts extended to wholesalers. In §447.504(b), we proposed to define average unit price. In §447.504(c), we proposed to define customary prompt pay discount. In §447.504(d), we proposed to define net sales. In §447.504(e), we proposed to define retail pharmacy class of trade. In §447.504(f), we proposed to define wholesaler. In §447.504(g), we described in detail the sales, rebates, discounts, or other price concessions that must be included in AMP. In §447.504(h), we described the sales, rebates, discounts, or other price concessions that must be excluded from AMP. In §447.504(i), we provided further clarification about how manufacturers should account for price reductions and other pricing arrangements which should be included in the calculation of AMP.

Determination of Best Price (§447.505)

Prior to the DRA, section 1927(c)(1)(C) of the Act provided that manufacturers must include in their best price calculation, for a single source or innovator multiple source drug, the lowest price available from the manufacturers during the rebate period to any wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States except for those entities specifically excluded by statute. Excluded from best price are prices charged on or after October 1, 1992, to the IHS, the DVA, a State home receiving funds under section 1741 of title 38, United States Code, the DoD, the PHS, or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA); any prices charged under the FSS of the GSA; any prices used under an SPAP; any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government; and prices to a Medicare Part D PDP, an MA–PD, or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals.

The statute further specifies that best price:

- Includes cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates (other than rebates under section 1927 of the Act), which reduce the price paid;
- Must be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package;
- Must not take into account prices that are merely nominal in amount.

Consistent with these provisions and the national rebate agreement, it has been our policy that in order to reflect market transactions, the best price for a rebate period should be adjusted by the manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

Best price should be adjusted for any bundled sale. The drugs in a ''bundle'' do not have to be physically packaged together to constitute a ''bundle,'' just part of the same bundled transaction.

Section 1927(c)(1)(C)(ii)(I) of the Act specifies that best price must include free goods that are contingent on any purchase requirement. Thus, only those free goods that are not contingent on any purchase requirements may be excluded from best price.

Section 103(e) of the Medicare Modernization Act of 2003 (MMA) modified the definition of best price by excluding prices which are negotiated by a PDP under part D of title XVIII of the Act, by any MA–PD plan under part C of such title with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2) of the Act) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title. Section 1002(a) of the MMA modified section 1927(c)(1)(C)(i)(I) of the Act by clarifying that inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA are exempt from best price.

Section 6003 of the DRA amended section 1927(c)(1)(C) of the Act by revising the definition of best price to clarify that the best price includes the lowest price available to any entity for any such drug of a manufacturer that is sold under an NDA approved under section 505(c) of the FFDCA.

In the proposed rule we proposed to define best price with respect to a single source drug or innovator multiple source drug of a manufacturer, including any drug sold under an NDA approved under section 505(c) of the FFDCA, as the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. It

continues to be our policy that best price reflects the lowest price at which the manufacturer sells a covered outpatient drug to any purchaser, except those prices specifically exempted by law. We proposed to define provider as a hospital; HMO, including an MCO or PBM; or other entity that treats individuals for illnesses or injuries or provides services or items in the provisions of health care.

As with the determination of AMP, the DRA does not establish a mechanism to clarify how best price is to be determined should new entities be formed after this regulation takes effect. We believe that we need to have the ability to clarify best price in an expedited manner in order to address the evolving marketplace for the sale of drugs. We proposed to address future clarifications to best price through the issuance of program releases and by posting the clarifications on the CMS Web site as needed. Even though the DRA did not require CMS to clarify the requirements for best price, we determined that it was reasonable to propose these provisions in the proposed rule, consistent with long-standing Medicaid Drug Rebate Program policy and the MMA with respect to best price as revised by the DRA.

We proposed to incorporate the explicitly listed exclusions in section 1927 of the Act, which are prices charged on or after October 1, 1992, to the IHS, the DVA, a State home receiving funds under section 1741 of title 38, United States Code, the DoD, the PHS, or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA); any prices charged under the FSS of the GSA; any prices paid under an SPAP; any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government; and payments made by a Medicare Part D PDP, an MA–PD, or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals. We proposed to codify this policy and require that manufacturers exclude the prices to these entities from best price. Because best price represents the lowest price available from the manufacturer to any entity with respect to a single source drug or innovator multiple source drug of a manufacturer, including an authorized generic, any price concession associated with that sale should be netted out of the price received by the manufacturer in calculating best price and best price should be adjusted by the manufacturer if other arrangements subsequently adjust the prices actually realized. We proposed to consider any price adjustment which ultimately affects those prices which are actually realized by the manufacturer as ''other arrangements'' and that such adjustment should be included in the calculation of best price, except to the extent that such adjustments qualify as bona fide service fees.

We proposed that best price be calculated to include all sales, discounts, and other price concessions provided by the manufacturer for covered outpatient drugs to any entity unless the manufacturer can demonstrate that the sale, discount, or other price concession is specifically excluded by statute or is provided to an entity not included in the rebate calculation. To the extent that an entity is not included in the best price calculation, both sales and associated discounts or other price concessions provided to such an entity should be excluded from the calculation. The specific terms we propose to clarify and the proposed clarification follow.

The national rebate agreement defines best price, in part, as the lowest price at which the manufacturer sells the covered outpatient drug to any purchaser in the United States. We proposed to codify this policy in the proposed rule.

Customary Prompt Pay Discounts: The DRA revises the definition of AMP to exclude customary prompt pay discounts to wholesalers; however, it does not change the definition of best price to exclude customary prompt pay discounts. Therefore, we proposed to include customary prompt pay discounts in best price.

PBM Price Concessions: We recognize that a major factor contributing to the determination of best price includes the treatment of PBMs. These entities have assumed a significant role in drug distribution since the enactment of the Medicaid Drug Rebate Program in 1990.

As noted in Manufacturer Release 28 and reiterated in Manufacturer Release 29, manufacturers have developed a myriad of arrangements whereby specific discounts, chargebacks, or rebates are provided to PBMs which in turn are passed on to the purchaser. In such situations where discounts, chargebacks, or rebates are used to adjust drug prices at the wholesaler or retail level, such adjustments are included in the best price calculation.

A GAO report, ''Medicaid Drug Rebate Program—Inadequate Oversight Raises Concerns about Rebates Paid to States,'' (GAO–05–102), in February 2005, indicated that the Medicaid Drug Rebate Program does not clearly address certain financial concessions negotiated by PBMs. The GAO recommended that we issue clear guidance on manufacturer price determination methods and the definitions of AMP and best price, and update such guidance as additional issues arise.

The issue regarding PBMs was also addressed in the recently issued OIG report, ''Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,'' (A–06–06–00063), in May 2006. In this report, the OIG recommended that we clarify the treatment of PBM rebates.

One of the most difficult issues with PBM discounts, price concessions, or rebates is that manufacturers contend that they do not know what part of these discounts, price concessions, or rebates are kept by the PBM for the cost of their activities and profit, what part is passed on to the health insurer or other insurer or other entity with which the PBM contracts, and what part that entity passes on to pharmacies.

Despite the difficulties of including certain PBM rebates, discounts or other price concessions in best price, excluding these price concessions could result in an artificial inflation of best price. We proposed to include PBM rebates, discounts, or other price concessions for the purpose of determining best price.

To the extent manufacturers are offering PBMs rebates, discounts, or other price concessions, these lower prices should be included in the best price calculations. Therefore, where the use of the PBM by manufacturers affects the price available from the manufacturer, we proposed that these lower prices should be reflected in best price calculations. We acknowledged that there are many PBM/manufacturer arrangements.

We believe that PBMs often obtain rebates, discounts, or other price concessions which adjust prices, either directly or indirectly. Unless the fees/discounts qualify as bona fide service fees (which are excluded), we proposed that the PBM rebates, discounts, or chargebacks should be included in best price. We proposed to consider these rebates, discounts, or chargebacks in best price calculations. CMS invited public comment on the inclusion of certain PBM price concessions in the determination of best price. Also, we solicited public comment on how these PBM price concessions should be reported to CMS to assure that appropriate price concessions are captured and included in the determination of best price.

We proposed to incorporate the explicitly listed exclusions in section 1927 of the Act and in the national rebate agreement. Because best price represents the prices available from the manufacturer for prescription drugs, best price should be adjusted by the manufacturer if other arrangements subsequently adjust the prices actually realized. We proposed to consider that any price adjustment which ultimately affects those prices which are actually realized by the manufacturer as ''other arrangements'' and that such an adjustment should be included in the calculation of best price. The specific terms we proposed to clarify and the proposed clarifications follow.

Administrative and Service Fees: We proposed that administrative fees which include service fees and distribution fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid Drug Rebate Program, should be included in the calculation of best price, if those sales are to an entity included in the calculation of best price. As previously discussed, the OIG has noted in its report, ''Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,'' (A–06–06–00063), May 2006, that confusion exists about the treatment of fees, such as service fees negotiated between a manufacturer and pharmaceutical distributor for AMP and best price. We believe that price adjustments which ultimately affect those prices which are actually available from the manufacturer should be included in best price. We proposed that manufacturers should include all such fees except bona fide service fees provided at fair market value in the best price calculation.

Treatment of Medicare Part D Prices: In the proposed rule, we proposed to clarify the treatment of prices which are negotiated by a Medicare Part D PDP, an MA–PD, or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals. We proposed that these prices are exempt from the best price. Section 1860D–2(d)(1)(C) of the Act specifically states that ''prices negotiated by a prescription drug plan, by an MA–PD plan with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)) with respect to such drugs on behalf of Part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).'' Therefore, while we proposed that the prices listed above be included for the purpose of calculating AMP, we proposed that prices negotiated by a PDP, an MA–PD, or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals not be taken into account for the purpose of establishing best price.

Manufacturer Coupons: In the proposed rule, we proposed to clarify how manufacturer coupons should be treated for the purpose of establishing best price. We believe that the redemption of coupons by any entity other than the consumer to the manufacturer ultimately affects the price paid by the entity (for example, retail pharmacy). We proposed to include coupons redeemed by any entity other than the consumer in the calculation of best price. We believe that the redemption of coupons by the consumer directly to the manufacturer does not affect the price paid by any entity whose sales are included in best price. In the proposed rule, we proposed to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of best price. CMS invited comments from the public on this proposed policy.

Medicaid Rebates and Supplemental Rebates: Section 1927(c)(1)(C)(ii)(I) of the Act and the national rebate agreement provide that any rebates paid by manufacturers under section 1927 of the Act are to be excluded from the calculation of best price. Therefore, we proposed to exclude Medicaid rebates from best price. Likewise, we considered rebates paid under CMS-authorized separate (supplemental) Medicaid drug rebate agreements with States to meet this requirement and proposed that these rebates be excluded from best price. In accordance with section 1927 of the Act pertaining to the determination of best price and our understanding of congressional intent, we proposed a new § 447.505. In § 447.505(a), we provided a general definition of the term best price. In § 447.505(b), we proposed to define provider. In § 447.505(c), we specified the sales and prices which must be included in best price. In § 447.505(d), we specified which sales and prices must be excluded from best price. In § 447.505(e), we further clarified the price reductions and other pricing arrangements included in the calculation of best price.

Authorized Generic Drugs (§ 447.506)

In the proposed rule, we stated that drug manufacturers participating in the Medicaid Drug Rebate Program are required to report the AMP for each covered outpatient drug offered under the Medicaid Program and the best price for each single source or innovator multiple source drug available to any wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity with certain exceptions.

For purposes of the Medicaid Drug Rebate Program, an authorized generic is any drug product marketed under the innovator multiple source drug or brand manufacturer's original NDA, but labeled with a different NDC than the innovator multiple source drug or brand product. According to our reading of the statute, authorized generics are single source or innovator multiple source drugs for the purpose of computing the drug rebate and are classified based on whether the drug is being sold or marketed pursuant to an NDA. Responsibility for the rebate rests with the manufacturer selling or marketing the drug to the retail pharmacy class of trade.

We proposed to implement section 6003 of the DRA by proposing to adopt the term ''authorized generic'' and define this term with respect to the Medicaid Drug Rebate Program, as any drug sold, licensed or marketed under an NDA approved by the FDA under section 505(c) of the FFDCA that is marketed, sold or distributed directly or indirectly under a different product code, labeler code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the listed drug.

Section 6003 of the DRA amended section 1927(b)(3)(A) of the Act to include drugs approved under section 505(c) of the FFDCA in the reporting requirements for the primary manufacturer (NDA holder) for AMP and best price. We proposed to interpret the language of section 6003 of the DRA to include in the best price and AMP calculations of the branded drugs, the authorized generic drugs that have been marketed by another manufacturer or subsidiary of the brand manufacturer (or NDA holder). We believe that to limit the applicability of this regulation to the sellers of authorized generic drugs would allow manufacturers to circumvent the intent of the provision by licensing rather than selling the rights to such drugs. This is why we proposed a broad definition of authorized generic drugs rather than a more narrow definition of such drugs. We proposed to require the NDA holder to include sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary in its calculation of AMP and best price. We welcomed comments on this issue.

The secondary manufacturer or subsidiary of the brand manufacturer would continue to pay the single source drug or innovator multiple source drug rebate for the authorized generic drug products based on utilization under its own NDC number, as required under current law. We welcomed comments on these issues.

In § 447.506(a), we proposed defining the term authorized generic drug for the purposes of the Medicaid Drug Rebate Program.

In § 447.506(b), we proposed requiring the sales of authorized generic drugs that have been sold or licensed to another manufacturer to be included by the primary manufacturer as part of its calculation of AMP for the single source or innovator multiple source drug (including all such drugs that are sold under an NDA approved under section 505(c) of the FFDCA).

In § 447.506(c), we proposed requiring that sales of authorized generic drugs by the secondary manufacturer that buys or licenses the right to sell the drugs be included by the primary manufacturer in sales used to determine the best price for the single source or innovator multiple source drug approved under section 505(c) of the FFDCA during the rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States. The primary manufacturer must include in its calculation of best price all sales of the authorized generic drug which have been sold or marketed by a secondary manufacturer or by a subsidiary of the brand manufacturer.

Exclusion From Best Price of Certain Sales at a Nominal Price (§ 447.508)

Pursuant to the terms of the national rebate agreement, manufacturers excluded from their best price calculations outpatient drug prices below ten percent of the AMP. The national rebate agreement did not specify whether this nominal price exception applied to all purchasers or to a subset of purchasers. Medicaid has used this definition since the start of the Medicaid Drug Rebate Program and Medicare Part B also adopted it in its April 6, 2004 interim final rule with comment period (69 FR 17935) that implemented the ASP provisions enacted in the MMA. It is also similar to the definition of nominal price in the VHCA.

We proposed to continue to define nominal prices as prices at less than 10 percent of the AMP in that same quarter; however, in accordance with the DRA, we further proposed to specify that the nominal price exception applies only when certain entities are the purchasers.

Section 6001(d)(2) of the DRA modified section 1927(c)(1) of the Act to limit the nominal price exclusion from best price to exclude only sales to certain entities and safety net providers. Specifically, it excluded from best price those nominal price sales to 340B covered entities as described in section 340B(a)(4) of the PHSA, ICFs/MR, and State-owned or operated nursing facilities. In addition, the Secretary has authority to identify as safety net providers other facilities or entities to which sales at a nominal price will be excluded from best price if he deems them eligible safety net providers based on four factors: the type of facility or entity, the services provided by the facility or entity, the patient population served by the facility or entity and the number of other facilities or entities eligible to purchase at nominal prices in the same service area.

Section 340B(a)(4) of the PHSA defines entities covered under that provision. Covered entities include: a federally qualified health center as defined in section 1905(l)(2)(B) of the Act; an entity receiving a grant under section 340A of the PHSA; a family planning project receiving a grant or contract under Section 1001 of the PHSA (42 U.S.C. § 300); an entity receiving a grant under subpart II of part C of title XXVI of the PHSA (relating to categorical grants for outpatient early intervention services for HIV disease); a State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHSA; a black lung clinic receiving funds under section 427(a) of the Black Lung Benefits Act; a comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Act; a Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988; an urban Indian organization receiving funds under the title V of the Indian Health Care Improvement Act, any entity receiving assistance under title XXVI of the PHSA (other than a State or unit of local government or an entity receiving a grant under subpart II of part C of title XXVI of the PHSA), but only if the entity is certified by the Secretary pursuant to section 340B(a)(7) of the PHSA; an entity receiving funds under section 318 of the PHSA (relating to treatment of sexually transmitted diseases) or section 317(j)(2) of the PHSA (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to section 340B(a)(7) of the PHSA; a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act) that (i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Act or eligible for assistance under the State plan under this title, (ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of the Act, and (iii) does not obtain covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement. We did not believe it necessary to elaborate further on these entities. We proposed to define ICF/MR, for purposes of the nominal price exclusion from best price, to mean an institution for the mentally retarded or persons with related conditions that provides services as set forth in 42 CFR 440.150. Additionally, we proposed to define nursing facility as a facility that provides those services set forth in 42 CFR 440.155.

The statute allows the Secretary to determine other facilities or entities to be safety net providers to whom sales of drugs at a nominal price would be excluded from best price. The Secretary's determination would be based on the four factors noted above established by the DRA. We considered using this authority to expand this exclusion to other safety-net providers. We considered proposing that we use the broader definition of safety net provider used by the Institute of Medicine (IOM). In its report, ''America's Health Care Safety Net, Intact but Endangered,'' the IOM defines safety-net providers as ''providers that by mandate or mission organize and deliver a significant level of healthcare and other health-related services to the uninsured, Medicaid and other vulnerable patients.'' We also considered proposing how the Secretary might use the four factors to allow the nominal price exclusion to best price to apply to other safety net providers. However, we believe that the entities specified in the statute are sufficiently inclusive and capture the appropriate safety net providers. Therefore, we chose not to propose to expand the

entities subject to this provision at this time. Additionally, we believe that adding other entities or facilities would have an undesirable effect on the best price by expanding the entities for which manufacturers could receive the best price exclusion beyond those specifically mandated by the DRA and lowering manufacturer rebates to the Medicaid Program. Because the statute gives the Secretary discretion not to expand the list of entities, we did not propose to do so in the proposed rule.

CMS has concerns that despite the fact that the DRA limits the nominal price exclusion to specific entities, the nominal price exclusion will continue to be used as a marketing tool. Historically, patients frequently remain on the same drug regimen following discharge from a hospital. Physicians may be hesitant to switch a patient to a different brand and risk destabilizing the patient once discharged from the hospital. We believe that using nominal price for marketing is not within the spirit and letter of the law. We considered crafting further guidance to address this issue. CMS invited comments from the public to assist us in ensuring that all aspects of this issue are fully considered.

In accordance with the provisions of the DRA, we proposed that the restriction on nominal price sales shall not apply to sales by a manufacturer of covered outpatient drugs that are sold under a DVA master agreement under section 8126 of title 38, United States Code.

We proposed a new § 447.508 in which we specified those entities to which a manufacturer of covered outpatient drugs may sell at nominal price and provided for the exclusion of such sales from best price.

Requirements for Manufacturers (§ 447.510)

On August 29, 2003, CMS finalized two of the provisions in the 1995 proposed rule through a final rule with comment period (68 FR 51912). We required manufacturers to retain records for data used to calculate AMP and best price for three years from when AMP and best price are reported to CMS. We also required manufacturers to report revisions to AMP and best price for a period not to exceed 12 quarters from the quarter in which the data are due. On January 6, 2004, we published an interim final rule with comment period replacing the three-year recordkeeping requirement with a ten-year requirement on a temporary basis (69 FR 508 (Jan. 6, 2004)). We also required that manufacturers retain records beyond the ten-year period if the records were subject to certain audits or government investigations. On November 26, 2004, we published final regulations (69 FR 68815) that require that a manufacturer retain pricing data for ten years from the date the manufacturer reports that period's data to CMS. We proposed to move the recordkeeping requirements at § 447.534(h) to § 447.510(f) and revise them by adding the requirement that manufacturers must also retain records used in calculating the customary prompt pay discounts and nominal prices reported to CMS.

Existing regulations at § 447.534(i) require manufacturers to report revisions to AMP and best price for a period not to exceed 12 quarters from the quarter in which the data were due. We proposed to move this provision to § 447.510(b) and revise it to require manufacturers to also report revisions to customary prompt pay discounts and nominal prices for the same period.

In order to reflect the changes to AMP as set forth in the DRA, we proposed allowing manufacturers to recalculate base date AMP in accordance with the definition of AMP in § 447.504(e) of this subpart. Base date AMP is used in the calculation of the additional rebate described in section 1927(c)(2) of the Act. This additional rebate is defined as the difference between the quarterly AMP reported to CMS and the base date AMP trended forward using the CPI–U. We proposed this amendment so that the additional rebate would not increase due to changes in the definition of AMP. We proposed giving manufacturers an opportunity to submit a revised base date AMP with their data submission for the first full calendar quarter following the publication of the final rule. We proposed to allow manufacturers the option to decide whether they will recalculate and submit to CMS a base date AMP based on the new definition of AMP or submit their existing base date AMP. We were giving manufacturers this option because we were aware that some manufacturers may not have the data needed to recalculate base date AMP or may find the administrative burden to be more costly than the savings gained.

Under section 1927(b)(3)(A) of the Act and the terms of the national rebate agreement, manufacturers that sign the national rebate agreement must supply CMS with a list of all product data (for example, date entered market, drug category of single source, innovator multiple source, or noninnovator multiple source) and pricing information for their covered outpatient drugs. In accordance with the statute, we proposed requiring manufacturers to report AMP and best price to CMS not later than 30 days after the end of the rebate period.

Section 6001(b)(1) of the DRA amended section 1927(b)(3)(A)(i) of the Act by adding ''month of a'' before ''rebate period.'' Section 6003(a) of the DRA restructured section 1927(b)(3)(A)(i) of the Act. The statute, as amended by these provisions, can be read in different ways. One interpretation is that the revisions made by section 6003(a) of the DRA supersede the revisions made by section 6001(b)(1) of the DRA, effectively eliminating the requirement that manufacturers report data to CMS on a monthly basis. However, we did not believe that this reading is the better reading of the statute. It is unreasonable to presume that Congress would simultaneously establish and render meaningless a new provision of law and we do not propose to adopt this interpretation. Another interpretation is that the revisions made by section 6001(b)(1) of the DRA, when read with the amendments made by section 6003 of the DRA, create a new requirement that AMP, best price, and customary prompt pay discounts be reported on a monthly basis. However, there is no compelling evidence in the legislative history which indicates that Congress intended to change the rebate period from quarterly to monthly. Best price is reported to CMS quarterly for purposes of our calculation of the unit rebate amount (URA) for single source and innovator multiple source drugs. While the DRA requires AMPs to be reported and disclosed to States on a monthly basis, it did not establish any similar monthly use for best price or customary prompt pay discounts. For these reasons, we proposed to interpret section 6001(b) of the DRA to require that manufacturers report only AMP to CMS on a monthly basis beginning January 1, 2007. To implement this provision, we proposed requiring in § 447.510(d) that manufacturers must submit monthly AMP to CMS not later than 30 days after each month. We also proposed requiring manufacturers to report quarterly AMP, best price, and customary prompt pay discounts on a quarterly basis.

We proposed that the monthly AMP will be calculated the same as the quarterly AMP, with the following exceptions. The time frame represented by the monthly AMP would be one calendar month instead of a calendar quarter and once reported, would not be subject to revision later than 30 days after each month. Because we recognized that industry pricing practices sometimes result in rebates or other price concessions being given by manufacturers to purchasers at the end

of a calendar quarter, if the monthly AMP were calculated simply using sales in that month, these pricing practices might result in fluctuations between the AMP for the first two months and the AMP for the third month in a calendar quarter. In order to maximize the usefulness of the monthly AMP and minimize volatility in the prices, we proposed allowing manufacturers to rely on estimates regarding the impact of their end-of-quarter rebates or other price concessions and allocate these rebates or other price concessions in the monthly AMPs reported to CMS throughout the quarter. We considered applying this same methodology to other cumulative rebates or other price concessions over longer periods of time, but were not certain that such rebates or other price concessions could be allocated with respect to monthly AMP calculations. We invited comments on allowing the use of 12-month rolling average estimates of all lagged price concessions for both the monthly and quarterly AMP. We also considered allowing manufacturers to calculate the monthly AMP based on updates of the most recent three-month period (that is, a rolling three-month AMP). While this methodology may minimize volatility in the data, we believed it would be fairly complex for manufacturers to operationalize. We encouraged comments on the appropriate methodology for calculating monthly AMP.

Section 6001(b)(2)(C) of the DRA amended the confidentiality requirements at section 1927(b)(3)(D) of the Act by adding an exception for AMP disclosure through a Web site accessible to the public. The statute does not specify that this exception only applies to monthly AMP; therefore, we also proposed to make the quarterly AMP publicly available. We noted that the quarterly AMP would not necessarily be identical to the monthly AMP due to the potential differences in AMP from one timeframe to the next.

Section 6001(d)(1) of the DRA modified section 1927(b)(3)(A)(iii) of the Act by adding a requirement that manufacturers report nominal prices for calendar quarters beginning on or after January 1, 2007 to the Secretary. To implement this provision, we proposed to require that manufacturers report nominal price exception data to CMS on a quarterly basis. We further proposed that nominal price exception data shall be reported as an aggregate dollar amount which includes all nominal price sales to the entities listed in § 447.508(a) of this subpart for the rebate period.

Section 1927(b)(3)(C) of the Act describes penalties for manufacturers that provide false information or fail to provide timely information to CMS. In light of these requirements, we proposed to require that manufacturers certify the pricing reports they submit to CMS in accordance with § 447.510. We proposed to adopt the certification requirements established by the Medicare Part B Program for ASP in the interim final rule with comment period published on April 6, 2004. Each manufacturer's pricing reports would be certified by the manufacturer's chief executive officer (CEO), chief financial officer (CFO), or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

We proposed that all product and pricing data, whether submitted on a quarterly or monthly basis, be submitted to CMS in an electronic format. When the Medicaid Drug Rebate Program was first implemented in 1991, electronic data transfer was one of three data submission options as the use of such electronic media was not yet as commonplace as it is today. Due to the new monthly data reporting requirements and additional quarterly data reporting requirements, we proposed to require manufacturers to use one uniform data transmission format to transmit and collect these data. We stated that CMS will issue operational instructions to provide additional guidance regarding the new electronic data submission requirements.

Aggregate Upper Limits of Payment (§ 447.512)

We proposed that the existing § 447.331 be revised and redesignated as a new § 447.512. We proposed to revise subsection (a) to clarify that the upper limit for multiple source drugs applies in the aggregate. We also proposed to update several cross-references to provisions in subpart I.

Upper Limits for Multiple Source Drugs (§ 447.514)

We proposed that the existing § 447.332 be revised in a new § 447.514.

A. Upper Limits for Multiple Source Drugs

Existing regulations at 42 CFR 447.331, 447.332 and 447.334 address upper limits for payment of drugs covered under the Medicaid Program. We proposed to redesignate existing regulations at §§ 447.331, 447.332, and 447.334 as new regulations at §§ 447.512, 447.514, and 447.516, respectively.

Existing regulations at § 447.332(a)(1)(i) state that an upper limit for a multiple source drug may be established if all of the formulations of the drug approved by the FDA have been evaluated as therapeutically equivalent in the current edition of the FDA's publication, ''Approved Drug Products with Therapeutic Equivalence Evaluations.''

Section 1927(e)(4) of the Act, as amended by OBRA 90, expanded the criteria for multiple source drugs subject to FUL reimbursement. Specifically, the statute required CMS to establish an upper payment limit for each multiple source drug when there are at least three therapeutically and pharmaceutically equivalent multiple source drugs, regardless of whether all additional formulations are rated as such. Effective January 1, 2007, the DRA changed the requirement such that a FUL must be established for each multiple source drug for which the FDA has rated two or more products as therapeutically equivalent.

Currently, if all formulations of a multiple source drug are identified as A-rated in the FDA's publication, ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' at least two formulations must be listed in that publication for CMS to establish a FUL for that drug. If all formulations of a multiple source drug are not A-rated, there must be at least three A-rated versions of the drug listed in ''Approved Drug Products with Therapeutic Equivalence Evaluations'' for CMS to establish a FUL for the drug. If a product meets the FDA criteria described above, we confirm that at least three suppliers (that is, manufacturers, wholesalers, re-packagers, re-labelers or any other entity from which a drug can be purchased) list the drug in published compendia of cost information for drugs available for sale nationally (for example, Red Book, First DataBank, or Medi-Span). Then, using these pricing compendia, we select the lowest price (for example, the average wholesale price (AWP), wholesale acquisition cost (WAC), or direct price) from among the A-rated formulations of a particular drug and apply the formula described in existing § 447.332 to determine the FUL for that drug. FUL lists and changes to those lists based on the methodology set forth in the statute and regulations are issued periodically through Medicaid Program issuances and are posted on the CMS Web site.

By the term, ''therapeutically equivalent,'' we mean drugs that are identified as A-rated in the current edition of the FDA's publication,

''Approved Drug Products with Therapeutic Equivalence Evaluations'' (including supplements or successor publications). We proposed that the FUL will be established, as per section 1927(e)(4) of the Act, only using an ''A'' rated drug. However, we proposed to continue our current practice of applying the FUL to all drug formulations, including those drug versions not proven to be therapeutically equivalent, (for example, B-rated drugs). We believe it is appropriate to apply the FUL to B-rated drugs in order not to encourage pharmacies to substitute B-rated drugs to avoid the FUL in the case where B-rated drugs would be excluded from the FUL. Current regulation does not prohibit or exclude B-rated drugs from the FUL reimbursement.

We proposed revising the methodology we use to establish FULs for multiple source drugs based on the modifications made by the DRA. Specifically, sections 6001(a)(3) and (4) of the DRA changed the definition of multiple source drug established in section 1927(k)(7)(A)(i) of the Act to mean, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which is rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''). Also, section 6001(a)(1) of the DRA changed the requirement for a FUL to be established for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent to a requirement for a FUL when the FDA has established such a rating for two or more products. Therefore, we proposed in § 447.514(a)(1)(ii) that a FUL will be set when at least two suppliers (for example, manufacturers, wholesalers, re-packagers, or re-labelers) list the drug in a nationally available pricing compendia (for example, Red Book, First DataBank, or Medi-Span).

Existing regulations at § 447.332(b) specify that the agency's payments for multiple source drugs identified and listed must not exceed, in the aggregate, payment levels determined by applying, for each drug entity, a reasonable dispensing fee established by the agency, plus an amount that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national pricing compendia) that can be purchased by pharmacies in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

Section 6001(a)(2) of the DRA added section 1927(e)(5) to the Act that changed the formula used to establish the FUL for multiple source drugs. Effective January 1, 2007, the upper limit for multiple source drugs shall be established at 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent. The currently reported AMP is based on the nine-digit NDC and is specific only to the product code, combining all package sizes of the drug into the same computation of AMP. We proposed to continue to use the AMP calculated at the nine-digit NDC for the FUL calculation. In accordance with the DRA amendments, we will no longer take the individual 11-digit NDC, and thereby the most commonly used package size into consideration when computing the FUL because the currently reported AMP does not differentiate among package sizes.

We considered using the 11-digit NDC to calculate the AMP, which would require manufacturers to report the AMP at the 11-digit NDC for each package size and that doing so would offer other advantages to the program for FULs and other purposes. An AMP at the 11-digit NDC would allow us to compute a FUL based on the most common package size as specified in current regulations. We did not believe computing an AMP at the 11-digit NDC would be significantly more difficult than computing the AMP at the 9-digit NDC as the data from each of the 11-digit NDCs is combined into the current AMP. The AMP at the 11-digit NDC would also align with State Medicaid drug payments that are based on the package size. It would also allow us to more closely examine manufacturer price calculations and allow the States and the public to know the AMP for the drug for each package size. It would also allow 340B covered entities, which are entitled to buy drugs at a discount that is in part based on calculations related to AMP, to know what the pricing is for each package size, as 340B ceiling prices are established per package size. Calculating the AMP at the 11-digit NDC level permits greater transparency, and may increase accuracy and reduce errors for the 340B covered entities where prices are established for a package-size product rather than a per unit cost using the product's weighted average AMP.

However, the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that the Congress intended that AMP should be restructured to collect it by 11-digit NDCs. We proposed to use the currently reported 9-digit AMP for calculating the FUL. Changing the current method of calculating the AMP would require manufacturers to make significant changes to their reporting systems and have an unknown effect on the calculation of rebates in the existing Medicaid Drug Rebate Program. In State Medicaid payment systems that consider a number of different factors in deriving payment rates, we also believed it would offer minimal advantages. Furthermore, we expected that because the AMP is marked up 250 percent, the resultant reimbursement should be sufficient to reimburse the pharmacy for the drug regardless of the package size the pharmacy purchased and that to the extent it does have an impact, it would encourage pharmacies to buy the most economical package size.

We specifically asked for comments on the alternative approach of using the 11-digit NDC to calculate the AMP. We invited comments on the merits of using both approaches in calculating the AMP for the FUL.

In computing the FUL, we proposed that the monthly AMP submitted by the manufacturer will be used. Using the monthly AMP will provide for the timeliest pricing data and allow revisions to the FUL list on a monthly basis. It will also permit us to update the FULs on a timely basis in accordance with the provisions of section 1927(f)(1)(B) of the Act, wherein the Secretary, after receiving notification that a therapeutically equivalent drug product is generally available, shall determine within seven days if that drug product should have a FUL.

Section 6001(c)(1) of the DRA redefines AMP to exclude customary prompt pay discounts extended to wholesalers. Due to this change in the computation, and the requirement that monthly AMP first be reported as of January 1, 2007, we proposed that a FUL update of drugs, using the new methodology first be published when the revised AMPs are available and processed.

We proposed to adopt additional criteria to ensure that the FUL will be set at an adequate price to ensure that a drug is available for sale nationally as presently provided in our regulations. When establishing a FUL, we proposed to disregard the AMP of an NDC which has been terminated. The AMP of a terminated NDC will not be used to set the FUL beginning with the first day of the month after the actual termination

date reported by the manufacturer. This refinement may not capture all outlier AMPs that would offset the availability of drugs at the FUL price. It is possible that a product that is not discontinued may be available on a limited basis at a very low price. As a further safeguard to ensure that a drug is nationally available at the FUL price and that a very low AMP is not used by us to set a FUL that is lower than the AMP for other therapeutically and pharmaceutically equivalent multiple source drugs, we proposed to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP for that drug. That is to say, that the AMP of the lowest priced therapeutically equivalent drug will be used to establish the FUL, except in cases where this AMP is more than 70 percent below the second lowest AMP. In those cases, the second lowest AMP will be used in the FUL calculation. We proposed to use this percentage calculation as a benchmark to prevent an outlier price from determining the FUL, but invited comments as to whether this percentage is an appropriate measure to use. We did consider other options, such as 60 percent below the next highest AMP so that at least drugs of two different manufacturers would be in the FULs group, but we were concerned that this percentage was insufficient to encourage competition where the cost of a particular drug was dropping rapidly. We also considered a test of a drug priced 90 percent below the next lowest priced drug, in line with how we look on nominal prices, as an indicator that the manufacturer was offering this drug on a not-for-profit basis. However, we noted that nominal price relates to best price for some sales and it is unlikely a manufacturer would sell all of its drugs at this price. We welcomed suggestions about other means to address outliers and whether outliers should be addressed at all.

We proposed an exception to the 30 percent carve-out policy when the FUL group only includes the innovator single source drug and the first new generic in the market, including an authorized generic. In this event, we would not apply the 30-percent rule as we believe the DRA intends that a FUL be set when new generic drugs become generally available so as to encourage greater utilization of a generic drug when the price is set less than its brand name counterpart.

We invited comments from the public on all issues set forth in this subpart. We invited suggestions on how best to accomplish the goal of ensuring that the use of AMP in calculating the FUL will ensure that a drug is available nationally at the FUL price. We asked commenters to please submit data supporting their proposals when available. Upper Limits for Drugs Furnished as Part of Services (§ 447.516)

We proposed that the existing § 447.334 be redesignated as a new § 447.516.

State Plan Requirements, Findings and Assurances (§ 447.518)

We proposed that the existing § 447.333 be redesignated as a new § 447.518.

FFP: Conditions Relating to Physician-Administered Drugs (§ 447.520)

Prior to the DRA, many States did not collect rebates on physician-administered drugs when they were not identified by NDC number because the NDC number is necessary for States to bill manufacturers for rebates. In its report, ''Medicaid Rebates for Physician Administered Drugs,'' (April 2004, OEI–03–02–00660), the OIG reported that, by 2003, 24 States either required providers to bill using NDC numbers or identified NDC numbers using a Healthcare Common Procedure Coding System (HCPCS)-to-NDC crosswalk for physician-administered drugs in order to collect rebates. Four of the 24 States were able to collect rebates for all physician-administered drugs, both single source and multiple source drugs (one State only collected these rebates from targeted providers). Section 6002 of the DRA added sections 1927(a)(7) and 1903(i)(10)(C) to the Act to require that States collect rebates on certain physician-administered drugs in order for FFP to be available for these drugs.

Section 1927(a)(7)(A) of the Act requires that, effective January 1, 2006, in order for FFP to be available, States must require the submission of utilization data for single source physician-administered drugs using HCPCS codes or NDC numbers. (HCPCS codes are numeric and alpha-numeric codes assigned by CMS to every medical or surgical supply, service, orthotic, prosthetic and generic or brand name drug for the purpose of reporting healthcare transactions for claims billing. Physician-administered drugs are assigned alpha-numeric HCPCS codes, and are commonly referred to as J-codes. However, physician-administered drugs are also coded using other letters of the alphabet. For this reason, we referred to the coding system, HCPCS, as opposed to one set of alpha-numeric codes in our discussion of section 6002 requirements.) If States collect HCPCS codes for single source drugs, they can crosswalk these codes to NDC numbers because most HCPCS codes for single source drugs include only one NDC in order to collect rebates.

Section 1927(a)(7)(C) of the Act requires that, beginning January 1, 2007, States must provide for the submission of claims data with respect to physician-administered drugs (both single source and multiple source drugs) using NDC numbers, unless the Secretary specifies that an alternative coding system can be used. The Secretary did not propose to specify an alternative coding system because we believe that NDC numbers are well established in the medical community and provide States the most useful information to collect rebates.

Section 1927(a)(7)(B) of the Act requires the Secretary, by January 1, 2007, to publish a list of the 20 multiple source physician-administered drugs with the highest dollar volume dispensed under the Medicaid Program. We proposed that the list be developed by the Secretary using data from the Medicaid Statistical Information System and published on the CMS Web site.

Section 1927(a)(7)(B)(ii) of the Act (when read with other DRA amendments) requires that, effective January 1, 2008, in order for FFP to be available, States must provide for the submission of claims for physician-administered multiple source drugs using NDC numbers for those drugs with the highest dollar volume listed by the Secretary.

We proposed, for the purpose of this section, that the term ''physician-administered drugs'' be defined as covered outpatient drugs under section 1927(k)(2) of the Act (many are also covered by Medicare Part B) that are typically furnished incident to a physician's service. These drugs are usually injectable or intravenous drugs administered by a medical professional in a physician's office or other outpatient clinical setting. Examples include injectables: lupron acetate for depot suspension (primarily used to treat prostate cancer), epoetin alpha (injectable drug primarily used to treat cancer), anti-emetic drugs (injectable drug primarily used to treat nausea resulting from chemotherapy) intravenous drugs primarily used to treat cancer (paclitaxel and docetaxel), infliximab primarily used to treat rheumatoid arthritis, and rituximab primarily used to treat non-Hodgkin's lymphoma. We believed that some oral self-administered drugs (administered in an outpatient clinical setting), such as oral anti-cancer drugs, oral anti-emetic drugs should also be included in the designation of physician-administered

drugs consistent with Part B policy and sections 1861(s)(2)(Q) and (T) of the Act.

Section 1927(a)(7)(D) of the Act allows the Secretary to grant States extensions if they need additional time to implement or modify reporting systems to comply with this section. We did not propose any criteria for reviewing these extension requests as we expected that most, if not all States would be able to meet the statutory deadlines for collection of NDC numbers on claims. Most States are already collecting rebates for single source drugs that are provided in a physician's office. For multiple source drugs, the States have nearly two years following enactment of the DRA before FFP would be denied for the 20 multiple source drugs specified by the Secretary as having the highest dollar volume.

We expected that States would require physicians to submit all claims using NDC numbers, as using multiple billing systems would be burdensome for physicians and States. This would also advantage States because rebates would be collectible on all physician-administered drugs.

For States not currently billing manufacturers for rebates on single source drugs, we believed that the Medicare Part B crosswalk may be helpful to crosswalk HCPCS codes to NDC numbers. This crosswalk may be found on the CMS Web site at *http://new.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp.*

To implement the provisions set forth in section 6002, we propose a new § 447.520. In § 447.520(a), we proposed to require States to require that claims for physician-administered drugs be submitted using codes that identify the drugs sufficiently to bill a manufacturer for rebates in order for the State to receive FFP. In § 447.520(b), we proposed requiring States to require providers to submit claims using NDC numbers. In § 447.520(c), we proposed allowing States that require additional time to comply with the requirements of this section to apply to the Secretary for an extension.

III. Analysis of and Responses to Public Comments

We received over 1,600 timely items of correspondence that addressed the issues in the proposed rule. We received comments from pharmacists and other health care providers, drug manufacturers, membership organizations, law firms, PBMs, consultants, State agencies, members of Congress, and individuals. A summary of the major issues and our responses follow.

General Comments

We received many comments expressing general support for the provisions of the proposed rule. One commenter specifically indicated support for Federal efforts that are designed to positively affect the affordability of and access to prescription drugs and healthcare professionals. Other commenters indicated support for CMS' efforts to clarify the definitions of significant terms as well as the treatment of various types of sales and prices in manufacturer calculations.

Comment: Commenters asked CMS to explain how we will reconcile the national rebate agreement with this final rule, which substantially changes a number of the definitions and requirements of the agreement. One commenter asked CMS to specify that it will not incorporate into a revised national rebate agreement any definitions or requirements until such provisions have been subject to notice-and-comment rulemaking.

Response: The national rebate agreement provides that manufacturers should comply with the Medicaid rebate statute, any amendments to that statute, and regulations issued by the Secretary to implement the statute. We will consider revising the national rebate agreement in accordance with applicable Federal statutes and regulations.

Effective Date

Comment: Many commenters asked CMS to clarify that the provisions of this final rule will be applied prospectively. One commenter specifically asked for clarification of the effective date of the provision regarding the treatment of Medicaid sales in AMP. Another commenter expressed concern that CMS should have published the proposed rule by September 1, 2006 to provide adequate time for community pharmacies to prepare for the implementation of the changes in the Medicaid Program.

Response: In this final rule, we are bringing together existing and new regulatory requirements in one cohesive subpart. Unless otherwise indicated, these regulations are effective on October 1, 2007. However, this rule is not designed to delay the effective date with respect to statutory provisions, regulations or policies that are already in effect. Those existing requirements that remain unchanged in this final rule will continue in force. In addition, to the extent that this rule addresses previous policies already established by the Agency, those policies will remain in effect. Further, the DRA provided specific effective dates for certain provisions as noted in the preamble to the proposed rule.

Comment: Many commenters asked us to consider delaying implementation of the final rule. Several commenters suggested that we delay the overall effective date of this final rule at least six months from the date of publication in order to provide manufacturers with necessary time to revise their systems and retrain personnel on the requirements of this final rule. One commenter noted that government pricing system vendors will need between six months to one year after the effective date of this final rule to code, implement and test the required computer changes.

Other commenters suggested a delay of four quarters for the entire rule. One commenter suggested we delay finalizing the rule until more detailed information regarding AMP and the established FUL is made available to the pharmacy industry; another commenter suggested a delay of 90 days after the release of the new FUL source file. Another commenter suggested a 180-day compliance period followed by a 90-day testing period, during which time the AMP may only be used for research and verification purposes only.

A few commenters specifically asked that we delay the implementation of the requirement that manufacturers submit a base date AMP. Another commenter noted that the practical implication of treating inpatient and outpatient hospital sales differently for AMP purposes would mean that hospital contracts for the purchase of prescription drugs would need to be renegotiated, which could necessitate a delay in the implementation of the AMP rule for six months to a year.

Response: The DRA provides specific timeframes for the implementation of many of the major provisions addressed in this final rule. Because the DRA was signed into law on February 8, 2006, we believe there was sufficient time for affected parties to prepare for the implementation of these provisions. In addition, CMS issued guidance to States and manufacturers in December, 2006 to address many of the details pertaining to the drug provisions in the DRA. Accordingly, we are not convinced that there is a compelling reason to delay implementation of the provisions of this final rule beyond the October 1, 2007, effective date.

Comment: One commenter recommended that CMS do more to educate Medicare participating

providers, particularly pharmacies, about the changes in reimbursement addressed in this final rule.

Response: We received hundreds of comments on the proposed rule from individual pharmacy providers and national pharmacy membership organizations. Therefore, we believe there is already a high level of awareness about how the provisions of this final rule will impact pharmacies. In addition, we recognize the vital role that States play in the State-Federal Medicaid partnership by establishing relationships with pharmacy providers. States process pharmacy claims, maintain participating provider lists, and provide a variety of information directly to pharmacies. Therefore, we continue to believe that States are in a better position to provide any education to pharmacies to the extent that States may opt to revise their payment rates.

Comment: One commenter noted that if we had published the proposed rule earlier, it would have been easier for all affected parties to meet the deadlines mandated in the DRA. The commenter asked that CMS extend the comment period for the proposed rule for an additional 60 days. One commenter expressed concern that our proposed rule did not contain enough discussion of the issue of bundled sales in § 447.502 to provide reasonable notice and an opportunity for comment. The commenter suggests that CMS provide some alternative mechanism or forum for manufacturers and other interested parties to have more substantial and more specific communication with CMS on this issue.

One commenter urged CMS to issue an interim final rule with comment period instead of this final rule. The commenter expressed confusion regarding the correct interpretation of a number of provisions in the proposed rule. The commenter believes that an interim final rule with comment period would foster even greater dialog between the pharmaceutical industry and CMS.

Response: We disagree with the commenters regarding the need for an additional comment period for the vast majority of issues addressed in this final rule. However, as discussed below in greater detail, we have decided to publish the AMP and FUL outlier provision as a final rule with an extended comment period. This will allow for further public comment after the clarified definition of AMP becomes effective and it will give CMS an opportunity to further revise this provision.

Definitions (§ 447.502)

Bundled Sale

Comment: One commenter supported the inclusion of bundled sales in the determination of AMP.

Response: We appreciate the support for this provision and have retained this requirement in the final rule.

Comment: One commenter said that the proposed definition of what constitutes a bundled agreement is confusing. For example, it could be assumed that any type of comprehensive, multi-product portfolio contract could fit within CMS' proposed new definition. The commenter does not believe that this is CMS' intent. The commenter asked us to provide examples of bundled discounts that meet the final definition.

Response: We appreciate the comment and are including an example to provide some additional clarity. This example is for illustrative purposes only as the complexity of the market place prevents us from describing every situation.

Bundled Sale Example

Products A and B are sold under a bundled arrangement and have a combined bundled discount equal to $200,000 on total undiscounted sales of $1 million. If Product A has undiscounted sales of $600,000 and product B has undiscounted sales of $400,000, the manufacturer would allocate 60 percent of the combined bundled discount to Product A when calculating AMP. Forty percent of the combined bundled discount would be allocated to Drug B. The effective unit price of each product would be calculated by subtracting the discount allocated to each drug product ($600,000 − $120,000 = $480,000 for Product A; $400,000 − $80,000 = $320,000 for Product B) and dividing the result by the number of units for each drug product in the bundled sale.

Comment: Several commenters requested that CMS explicitly clarify how bundled discounts that meet the definition should be allocated across products.

Response: We appreciate this comment and have clarified the regulation at § 447.502 to specify how to allocate a discount. We have clarified that where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement should be proportionately allocated across all the drugs in the bundle.

Comment: Several commenters said that CMS should not include sales of the same drug in the definition of bundled sale. Another commenter requested that CMS confirm that the proposed ''bundled sale'' definition applies to sales of the same drug only where the manufacturer provides free or discounted goods contingent on a purchase requirement. The commenter stated that they can conceive of only one instance where sales of the same drug properly should be considered bundled—where the manufacturer provides a discount or free drugs if the purchaser agrees to buy a certain amount of the same drug; for example, ''buy nine, get one free'' or ''buy nine, get the tenth at half price.'' The commenter believes that such sales essentially represent volume discounts, and the discount properly should be apportioned across the drugs provided by the manufacturer in the bundled (or contingent) arrangement. The commenter stated that the Medicaid rebate statute mandates such a result, requiring ''free goods that are contingent on any purchase requirement'' and volume discounts to be included in best price.

Response: A contingent arrangement involving drugs with different NDC–9s constitutes a bundled arrangement. A contingent arrangement involving drugs that share the same NDC–9 may constitute a bundled sale or volume discount. For these types of arrangements, the aggregate value of all the discounts must be allocated proportionately to all drugs within the bundled or volume discount arrangement.

Comment: One commenter stated that CMS should define ''drugs of different types'' as those with different 9-digit NDC codes and clarify that it is the aggregate value of all the bundled discounts that must be allocated across the drugs in the bundle.

Response: We agree. The definition of bundled sale provides that drugs are considered to be the same drug when they share a 9-digit NDC and are considered to be drugs of different types when their 9-digit NDCs are not the same.

Comment: A few commenters said that the proposed definition differs significantly from the definition of bundled sales provided in the Medicaid rebate agreement and that it contains a number of vague and ambiguous terms.

Response: The clarification of the bundled sales definition in this final rule does not create a new definition or impose new obligations that did not already exist under the Rebate Agreement. It has always been our policy that AMP and best price must be adjusted to reflect discounts offered in bundled sale arrangements to those

entities included in the determination of AMP and best price.

Comment: Several commenters said that CMS does not provide any explanation for why it proposes to change the definition of bundled sale, describe the policy objectives the changes are intended to promote, or provide sufficient specificity to give adequate notice and opportunity to comment. Should CMS wish to pursue this new definition, the commenters requested that CMS provide additional information regarding the new definition and another opportunity for comment before the definition is finalized. In the interim, CMS should clarify that manufacturers may continue to rely on the definition included in the national rebate agreement.

Response: We believe that it is necessary to clarify the definition of a bundled sale because of questions we have received from manufacturers. Our policy objective is unchanged from that set forth in the rebate agreement inasmuch as manufacturers are required to report the effect of these and other arrangements that affect price on AMP and best price. The proposed rule was designed to clarify the definition in the rebate agreement and program guidance and to specify that AMP and best price must be adjusted to reflect discounts, rebates or other price concessions for all drugs in a bundled or contingent sale arrangement.

Comment: One commenter said that there are important implications that CMS should evaluate regarding the proposed new definition of ''bundled sale'' given that it differs significantly from that term's definition in the Medicaid Drug Rebate Agreement. The commenter believes that the new proposed definition would not improve the accuracy of rebate calculations. Since there is no compelling policy rationale for the new proposed definition and there is no demonstrated problem with the current definition, the proposed change does not appear necessary and serves no purpose.

Response: We believe that this clarification will enable manufacturers to better understand what constitutes a bundled sale and how discounts offered with bundled sales must be allocated when reporting the AMP and best prices for drugs in the bundle.

Comment: One commenter requested that CMS clarify how discounts should be allocated when a bundled sale arrangement includes both contingent and non-contingent discounts and rebates.

Response: We consider all contingent and non-contingent drugs to be within the bundled sale if any drug must be purchased in order to get a discount on any drug in the bundle regardless of whether any drug is purchased at full price. Additionally, a bundled sale exists where the discounts available are greater than those which have been received had the drug products been purchased separately and apart from the bundled arrangement.

Comment: Several commenters recommended that CMS apply the bundled sale definition only in situations where a manufacturer cannot determine the price of a specific item and clarify how discounts involved in a bundled sale are to be allocated proportionately when such allocation is needed.

Response: We disagree. To assure the consistent application of this policy by all manufacturers, we believe that the definition, as clarified in this final rule at § 447.502, is needed to clearly and uniformly specify what constitutes a bundled sale and how discounts must be allocated across products in the bundle.

Comment: Another commenter expressed disappointment with the lack of meaningful detail in the proposed rule and noted that it essentially mirrors the bundling proposal CMS articulated last year for ASP in the 2007 Medicare Physician Fee Schedule Proposed Rule.

Response: We have provided further details on the application of this policy in this final rule. We believe a consistent methodology for addressing bundled sales in the Medicaid and Medicare Part B programs will reduce the burden and likelihood of errors for manufacturers calculating and reporting Medicaid rebate prices and ASP.

Comment: One commenter requested that CMS clarify that the new definition does not apply for periods prior to the effective date of this final rule.

Response: The provisions of this final rule do not create a new definition for bundled sales, but merely clarify the existing definition.

Comment: One commenter said that a figure for a prior period may be used as the basis of performance for the current period. For example, if the market share during the previous quarter was 20 percent, and an increase of 2 percent to 22 percent will gain the purchaser a discount of 5 percent, the commenter requested that CMS clarify whether the 5 percent discount should be reallocated to the sales in the prior quarter. The commenter asserts that the five percent discount need not be reallocated to the prior period.

Response: We have clarified in § 447.502 that the bundled sale applies to all drugs for all quarters including prior purchases used in the calculation of the discount for the contingent and non-contingent drugs. The data used in the determination of bundled sales arrangement should reflect and apply to the month or quarter being used in the determination, for example, in a situation where a manufacturer must achieve a certain market share of the product in one quarter to achieve a discount in the second quarter, CMS would treat the contingent discount as a bundle. The quarter for the prior purchase and current purchase would be used in the determination of the bundled sale arrangement.

Comment: One commenter said that discounts for bundled sales should be used only if the bundled sales are available to a majority of retail pharmacies, and the manufacturer should not include bundled sales available to institutional long-term care or mail order pharmacies.

Response: We do not agree. AMP is based on the ''average'' price paid to a manufacturer by wholesalers. It does not take into account prices available to a certain percentage of pharmacies. As discussed previously, the calculation of AMP is based on the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade. It is calculated to include the sale, as well as the discount, rebate, and other price concession associated with that sale, unless the discount, rebate, or other price concession is excluded by statute or regulation. Accordingly, in a bundled sale, the discount should be allocated to the drugs sold in the bundled sale arrangement, regardless of whether the discount is only available to certain retail pharmacies. We do not include institutional long-term care pharmacies in the retail pharmacy class of trade, while we do include mail order pharmacies.

Comment: One commenter suggested that the language should be clarified to remove room for interpretive error regarding the intent. The phrase ''allocated proportionately to the dollar value of the units'' should be slightly modified to state ''allocated proportionately to the *total* dollar value of the units'' and the word ''should'' in the last sentence should be amended to ''shall.''

Response: We agree and have revised the regulation text in § 447.502 to reflect the recommended changes.

Comment: One commenter stated that drugs placed on a formulary without a purchase requirement do not represent a discount on another product and should not be the basis for considering a sale to be bundled. The commenter further stated that the requirement that

the value of the discounts be proportionately allocated across all of the drugs in the bundle could open the door to manipulation of prices reported for bundled products. In addition, there is a large administrative burden for manufacturers to implement a system for aggregating and allocating discounts for bundled sales.

Response: We believe that the clarification of a bundled sale in this final rule at § 447.502 will ensure the accuracy of the AMP and best price calculation and reduce the opportunity for improper manipulation. A bundled sale exists where the rebate, discount, or price concession is ''conditioned'' upon additional purchase requirements. A bundled sale also exists where the discounts under the arrangement are greater than those which have been received had the drug products been purchased separately and apart from the bundled arrangement. The requirement to allocate discounts for bundled sales is not new for manufacturers that have been participating in the Medicaid drug rebate program. It has always been our policy that AMP and best price must be adjusted to reflect discounts offered as part of bundled sales. Therefore, we do not believe that this final rule places new obligations or additional administrative burdens on manufacturers.

Comment: A few commenters asked CMS to clarify that manufacturers may continue to rely on the definition of bundled sale in the national rebate agreement. Several commenters stated that the definition that is set forth in the national rebate agreement should be retained.

Response: The final regulation does not change the definition of bundled sales at § 447.502 but clarifies the existing definition.

Comment: A few commenters asked for additional guidance on how to treat a discount when its receipt is conditioned on utilization levels for multiple drug products.

Response: We have clarified in this final rule at § 447.502 that aggregate value of all discounts are to be allocated across all the products within the bundled arrangement.

Comment: One commenter stated that the concept of bundled sale does not seem to apply to market share arrangements and asked CMS to clarify what discounts on market based contracts are considered bundled sales for which discounts must be allocated.

Response: Discounts that are contingent on performance requirements, such as the achievement of market share may result in either a bundled arrangement or a volume discount. In such an arrangement, the aggregate or total value of all the discounts must be allocated to all the drugs in the bundle. For example, if Drug A is discounted to a purchaser if the purchaser achieves a set market share of Drug B, Drugs A and B are part of a bundled arrangement. The total discount for Drug A and any discount on Drug B must be proportionately allocated to both drugs.

Comment: One commenter expressed concern that CMS broadens the definition of ''bundled sale'' in the proposed rule to potentially include routine multiple drug sales to entities such as wholesalers and GPOs. The commenter does not believe that CMS intended to require that manufacturers allocate on an item-by-item basis the discounts on the price of the drug product had it been sold separately. The commenter recommends that CMS should not broaden the definition of the term ''bundled sale.''

Response: We disagree. A bundled sale occurs whenever a discount is given for the purchase of a group of drugs, contingent on the sale of another drug, a performance requirement such as market share arrangements or other purchases. Additionally, a bundled sale also exists where the discounts are greater than those which would have been received if the drugs were purchased separately and outside the bundled arrangement.

Comment: One commenter requested that CMS confirm the information provided in the Medicaid Drug Rebate Operational Training Guide that bundled sale arrangements are limited to arrangements that involve covered outpatient drugs.

Response: We have clarified in the regulation text at § 447.502 that a bundled sale arrangement involves an arrangement for the sale of covered outpatient drugs or some other purchase requirement.

Dispensing Fee

Comment: Some commenters asserted that the proposed definition of dispensing fee inferred a cost-based methodology not reflective of economies and competition in the marketplace. One commenter stated that the proposed definition of dispensing fee inadvertently infers that a pharmacy is entitled to a dispensing fee every time a covered outpatient drug is dispensed. The commenter goes on to say that such a definition does not assure efficient filling schedules for maintenance drugs, and encourages pharmacies to split prescribers' orders to receive more reimbursement, (for example, split a 30-day supply prescription into two 15-day supplies) particularly in the nursing home setting. Several commenters said that the definition of dispensing fee should incorporate the true cost of a pharmacist's time spent and other real costs such as rent and utilities. One commenter agreed that the definition should be sufficiently broad to accommodate any future costs that pharmacies might incur in dispensing prescriptions to Medicaid beneficiaries, and supported the terminology ''includes'' and, ''are not limited to'' in the final definition. One commenter would add ''professional'' fees to the definition. One commenter notes that the proposed definition refers to ''point of sale'' which seems to preclude dispensing to Medicaid populations in nursing homes, home and community based settings, etc. A more appropriate replacement would be ''point of service.'' Several commenters stated that the CMS definition of dispensing fee specifies that pharmacy costs do not include ''administrative cost incurred by the States in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies,'' and that this disclaimer is unnecessary and confusing as it is obvious that States' costs are not those of pharmacy providers.

Response: We provided a definition in order to assist States in their evaluation of factors used in establishing a reasonable dispensing fee. We did not intend to mandate a specific formula or methodology which States must use when calculating those fees. Therefore, we believe that the definition of dispensing fee is generally sufficient to capture the activities involved with the dispensing of a drug. However, we concur with the commenter about the need to recognize different service settings. Therefore, in the final rule, we are revising the definition of dispensing fee by adding ''or service'' after ''point of sale'' in § 447.502. States may also require the prescriptions be filled in specified quantities or to have other measures in place in order to avoid paying additional dispensing fees and encourage efficient filling schedules.

Comment: Many commenters expressed concern that CMS did not propose that States be required to pay a minimum dispensing fee to ensure that pharmacies' operating costs are covered. A few commenters stated that CMS should require States to make a specific finding that their dispensing fee is adequate to cover the cost of dispensing prescriptions to the Medicaid population. Other commenters suggested that we include a comprehensive and accurate definition of dispensing fee in the final rule, issue

formal guidance to States, and require States to conduct annual surveys or studies on the pharmacy provider's cost to dispense a prescription. One commenter stated that the pharmacy dispensing fee should be increased based on the Federal Cost of Living Adjustment. One commenter stated that CMS should advise States if we intend that some profit to the pharmacy be included in the dispensing fee. One commenter believed that the proposed rule should remain silent on the criteria for calculating dispensing fees.

Response: We do not agree that CMS should establish or mandate specific criteria for States to use when setting their dispensing fees. We proposed to define the term dispensing fee in regulation to assist States in their evaluation of factors in establishing a reasonable dispensing fee to providers, and we continue to believe that we should not mandate a specific formula or methodology which the States must use to determine the dispensing fee. We believe that the flexibility provided States is sufficient to allow them to set reasonable dispensing fees. We have not separately identified profit as a component of the dispensing fee as we believe the components of the dispensing fee we have already identified include a reasonable profit. We also do not agree that we should remain silent on the criteria for calculating dispensing fees as we believe it is important that pharmacies be reasonably compensated for the services they provide in dispensing a prescription.

Comment: A few commenters said that allowing the States to determine their dispensing fees, without Federal guidelines or mandates, would permit States with financial problems the latitude to arbitrarily cut dispensing fees. Another commenter suggested that CMS expeditiously approve State plan amendments (SPAs) that would increase pharmacies' professional fees so that they are closer to the actual cost of dispensing and provide a reasonable return. The commenter also proposed that CMS disapprove SPAs that decrease reimbursement paid to pharmacies for the ingredient cost component unless they increase the dispensing fee. One commenter suggested that the language of the proposed regulation should be changed to clarify that States will retain the authority to set reimbursement rates and dispensing fees for single source drugs. Several commenters stated that it is inappropriate for CMS to require States to increase dispensing fees to compensate for decreased reimbursement. One commenter noted that a State decided to raise dispensing fees for drugs reimbursed with FUL pricing, but admitted that until the State has experience with FUL prices, the State will not know if this dispensing fee compensates pharmacies appropriately.

Response: Dispensing fees must be approved as part of the Medicaid State plan. We encourage States to set reasonable dispensing fees to appropriately pay pharmacies for their costs. We will review State requests to change dispensing fees as to their reasonableness. States need to describe in their State plan the methodology they use to establish drug payment rates (which include dispensing fees) and demonstrate that their dispensing fees are reasonable. We will evaluate requests to change reimbursement for ingredient costs and dispensing fees separately but we encourage States to review their dispensing fees when they consider changes to reimbursement for ingredient costs.

Comment: Many commenters stated that dispensing fees must cover costs to safely and effectively dispense a prescription. Many commenters communicated the findings of surveys such as the Grant Thornton LLP National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies, prepared for the Coalition for Community Pharmacy Action (CCPA), published in January 2007, and accessible at *http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=7641&TEMPLATE=/CM/ContentDisplay.cfm* that reported the average national cost to dispense a prescription to be $10.50.

Response: We agree that States should set reasonable dispensing fees; however, we disagree that they should be required to use any specific methodology including the Grant Thornton study to do so. States may continue to use other sources to set dispensing fees, such as their own surveys. They may also look at dispensing fees paid to pharmacies by other payers or the amount of dispensing fees paid in neighboring States. CMS intends to permit States to retain the authority to set reasonable dispensing fees and exercise flexibility in setting their dispensing fees.

Comment: Several commenters pointed out that the Congressional Budget Office's (CBO) estimates of savings to the Medicaid Program based on the provisions of the DRA, assumed that States will raise dispensing fees to mitigate the effects of the revised payment limit on pharmacies.

Response: CMS will review any State plan amendments or revisions to drug payment rates, including any revisions to the dispensing fees, to assure compliance with the applicable statutes and regulations.

Comment: Several commenters stated that CMS should specifically instruct States to establish higher reimbursement for specialty pharmacies, as Medicare Part B has done. Citing section 303(e)(1) of the MMA, which created a furnishing fee for certain blood clotting factors, some commenters felt that a separate furnishing fee should be established for Medicaid providers who dispense prescriptions that may require more time or resources for handling, storing, or delivery.

Response: We do not agree. CMS believes its proposal/provision provides a definition which is reasonable. While CMS appreciates the comment, the MMA provision is not applicable to Medicaid.

Comment: Some commenters stated that a formula for prescription drug reimbursement should include a dispensing and/or education fee as an actual part of the reimbursement. Another commenter stated that a percentage standard or a flat fee should be added to prescription reimbursement to achieve an adequate reimbursement to pharmacy providers.

Response: We disagree. The dispensing fee is determined separately from the cost of the drug ingredient and covers the cost of dispensing the drug as defined in this regulation. As discussed in the proposed rule, dispensing fees are related to the transfer or possession of the drug to the beneficiary. If dispensing fees were bundled with ingredient cost, it would be difficult for CMS or States to determine whether the dispensing fees, as discussed in this regulation, are reasonable.

Comment: Many commenters expressed concern that current dispensing fees, in light of the DRA provisions that change ingredient reimbursement for FUL drugs to a methodology based on AMP, will not cover the pharmacy provider's cost of dispensing medications to the Medicaid population and that, as a result, the dispensing fee should be increased for generic drugs. One commenter asserted that retail pharmacies that serve large numbers of Medicaid beneficiaries may be particularly hard hit. One commenter stated that the proposed rule suggested that the States examine the market realities and adjust their dispensing fee to compensate pharmacies, and while this was an important correction to the reimbursement system, it did not solve the underlying problem presented by an unreasonable system for calculating the FUL.

Response: We believe that States are in the best position to identify and

address what is a reasonable dispensing fee and we encourage them to evaluate and set such dispensing fees. Since the dispensing fee is meant to reflect the cost of dispensing a drug, it should not be affected by the determination of ingredient cost. As we have said elsewhere in this regulation, we believe the system for calculating the FUL will permit pharmacies to be reasonably compensated for drugs they dispense to Medicaid beneficiaries.

Estimated Acquisition Cost

Comment: One commenter suggested that CMS revise the definition of estimated acquisition cost (EAC) by adding at the end, ''within the previous twelve months as provided to State Medicaid agencies by the Centers for Medicare & Medicaid Services.'' This would provide States with more specific guidance and a source from which to draw the information regarding the package size of drug most frequently purchased by providers.

Response: The DRA did not modify the definition of EAC and we have not made any modifications in this regulation. Additionally, States currently report all utilization information to CMS by package size; however, we do not sort by most frequently dispensed or utilized package size. This information is posted on our Web site at *http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp*.

Innovator Multiple Source Drug

Comment: One commenter noted that our definition of innovator multiple source drug does not address the situation where, at the end of the life cycle of a particular drug product, the only covered outpatient drug remaining on the market in the U.S. happens to be a version of the product that was originally approved by the FDA under an abbreviated NDA (ANDA). The commenter also noted that we did not address products that came to market before 1962 and remain commercially available today. The commenter suggested that CMS revise the definition of innovator multiple source drugs to address these situations. Other commenters requested that we revise the definition of innovator multiple source drug to include those drugs approved under a biological license application (BLA).

Response: By statute, an innovator multiple source drug is a drug that was originally marketed under an original NDA approved by the FDA. We do not believe that it would be consistent with the statute to modify the definition to include drugs marketed under an ANDA. To clarify the distinction between multiple source drugs approved under an ANDA and multiple source drugs approved under an NDA, we are adding a definition of noninnovator multiple source drug in this final rule. Noninnovator multiple source drugs are defined as multiple source drugs marketed under an ANDA or an abbreviated antibiotic drug application.

In response to the comments regarding drugs that entered the market prior to 1962, we believe these drugs are not classified as innovator multiple source drugs unless they are marketed under an NDA. Further, we recognize the need to classify drugs that entered the market prior to 1962 that are not marketed under an NDA. Therefore, we are further defining noninnovator multiple source drugs as drugs that entered the market prior to 1962 that were not originally marketed under an original NDA.

In response to comments regarding drugs approved under a BLA, we believe the statutory definition of covered outpatient drug in section 1927 of the Act is sufficient to address these concerns without further revision to the definition of innovator multiple source drug.

Manufacturer

Comment: One commenter recommended that the definition of manufacturer be narrowed such that entities that repackage drugs simply for distribution to retail pharmacies not be considered manufacturers. The commenter noted that these retail pharmacy service repackagers prepare ''unit of use'' quantities in a highly efficient manner, increasing the efficiencies of prescription dispensing for retail pharmacies, and they should not be responsible for signing rebate agreements with the Secretary of HHS or paying rebates to Medicaid.

Response: The statutory definition of manufacturer clearly includes such repackagers, so we are not excluding them from the definition of manufacturer in this final rule.

Comment: One commenter asked CMS to clarify the meaning of ''legal title'' in the definition of manufacturer. Specifically, if a product is sold from one manufacturer to another, are the manufacturers required to calculate data based on both labeler codes?

Response: Except as noted in the regulatory provisions pertaining to authorized generics, we would consider the manufacturer holding legal title to the drug to be the labeler whose NDC appears on the label at the time the drug is dispensed. This is also the labeler responsible for paying rebates.

Comment: One commenter suggested that ''manufacturer'' should include an entity that does not possess legal title to the NDC but that markets a drug through a private labeling arrangement.

Response: This final rule incorporates the definition in the proposed rule with respect to drugs subject to private labeling arrangements, and provides that, with respect to drugs, the term ''manufacturer'' will also include the entity that does not possess legal title to the NDC.

Multiple Source Drug

Comment: One commenter suggested that CMS revise the definition of multiple source drug in two ways. First, the commenter asked us to consider the situation where, at the end of the life cycle of a particular drug product, the only covered outpatient drug remaining on the market in the U.S. happens to be a version of the drug that was originally approved by the FDA under an ANDA. Second, the commenter asked us to include products that came to market before 1962 and remain commercially available today.

Response: Multiple source drugs that are marketed under an ANDA are considered noninnovator multiple source drugs. We have added a definition of noninnovator multiple source drugs to this final rule, which we believe addresses this concern as well as the concern regarding products that came to market before 1962.

Comment: One commenter asked us to consider adding products approved under BLAs to the definition of multiple source drug.

Response: The definition of covered outpatient drug in section 1927 of the Act includes biological products, other than vaccines, that are licensed under section 351 of the PHS Act. Drugs that are approved under this statutory provision include products approved under BLAs.

Comment: A few commenters asked us to consider revising or creating separate definitions for multiple source drugs. One component of the definition should define this term with respect to the establishment of the FUL since the FUL will be applied on a particular date of service on a pharmacy claim, while the other component would address this term with respect to the payment of rebates. One of the commenters recommended maintaining the current definition of multiple source drug listed at 42 CFR § 447.301 with a note specifying that FULs are placed on multiple source drugs complying with

the requirements in §§ 447.512 and 447.514.

Response: We disagree with the commenters about the need to revise the definition of multiple source drugs in order to address the application of that term in the context of the FULs. The DRA amended the definition to require that two or more drug products be rated as therapeutically equivalent, pharmaceutically equivalent, or bioequivalent. The DRA also requires CMS to calculate a FUL for each drug that qualifies as a multiple source drug. We believe the regulatory provisions at § 447.514 are sufficient to address the application of the FULs to multiple source drugs.

Comment: One commenter supported the revised definition of multiple source drug, which requires only one other covered outpatient drug to be rated as therapeutically equivalent, pharmaceutically equivalent, and bioequivalent.

Response: We appreciate the support for this definition and agree because the FUL will apply to more drugs.

National Drug Code (NDC)

Comment: A few commenters asked for clarification of the relationship between the 10-digit NDC maintained by the FDA and the 11-digit NDC referenced in the proposed rule. One of these commenters suggested that we define NDC as ''the segmented, 10-digit numerical code maintained by the FDA that indicates the labeler, product and package size, and that for commercial and technical reasons, must be converted to an unsegmented 11-digit number by inserting a place-holding zero.'' The commenter also noted that the FDA recently published a proposed rule which contemplates changes to the NDC system maintained by the FDA and recommended that CMS consult with FDA prior to finalizing this rule so that, to the extent possible, the agencies can determine how best to harmonize the definition of NDC. Other commenters expressed support for our proposed definition of NDC, particularly as it pertains to 11-digits vs. 9-digits.

Response: We are retaining the use of the 11-digit NDC in the Medicaid Drug Rebate Program. Because we have used the 11-digit code since the start of the Medicaid Drug Rebate Program, we do not believe that it is necessary to clarify this further in the regulation. If the FDA makes changes to the NDC number, at some point in the future, we will determine the effect of this change on the program and respond accordingly.

Rebate Period

Comment: One commenter urged CMS to redefine the rebate period as a monthly period rather than a quarterly period. The commenter cited the new requirement that AMP be reported monthly as support for this change, in addition to the observation that Congress did not explicitly prohibit such a change in the provisions of the DRA.

Another commenter indicated support for maintaining a quarterly rebate period. The commenter noted that in addition to the lack of legislative intent to change the rebate period, establishing a different or more frequent time period would place unnecessary burdens on changing drug manufacturers' government reporting systems without additional public benefit.

Response: We don't see a need to redefine the rebate period at this time, so we are maintaining a quarterly rebate period.

Single Source Drug

Comment: A few commenters expressed concern with our definition of single source drug. The commenters noted that certain FDA regulations require biologic products to be approved under a BLA under section 351 of the PHS Act. The proposed definition of single source drug excludes these products. The commenters suggested we revise the definition to include these products as follows: ''a covered outpatient drug that is produced or distributed under an original NDA or BLA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA or BLA.''

Another commenter noted that our definition does not address the situation where, at the end of the life cycle of a particular drug product, the only covered outpatient drug remaining on the market in the U.S. happens to be a version of the product that was originally approved by the FDA under an ANDA. The commenter also noted that we did not address products that came to market before 1962 and remain commercially available today. The commenter suggested CMS revise the definition of single source drugs to address these situations.

Response: As noted above, we have added a definition of noninnovator multiple source drug to this final rule in order to clarify the distinction between drugs approved under an NDA and drugs approved under an ANDA. We concur with the commenters about the need to address products approved under a BLA in the definition of single source drug, and have revised the definition in § 447.502 accordingly. However, we believe the statutory definition of covered outpatient drug in section 1927 of the Act is sufficient to address the remainder of these concerns without further revision to the definition of single source drug.

Terms Not Defined in the Proposed Rule

Comment: A few commenters recommended that CMS include in this final rule a definition of covered outpatient drug that addresses both over-the-counter (OTC) products and prescription drug products. The commenter also noted that the statutory definition of covered outpatient drug incorporates grandfathered products and drugs still undergoing the Drug Efficacy Study Implementation (DESI) review process.

Response: We believe the statutory definitions of covered outpatient drug and nonprescription drug in section 1927(k) of the Act, as well as the definition of noninnovator multiple source drug in this final rule, are sufficient to address the concerns raised by the commenters. We do not believe there would be an additional benefit to incorporating a definition of covered outpatient drug in this final rule.

Comment: One commenter asked us to define the term NDA. The commenter states that the term is not defined in the Medicaid Rebate statute, the national rebate agreement, or the FFDCA. Another commenter asked us to define the term ''original NDA.''

Response: The FDA has extensive information about the NDA process on its Web site at *http://www.fda.gov/cder/regulatory/applications/nda.htm.* We do not see the need to add a definition of NDA in this final rule. Further, the FDA does not make a distinction between an NDA and an original NDA; therefore, we view these terms as having the same meaning.

Comment: One commenter asked CMS to specify that the ''United States'' means the 50 States and the District of Columbia.

Response: It has been our longstanding policy to define States as the 50 States and the District of Columbia; this is the definition we adopted in the national rebate agreement. Therefore, we concur with the commenter and have added a definition of States as the 50 States and the District of Columbia.

Determination of AMP (§ 447.504)

Definition of Net Sales

Comment: Several commenters requested that CMS clarify that the term

''revenue'' in the ''net sales'' definition refers only to sales dollars associated with a transaction and not revenue recognized for a transaction for financial accounting purposes. This interpretation is consistent with the position CMS already has taken in the context of ASP reporting. Another commenter believes that it is appropriate to define net sales as a measure of actual sales made regardless of the financial accounting treatment of the transaction.

Response: Net sales should be calculated as gross sales less cash discounts allowed and other price reductions (other than the rebates or price reductions excluded by the statute or regulations) which reduce the amount received by the manufacturer. We have defined AMP to center on the concept of a transaction, such that any given transaction includes both the ''sale'' and any discounts, rebates, or other price concessions associated with that sale. In certain instances, the statute or regulations specifically exclude from the calculation of AMP either certain portions of a transaction or entire transactions with certain entities. Absent such specific exclusions, we believe that manufacturers should calculate AMP by matching sales with their associated price concessions. In the absence of specific guidance, a manufacturer may make reasonable assumptions in its calculations, consistent with the general requirements and the intent of the Act, Federal regulations, and its customary business practices.

Comment: One commenter expressed support for the definition of net sales because it addresses quarterly gross sales revenue less discounts and price reductions which reduce the amount received by the manufacturer.

Response: We appreciate the support for this provision and have retained this requirement in this final rule at § 447.504(d).

Definition of Nursing Home Pharmacies

Comment: One commenter stated that CMS should unambiguously define nursing home pharmacies.

Response: We do not believe that it is necessary to define these entities in the final rule. We remind manufacturers that in the absence of specific guidance, they may make reasonable assumptions.

Definition of Repackagers/Relabelers

Comment: One commenter stated that CMS should unambiguously define repackager/relabelers.

Response: We have defined manufacturer to mean the entity that (except with respect to certain private labeling arrangements) possesses legal title to the NDC for the covered outpatient drug. We do not believe that further definition is necessary at this time.

Private Labeling Arrangements

Comment: One commenter requested that CMS clarify whether sales under private labeling agreements are or are not included in AMP.

Response: We have clarified that sales to another manufacturer which acts as a wholesaler and does not repackage/relabel under the purchaser's NDC including private labeling agreements are included in AMP.

Definition of Retail Pharmacy Class of Trade

Comment: Some commenters requested that CMS define the term ''general public'' used in the proposed definition of retail pharmacy class of trade.

Response: We appreciate the comment but do not believe that further definition is necessary at this time. We remind manufacturers that in the absence of specific guidance, they may make reasonable assumptions.

Comment: A commenter said that retail pharmacy class of trade is not universally defined. Variations may exist in the marketplace among manufacturers as to the class of trade to which PBMs and mail order pharmacies belong. One commenter requested that CMS reconsider the definition of retail pharmacy which will be used in the calculation of AMP. Several commenters requested that CMS define the retail pharmacy class of trade as defined in the Prescription Drug Marketing Act (PDMA) and FDA regulations.

Response: We have revised the definition of retail pharmacy class of trade in § 447.504(e) to mean any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.

Comment: Several commenters noted that the proposed definition is different from the definition of ''retail pharmacy'' under Medicare Part D which defines retail pharmacy as a licensed pharmacy that is not a mail order pharmacy from which Part D enrollees can purchase a covered Part D drug. The commenters believe that adopting the Part D definition of retail pharmacy for retail pharmacy class of trade would result in an AMP that more accurately reflects the prices at which retail pharmacies acquire prescription drugs and prevent confusion and burdensome administrative and recordkeeping requirements for drug manufacturers, health plans, wholesalers, and pharmacies that would result from use of inconsistent definitions.

Response: These statutory requirements applicable to the Medicaid drug rebate program are different from those applicable to Part D. We believe that the definition of retail pharmacy class of trade included in this rule at § 447.504(e) is defined for the purpose of the Medicaid Drug Rebate Program consistent with our interpretation of the applicable statutory requirements.

Comment: One commenter said that the inclusion of ''other outlets'' provides for a number of entities that are typically not considered retail pharmacies. For example, outpatient clinics are outlets that purchase drugs and provide these drugs to the general public; however, they are not retail pharmacies. The commenter further stated that it seems that the calculation of AMP would have to include these entities since they are not expressly excluded in subsequent paragraphs of the proposed rule.

Response: We believe that the inclusion of ''other outlets'' allows for the inclusion of sales for those entities, for example physician offices and outpatient clinics, that purchase drugs from the manufacturer and provide them to the general public.

Comment: A commenter stated that the definition of retail pharmacy class of trade should not use general and undefined descriptions such as ''independent'' or ''mail order'' pharmacy, or ''other outlet.'' The definition should be amended to mean any entity in the United States that is licensed as a pharmacy which provides drugs to the general public.

Response: We disagree. We believe that a narrow definition of retail pharmacy class of trade which would exclude independent and mail order pharmacies does not encompass the universe of entities which purchase drugs from manufacturers and provide them to the general public.

Wholesaler

Comment: Several commenters said that CMS should define the term ''wholesaler'' to mean any entity that purchases drugs from a manufacturer for purposes of resale. This would be consistent with the definition in the national rebate agreement. Another commenter said that ''wholesaler'' should be defined in a manner that better reflects current law and practice. The commenter proposed wholesaler to

mean any entity that is licensed in a State as a wholesaler distributor of pharmaceuticals to which the manufacturer sells, or arranges for the sale of, covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug. Several commenters requested that CMS define the terms wholesaler, wholesale distribution and distributor be consistent with FDA regulation. The FFDCA defines wholesale distributor as any person (other than the manufacturer or the initial importer) who distributes a device or drug from the original place of manufacture to the person who makes the final delivery or sale of the device or drug to the ultimate consumer or user. Under the PDMA regulations, wholesale distributor means any person engaged in the wholesale distribution of prescription drugs, including, but not limited to manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions. Several commenters support warehousing pharmacy chains, warehousing mass merchant and supermarket pharmacy operations being treated as wholesalers.

Response: We believe that for this final rule to be consistent with current law as well as reflect recommendations made to us by the OIG and relevant comments, it is necessary to revise the definition of wholesaler. We have revised wholesaler at § 447.504(f) to mean any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drug, but that does not relabel or repackage the covered outpatient drug.

Comment: Another commenter said that the only transactions that should be included in AMP are those prices that (1) are paid by wholesalers to manufacturers, and (2) apply to the purchase of prescription drugs by wholesalers from manufacturers for the wholesalers' redistribution to the retail pharmacy class of trade. The commenter believes that because Congress specifically exempted customary prompt pay discounts between the manufacturer and wholesalers from the definition of AMP, it is reasonable to conclude that they intended that only price concessions between manufacturers and wholesalers be included in AMP.

Response: We disagree. We have defined AMP in § 447.504(a) to be consistent with the provisions of the DRA and section 1927 of the Act, and include cash discounts and all other price reductions. We have defined wholesaler at § 447.504(f) to mean any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug. The DRA amendment excluded customary prompt discounts ''extended to wholesalers'' but not other discounts or price reductions applicable to AMP.

Comment: One commenter stated that mail order purchases and discounts, Medicaid or SCHIP payments and discounts, or Medicare Part D payments and discounts should not be included in AMP because the discounts associated with these programs are not provided to entities which qualify as not wholesalers.

Response: We continue to believe that mail order pharmacies serve the general public and have included them in the retail pharmacy class of trade in this final rule at § 447.504(g)(9). We agree, in part with the comments on discounts, rebates or other price concessions from manufacturers to Medicaid, SCHIP, and Part D programs and have clarified at § 447.504(h)(23) that such discounts, rebates, or other price concessions when provided to third party payers such as a SCHIP program or an MA–PD are not included in the determination of AMP. We retained in the regulation text at § 447.504(g) that sales to wholesalers for drugs distributed to the retail pharmacy class of trade (including sales, which are provided to a SCHIP program or an MA–PDP) are included in AMP.

Comment: One commenter stated that it is not possible to determine AMP for direct sales to wholesalers where the wholesaler then sells to an entity that is unknown to the manufacturer. The manufacturer is not able to identify the purchaser or to assess whether the entity was in the retail pharmacy class of trade.

Response: We have modified this final rule at § 447.504(g)(1) to state that manufacturers should include sales to the wholesaler except where the subsequent sale of the drug to an excluded entity could be adequately documented.

Comment: One commenter said that many manufacturers rely on chargeback data to identify the retail pharmacy class of trade for AMP. The commenter requested that CMS confirm that to the extent that there is no chargeback associated with a sale and a manufacturer has no way of knowing whether the end purchaser was ''retail,'' those sales are excluded from AMP.

Response: We have modified this final rule at § 447.504(g)(1) to state that where the manufacturer can identify with adequate documentation that subsequent sales from the wholesaler are to an excluded entity, the manufacturer can exclude such sales from AMP.

Comment: A few commenters requested that CMS clarify that clearly identifiable indirect sales to excluded entities should be excluded from AMP (for example, sales identified through chargeback data). Similarly, they asked that we confirm that indirect sales to excluded entities, if not identifiable as such by the data available to a manufacturer, are not required to be ''excluded.''

Response: We have modified this final rule at § 447.504 to state that manufacturers should only exclude sales to the wholesaler where the subsequent sale of the drug to an excluded entity could be adequately documented.

Comment: One commenter noted that the proposed rule does not address whether sales to entities that relabel or repackage under the purchaser's NDC are included in AMP.

Response: We have defined manufacturer at § 447.502 to mean the entity that (except with respect to certain private labeling arrangements) possesses legal title to the NDC for the covered outpatient drug. Therefore, we decided in the final rule that sales to other manufacturers who repackage/relabel under the purchaser's NDC are excluded from AMP.

Comment: One commenter stated that they interpret the definition of wholesaler to mean it is exclusive of any entity that purchases a covered outpatient drugs and repackages or relabels using the purchaser's own NDC. The commenter requests that CMS confirm or provide guidance on what is meant for an entity to relabel or repackage under § 447.504(f).

Response: We have clarified at § 447.504(f) that wholesaler means any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug. Furthermore, we are requiring at § 447.504(g)(2) that sales to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC are included in AMP.

Comment: One commenter requested that CMS delete from the definition of wholesaler, the parenthetical

''(including a pharmacy, chain of pharmacies or PBM).''

Response: We have clarified the definition of wholesaler for these entities in the regulation text at § 447.504(f).

Customary Prompt Pay Discounts

Comment: One commenter asked that CMS confirm that a customary prompt pay discount is the discount ''routinely offered by the manufacturer to an individual wholesaler at the time of payment,'' and not a historical amount approximating the typical discount offered to all wholesalers.

Response: We agree and have clarified this issue in this final rule at § 447.504(c).

Comment: Several commenters said that customary prompt pay discounts extended to wholesalers should be included in the AMP calculation.

Response: We disagree. The statute requires that customary prompt pay discounts to wholesalers be excluded from AMP.

Comment: One commenter said that the word ''routinely'' should be deleted from the definition so that any customary prompt pay discounts the manufacturer passes on to the retail pharmacy class of trade are excluded from AMP. The commenter further believes that the definition is overly restrictive because manufacturers may have a standard customary prompt pay policy but may also occasionally offer other prompt pay discounts when a product is introduced or production is expanded to encourage wholesalers and retailers to stock a product without a proven demand. Additionally, manufacturers establish prompt pay standards that are intended to apply to the retail marketplace and expect the wholesaler to honor this policy. Another commenter said that CMS should clarify what is meant by ''routinely offered'' and specify the criteria that manufacturers should use to determine what is ''routine.'' In particular, CMS should address whether a customary prompt pay discount is considered routine if (1) it differs across customers; (2) it changes over the life cycle of the product; for example, the prompt pay discount offered at the introduction of the product differs from the prompt pay discount offered for the remainder of the product's life cycle; and (3) it is different across products.

Response: CMS proposed a definition which we believe is consistent with customary business practice regarding a routine discount extended to all purchasers for payment within a set time period; for example, 30, 60, or 90 days and that would be flexible and accommodate prompt pay policies for standard sales. Discounts that do not meet this standard which are used for other purposes (for example, marketing, sales, and promotional strategies, special package discounts, incentives, and performance based discounts) are not considered customary prompt pay discounts and should not be excluded from AMP.

Comment: One commenter said that, in restating the base date AMP, if prior data is not available, ''customary prompt pay discounts'' should be the discount that was typically offered by the manufacturer to wholesalers for prompt pay at the time of the price reporting submission related to such utilization, as reasonably determined by manufacturers. The commenter believes that any other reading would be arbitrary, impractical to implement, and inconsistent with congressional intent. The commenter requested that CMS confirm this interpretation.

Response: Manufacturers must have data on actual prompt pay discounts provided during the period for which the base date AMP applies in order to recompute their base date AMPs. Manufacturers should document how they calculated their base date AMPs and maintain supporting documentation.

Comment: One commenter said that prompt pay discounts, if included in AMP, will have a negative impact on the wholesaler drug distribution system, which needs that cash flow. The commenter further stated that the incentive for customary prompt pay discounts will be eliminated; therefore the impact will be negative to the economy of the industry. If wholesale distribution is negatively impacted, it will have direct consequences on drug availability at the patient level.

Response: The law requires that manufacturers exclude customary prompt pay discounts extended to wholesalers from AMP beginning in January 2007.

Comment: A few commenters agreed with the exclusion of customary prompt pay discounts from the AMP calculation.

Response: We appreciate the support for the provisions. This is a requirement of law and we have retained this requirement at § 447.504(h)(20) in the final rule.

Comment: Several commenters stated that many people in the industry have historically referred to ''prompt pay discounts'' as ''cash discounts;'' therefore, to avoid confusion, CMS should clarify the term ''cash discounts.'' Another commenter requested that the final rule should further clarify ''cash discounts'' to exclude any discount off of the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time from when the payment is due. Another commenter requested that CMS add a parenthetical phrase reading ''(except customary prompt pay discounts extended to wholesalers)'' after the term ''cash discount'' in § 447.504(d) and (i).

Response: We agree and have clarified what we mean by cash discounts in the regulation at § 447.504(d). We have also changed §§ 447.504(d) and (i) to add ''except customary prompt pay discounts'' after ''cash discounts.''

Comment: One commenter requested that CMS refrain from defining ''cash discounts'' in a manner that is inconsistent with the definition of customary prompt pay discounts in the proposed rule. Clarity and consistency of pricing terms is essential for the accurate submission of AMP data.

Response: We agree and have clarified cash discounts in this final rule at § 447.504(d).

Comment: One commenter said that customary prompt pay cash discounts extended by wholesalers to pharmacies should be omitted from AMP. Cash discounts are provided to some retail pharmacies based on financing terms negotiated between the wholesaler and the pharmacy. These are not performance-based discounts. Not all pharmacies, especially independent pharmacies, have the distribution capabilities or the cash flow to take advantage of these terms.

Response: The statute defines AMP as the average price paid to the manufacturer by wholesalers for covered outpatient drugs distributed to the retail pharmacy class of trade, without regard to customary prompt pay discounts extended to wholesalers. Therefore, neither prices nor discounts to those prices offered by wholesalers to pharmacies affect AMP.

Comment: A few commenters agreed with the definition of customary prompt pay discount, but requested that CMS confirm that manufacturers may make reasonable assumptions in applying this definition to their AMP calculations and in the reporting of such discounts each quarter. One commenter expressed hope that CMS will take note of the significant administrative burdens associated with tracking customary prompt pay discounts on an individual basis.

Response: As with other pricing calculations, in the absence of specific guidance, manufacturers may make reasonable assumptions consistent with

the statute, Federal regulations, and customary business practices. We believe that manufacturers should maintain documentation to support the customary prompt pay discounts reported to CMS. However, manufacturers may not assume an across the board percentage for customary prompt pay discounts. We recognize that reporting the amount of customary prompt pay discounts is a new requirement but that it is required by law.

Comment: A commenter requested that CMS clarify that ''prompt'' is defined by the manufacturer regardless of the length of time in which the purchaser can receive the discount.

Response: The length of time in which the purchaser can receive the discount should be consistent across purchasers for that manufacturer as well as consistent with customary business practice.

Comment: A commenter requested that CMS clarify that, in accordance with current industry practice, it is appropriate for manufacturers to calculate customary prompt pay discounts by applying the available prompt pay discount percentage (for example, two percent) to total direct sales.

Response: We do not agree. Manufacturers must report the actual amount of customary pay discounts provided for the period.

Comment: One commenter requested that CMS clarify that ''any discount'' means a discount regardless of the amount that is conditioned on the timing of payment.

Response: We disagree. ''Any discount'' should be the discount off of the purchase price of a drug provided when payment is made within a specified time that is consistent with customary business practices.

Comment: One commenter requested that we clarify the term ''routine'' to apply only to those discounts that are provided to entities that satisfy manufacturer defined, objective criteria.

Response: We agree and have clarified in § 447.504(c) that the discount should be consistent with customary business practice.

Comment: One commenter requested that CMS clarify the term ''prompt pay.''

Response: The term ''prompt pay'' refers to a discount provided consistent with industry customary business practices for payment within a specific timeframe.

Comment: One commenter requested that CMS clarify whether prompt pay discounts paid to pharmacies and PBMs are eligible for exclusion from AMP based on the definition of wholesaler.

Response: As specified in statute, only prompt pay discounts to wholesalers, as defined in this final rule in at § 447.504(c) are to be excluded from AMP.

Comment: Several commenters support the definition of customary prompt pay discount.

Response: We appreciate the support for this definition.

Comment: One commenter requested that CMS exclude customary prompt pay discounts from the calculation of ASP.

Response: These issues are not addressed in the proposed rule and are outside the scope of this rulemaking document. Therefore, we have not considered these comments as we consider revisions to the final rule.

Comment: One commenter stated that the exclusion of customary prompt pay discounts from AMP will effectively increase the AMP, resulting in incremental increases to the rebates for drugs to States and the Federal Government.

Response: CMS does not have data sufficient to predict how AMP will change to the exclusion of customary prompt pay discounts or other changes in this rule.

Comment: One commenter agreed that CMS should not specify payment amounts or time terms in the definition. Although some manufacturers may ask CMS to further define the various aspects of customary prompt pay discounts, the commenter encouraged CMS to maintain the proposed definition in this final rule because this approach allows manufacturers and wholesalers the necessary flexibility to negotiate payment terms, including customary prompt pay discounts based on their particular situations and the commercial conditions at the time of the particular transaction. Additionally, this flexibility promotes competition in the healthcare distribution business, which ultimately will lower distribution costs.

Response: We appreciate the support but note that customary prompt pay discounts must be routinely offered in order to be excluded from AMP.

Determination of AMP

Comment: One commenter stated that the law clearly limits prices included in AMP to be prices paid by wholesalers, including discounts received by wholesalers. However, CMS proposed to require that manufacturers include prices that are not paid by wholesalers, such as to PBMs, as well as discounts on drugs that are not received by wholesalers. The commenter believes that the proposal is inconsistent with both congressional intent and CMS' longstanding interpretation of the statute.

Response: We have clarified in this final rule in § 447.504 that AMP should be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by the statute or regulation or is provided to an entity excluded by statute or regulation. We have also clarified that rebates, discounts, or other price concessions to PBMs should not be included in AMP because we believe they do not adjust the price actually realized. We believe that this final rule provides a definition of AMP and wholesaler consistent with the provisions of the DRA and section 1927 of the Act.

Comment: One commenter stated that they know that an imprecise definition of AMP, especially if publicly posted, will be misleading to State Medicaid Directors and others who will use this as a reference point for setting pharmacy reimbursement.

Response: We have clarified the definition of AMP in § 447.504(a) to be consistent with the current law. We intend to clarify in guidance that posted AMPs are not designed to reflect prices paid by specific pharmacies.

Comment: Another commenter said that CMS proposes to include in AMP all sales to wholesalers except for those sales that can be identified with ''adequate documentation'' as being subsequently sold to any excluded entity. The commenter requested CMS to specify what constitutes adequate documentation. In the absence of further guidance, the commenter presumes that manufacturers may make reasonable assumptions in determining whether they have satisfied the adequate documentation requirement. However, the commenter requests that CMS provide an opportunity for manufacturers to comment on any further guidance prior to issuing a final rule.

Response: We have clarified that adequate documentation includes, but is not limited to, chargeback data or data for which an outside auditor, certified public accounting firm, CMS, the OIG, or another authorized government agency could reconstruct the transaction. Manufacturers may continue to make reasonable assumptions that are consistent with this final rule, statute, and general business practices. We do not specifically request comments on guidance issued to implement the rebate

program but we intend to respond to comments received before and after such guidance.

Comment: One commenter suggested that CMS reconsider whether all of the sales enumerated under § 447.504(g) are appropriately ''included'' in AMP based on the definition of ''wholesaler.''

Response: We appreciate the comment and have revised the regulation text in § 447.504 to reflect revisions based upon comments received on this issue.

Comment: Several commenters requested that CMS provide a clear definition of AMP. Other commenters said that it must be defined fairly and equitably. Another commenter also said that the current definition of AMP is ambiguous and has never been adequately defined by CMS. One commenter said that AMP cannot be clearly defined as the industry does not have a true standard definition.

Response: We believe that this final rule provides a clear and adequate definition of AMP consistent with the provisions of the DRA and helps resolve ambiguities and confusion that may have existed with the pre-DRA definition.

Comment: One commenter said that they did not support the current definition of AMP.

Response: We have revised the regulation text at § 447.504 to reflect revisions based upon comments received.

Comment: One commenter said that this final rule should be consistent with established Medicaid rebate policies, definitions and terms set forth in current CMS guidance, such as program releases and the national rebate agreement.

Response: We have clarified previous policies as well as incorporated changes mandated by the DRA. This final rule is consistent with current law and it reflects recommendations made to us by the OIG and relevant comments.

Comment: One commenter requested clarification regarding whether the definition of AMP is being changed. The commenter requested clarification regarding whether AMP is the price received by the manufacturer, the price recognized by the manufacturer, or the price paid by the retail pharmacy class of trade.

Response: We have clarified at §447.504(a) that the AMP is the average price received by the manufacturer for the drugs in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade, without regard to customary prompt pay discounts extended to wholesalers, and inclusive of sales and associated discounts, which reduce the amount received by the manufacturer (unless the sale or discount is excluded by the statute or regulation). We have clarified the definition in the regulation.

Comment: One commenter requested that CMS clarify the phrase ''prices which are actually available'' used in the proposed rule. Available prices should not be used to define AMP. If a price is offered and not taken, it is irrelevant to prices received by manufacturers or prices paid by retail pharmacies.

Response: Actual sales must occur in the period in order for a particular price to be reflected in AMP.

Comment: One commenter requested that AMP be defined as, ''with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the FFDCA) for a calendar month, the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade. ''AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers.'' The commenter requested that AMP be defined to include only sales to chain and independent pharmacies, and discounts to retail pharmacies, but only to the extent that such discounts reduce the actual price paid by retail pharmacies.

Response: We disagree. In light of our understanding of the statute and DRA amendments, we have decided to include in the AMP and retail pharmacy class of trade, sales to chain, independents, and mail order pharmacies, as well as discounts to such entities to the extent that they reduce the amount received by the manufacturer and are not otherwise excluded by statute and regulation.

Comment: One commenter requested that CMS clarify the meaning of the term, ''associated with,'' referenced in §447.504(g)(10) in the proposed rule.

Response: The term, ''associated with'' means with respect to the AMP calculation, that manufacturers should include all sales and associated rebates, discounts, or other price concessions which relate to the sale, unless those sales, rebates, or other price concessions are excluded by statute or regulation.

Comment: One commenter requested that CMS exclude from AMP price adjustments that do not affect the actual price provided by the manufacturer and that are not received by retail community pharmacies.

Response: As noted previously, we have defined AMP to include sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by the statute or regulation or is provided to an entity excluded by statute or regulation. Absent such specific exclusions, we believe that manufacturers should calculate AMP by matching sales with their associated price concessions.

Comment: Many commenters asked that CMS issue a clear definition of AMP that covers community, independent and chain pharmacy acquisition costs. This definition should be issued as soon as possible, before AMP takes effect.

Response: We have defined AMP consistent with our understanding of the current law. Because AMP is based on the average price received by the manufacturer for the drug, it does not necessarily reflect a pharmacy's acquisition cost for the drug.

Comment: One commenter commended CMS for articulating the rationale behind our proposals regarding the determination of AMP. For example, in the definition of ''retail pharmacy class of trade,'' CMS articulated an assessment based on whether or not sales are available to the general public. The commenter appreciated this effort to describe the history and development of the Agency's thinking. However, the commenter was concerned that the test, as articulated, lacks sufficient clarity. The commenter believed that the proposed rule represents an important and necessary step forward in standardizing AMP calculations. However, the commenter urged CMS to significantly refine its guidance.

Response: We believe that this final rule provides a clearer, accurate and precise definition of AMP to allow manufacturers to accurately calculate AMPs. We expect to continue to issue further guidance and answer specific questions to the extent necessary to provide additional clarity. Furthermore, this final rule period allows for additional public comment on AMP.

Comment: One commenter said that the proposed definition of AMP is unfair to retail pharmacies because it includes sales to PPOs, HMOs, and outpatient clinics, all of which receive bid prices from drug companies. To be fair, the cost should be derived from the prices paid by retail pharmacies. Many commenters said that if AMP is to accurately serve as both the basis for rebates and payment, CMS must define AMP to reflect the actual acquisition cost with respect to prices paid for

drugs by retail pharmacies, excluding all rebates and price concessions not available to retail pharmacy.

Response: As we noted previously, the statute defines AMP, in part, as the average price received by the manufacturer for drugs distributed to the retail pharmacy class of trade. Accordingly, AMP does not necessarily reflect the pharmacy's acquisition cost. We note that when the AMP is used in the calculation of FULs, the calculation includes a markup of 250 percent and excludes certain outlier prices, as described elsewhere in this regulation. The DRA does not require the States to otherwise base their payments on AMPs. To the extent that they do so, we would expect them to look at appropriate mark-ups and any other relevant factors to ensure access. Such changes in payment would also require the submission and CMS approval of a State plan amendment.

Comment: One commenter agreed with CMS' interpretation of congressional intent that both direct and indirect pharmacy sales be included in AMP. The commenter requested that CMS incorporate direct retail pharmacy sales in AMP without adopting a strained, overly-broad definition of wholesaler. It should be sufficient to include a provision in the final rule expressly stating that net sales to retail pharmacies are to be included when AMP is calculated, but CMS could avoid all ambiguity about the requirement to include direct pharmacy sales in AMP by adding the parenthetical, ''(direct and indirect)'' after the word ''sales'' at the beginning of proposed § 447.504(g)(5).

Response: We appreciate the comment and believe that we have defined AMP to be consistent with the provisions of the DRA and section 1927 of the Act, and include sales, rebates, and price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade. In addition the definition of wholesaler has been revised.

Comment: One commenter said that the new determination of AMP will cause many pharmacies to consider disenrolling from Medicaid pharmacy programs. Commenters said that the current definition of AMP will cause their retail pharmacy to lose money with each prescription that is filled. A few commenters stated that AMP must be defined as it relates to the retail pharmacy class of trade. Retail pharmacy must be able to purchase these drugs at a price that is less than the reimbursement it is to receive, including the cost of electronic transmission to the PBM, labeling, container, counseling time, delivery costs, and packaging. Another commenter stated that the formula must be tweaked to provide a true cost.

Response: We disagree. As we have noted elsewhere in this regulation, the AMPs will be used to establish FULs, which is calculated based, in part, on 250 percent of the AMP. To the extent States decide to use AMPs for reimbursement that decision will be subject to our review and approval through a State plan amendment approval process. We believe that this final regulation provides an adequate opportunity for States to set adequate reimbursement rates for drugs subject to the upper limits. We also believe that States that opt to use AMP as a basis for their pharmacy reimbursements will also use other resources available to them to determine fair and reasonable reimbursement to ensure continued access to pharmacy services for Medicaid patients. We also note that we encourage States to reevaluate their dispensing fees to ensure that they are reasonable and cover the costs to dispense drugs identified in this final rule.

Comment: A few commenters said that a new definition for AMP is needed, which should be Average Retail Price (ARP).

Response: Current law requires that AMP be computed based, in part, on the average price received by manufacturers and submitted by manufacturers and it provides no authority for us to define AMP as an average retail price.

Comment: A few commenters stated that the field is skewed against independent pharmacies. If CMS proceeds with AMP, then there needs to be a different AMP for different classes of trade. Some commenters stated further that mail order, retail, hospital, and long-term care pharmacies all purchase drugs at different costs and the same AMP should not be used for every class of trade. One commenter said that the formula is taking into account all of the rebates and special pricing afforded to the ''closed door'' specialties such as nursing homes, mail order houses, and hospitals. It has already been shown that the actual reimbursement proposed will be far less than what retail pharmacies can purchase the product for.

Response: We disagree. We know of no evidence at this point that the payments, which would be set as a result of the revised FULs or publication of AMPs would be any less than pharmacy acquisition prices especially given that neither the FUL methodology nor AMP data has been established or available prior to publication of this rule. Current law provides no authority for a different AMP for different types of entities. However, we believe that the publication of AMP will provide the Federal and State Governments with more transparency with respect to the average price received by manufacturers for prescription drugs, and provide a basis on which to set payments rates. We further believe that, in light of the methodology for calculating the FULs, the AMPs will be fully adequate for computing the upper limits and that States will make their own best decisions, subject to the State plan amendment process, with respect to how to use AMP as a factor in provider payment.

Comment: One commenter said that it will be harder for community pharmacies to compete with the retail giants as their prescription volume is much lower and it will be harder to recover their expenses. Community pharmacies will not necessarily receive the discounts that the larger retail pharmacies receive when purchasing generic drugs.

Response: We believe that any payment revisions that states may establish as a result of these provisions will not prevent community pharmacies from competing with other pharmacies. CMS has calculated the FULs without regard to any outlier AMPs and will review any state plan amendment submission as a result of those FULs to ensure sufficient access. We further note that States maintain the authority to vary payment rates by rural area as well as by the type of the provider.

Comment: Several commenters said that the proposed rule would unduly reduce AMP.

Response: We appreciate the comment and have revised AMP at § 447.504 to address similar concerns.

Comment: One commenter said that it is clear from the proposed rule discussion that CMS has struggled to balance AMP-based rebate collection and AMP-based reimbursement through the inclusion of non-pharmacy entities. Should CMS believe it important to maintain these entities in AMP for the purposes of reducing manufacturer rebates, then an alternative would be to have monthly and quarterly rebates calculated differently. Monthly and quarterly AMPs would afford CMS the opportunity to use the monthly AMP to establish the FUL in a way that would provide a more accurate reflection of traditional retail pharmacy purchasing (that is, only including licensed pharmacies and excluding other entities such as PBMs) and maintain the CMS decision to reduce manufacturer rebate liabilities by the inclusion of the various

non-pharmacy entities in the quarterly AMP reporting. Another commenter said that the best method of resolving any conflict between the two functions of AMP (paying rebates and payment) is to examine the basic purposes of the statutes and craft the definition and use of AMP to better fit those purposes. The commenter did not believe the proposed rule dealt with these purposes adequately.

Response: We do not agree. There is only one definition of AMP, as revised by the DRA, that is applied for both rebate and FUL purposes. By using only one definition, these AMPs become much more transparent and provide information regarding the average price received by manufacturer from wholesalers for drugs distributed to the retail pharmacy class of trade. We believe that the definition of AMP as clarified in this final rule at § 447.504(a) accurately reflects the dual purposes of AMP.

Comment: One commenter stated that the approach that CMS used in the determination of AMP is overly broad, in that past policy reflects a different focus on the use of AMP and the agency's interpretation of the marketplace does not provide adequate consideration of the obvious inconsistencies that occur when FULs based on AMPs are defined in the proposed rule as approximations for estimated acquisition cost (EAC). The transactions included in AMP should be based on a more narrow view of what is meant by the retail pharmacy class of trade, but should also consider more significantly the link between FULs and EAC.

Response: We agree that although AMP was defined in the rebate agreement, the list of sales included in the AMP calculation was not well established when the DRA was enacted. While we have reviewed the OIG's recommendations and those of commenters, and incorporated changes where we thought appropriate, we believe that we have crafted a definition of AMP that reflects the requirements of the law and serves as a basis for both rebates and the FULs program.

Comment: A few commenters said that without clear and concise guidance from CMS regarding how AMP is to be calculated, including what classes of trade are eligible and which classes of trade are not eligible, for inclusion in the AMP calculation manufacturers who compete in the same therapeutic area could have differing methodologies resulting in unfair physician reimbursement calculations. CMS needs to provide clear guidance on the calculation of AMP in order to maintain a fair and level playing field for physician reimbursement.

Response: We believe that we have developed requirements in this final regulation that are clear and concise and that can provide a basis for consistent calculations and fair reimbursement rates.

Comment: One commenter stated that AMP would be valid for determining transactions between a manufacturer and the next step down the trade chain (for example, a drug wholesaler) but using AMP is not valid to compute the price of the drug at the point a community pharmacist is dispensing it to his or her patients.

Response: The statute provides that manufacturers calculate Medicaid rebates and CMS calculates the FULs based in part, on AMP. In accordance with the statute, we have defined AMP as the average price received by the manufacturer from wholesalers for drugs distributed to the retail pharmacy class of trade, excluding customary prompt pay discounts extended to wholesalers and including certain sales and associated discounts. As stated elsewhere in this final rule, we have not only applied the 250 percent markup to the lowest price therapeutically equivalent drug, we have implemented other policies to assure that the resulting FULs, in the aggregate, are reasonably established to reflect the pharmacy acquisition cost of drugs subject to the FULs, while protecting the taxpayer against excessive costs.

Comment: A commenter recommended that the playing field on drug pricing be leveled by making the discounts extended to PBMs, mail order pharmacies, and government contracts available to retail pharmacies and allow a reasonable profit structure as any business deserves.

Response: These issues were not addressed in the proposed rule; therefore, we can not consider these comments as we consider revisions to be included in the final rule.

Comment: One commenter stated that the definition of AMP must be operational and feasible for manufacturers. Manufacturers are frequently not aware of the subsequent sales of their drug products after the first sale. Manufacturers do not have information about sales to hospitals, other wholesalers, mail order pharmacies, and PBMs.

Response: We have modified the requirements in § 447.504(h) with respect to AMP calculations to exclude certain sales to hospitals and PBMs. The requirement of AMP specifies that where sales to excluded entities are documented, they should be excluded from AMP.

Comment: One commenter said that AMP should be calculated based on the average price, not the lowest price.

Response: We agree. The AMP, as amended by the DRA, represents the average unit price, not the lowest price, received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade, without regard to customary prompt pay discounts extended to wholesalers as noted previously, AMP should be calculated to include sales and associated discounts and other price concessions provided by a manufacturer for drugs distributed to the retail pharmacy class of trade (unless the sale, discount, or other price concession is specifically excluded by statute or regulation), which reduce the amount received by the manufacturer.

Comment: One commenter said that an appropriate calculation of AMP depends on an accurate definition of retail pharmacy class of trade, accurate identification of manufacturers' prices paid by wholesalers for drugs distributed to retail pharmacies, and an appropriate definition of wholesaler. The commenter stated that CMS' proposed definition has problems in all three areas.

Response: In response to comments, we have clarified the definition of retail pharmacy class of trade at § 447.504(e), wholesalers at § 447.504(f), and the list of sales included in the determination of AMP at § 447.504(g).

Comment: One commenter said that AMP is as ambiguous as AWP or ASP in that it can be interpreted many ways and does not consider business overhead requirements of drug wholesalers and distributors.

Response: We do not agree. ASP and AMP are defined in the statute and Medicare regulations. However, AWP is a term that is not further defined in the regulation and has been found to frequently overstate the actual cost of drugs.

Comment: One commenter stated that AMP should have full transparency. Another commenter said that the AMP calculation should be solidified and that a more transparent method should be developed.

Response: We have clarified at § 447.504(i)(2) and § 447.510(d)(2) how manufacturers should calculate and report AMP on both a quarterly and monthly basis, and we expect to post AMP data for public review on our Web site. Although the manufacturers' documentation for these calculations will not be made available to the general

public, they are subject to Federal Government verification.

Comment: Many commenters stated that all rebates and price concessions are appropriately included in best price but should not be included in AMP. Another commenter said that CMS should exclude from AMP those sales that are exempt from best price under section 1927(c)(1)(C)(i) of the Act. The commenter asserts that including sales to SPAPs and Part D Plans that are exempt from best price in AMP will artificially lower AMP as a reimbursement benchmark by including discounts in AMP to which pharmacists do not have access.

Response: We have revised this final rule in § 447.504(h)(23) to exclude rebates and other price concessions provided to SPAPs and Part D plans. It is our understanding that such rebates and price concessions do not adjust the prices actually realized. We have continued in § 447.504(g)(15) to include sales with respect to such programs and plans to the extent that they occur through the retail pharmacy class of trade.

Comment: One commenter asked whether CMS' intent is to continue to allow manufacturers to treat an entity as either included or excluded in the retail pharmacy class of trade based on its function, provided that the manufacturer can provide sound rationale.

Response: In the final rule we have defined that AMP be calculated to include sales and associated discounts and other price concessions provided by the manufacturer to wholesalers for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by the statute or regulation or is provided to an entity excluded by statute or regulation. Sales and associated price concessions should be included in AMP to the extent they concern sales at the retail pharmacy class of trade and are not otherwise exclude.

Comment: One commenter stated that any entity that does not directly purchase drugs from the wholesaler should be excluded from AMP.

Response: We have revised wholesaler in § 447.504(g) to mean any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug.

Comment: A commenter stated that CMS will need to be exceedingly clear in the guidance that it provides to manufacturers in calculating AMP to ensure that manufacturers are able to determine the sales and associated price concessions that should not be included in AMP and to ensure consistency in AMP calculations across all manufacturers.

Response: We have clarified in the regulation text at § 447.504(g) those sales and associated price concessions included in AMP.

Comment: A commenter stated that §§ 447.504(a), (g) and (i) indicate types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. By including these discounts and concessions, the proposed rule incorrectly based AMP, not on the amounts paid by wholesalers—the predominant supply source for retail pharmacies—but instead includes amounts that manufacturers have contracted to pay other entities. While these discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies.

Response: Our definition of AMP is consistent with our understanding of the section 1927(k)(1), as amended by the DRA. While we understand that some commenters do not agree with that definition because it does not represent the exact amount at which pharmacies purchase drugs, we believe that our definition is consistent with the statute. As we explain elsewhere in this final rule, the statute requires the use of AMPs in the FUL calculation with a sufficient markup of the AMP and we have included other exclusions in the FUL calculation to assure that these FULs prices in the aggregate are sufficient to cover pharmacists' costs.

Comment: One commenter said that § 447.504(a) through (i) proposed revisions to various definitions and directions to manufacturers related to AMP calculation. The validity of CMS' consideration for inclusion or exclusion of factors in determining AMP is essential for obtaining data that accurately reflects drug pricing. The commenter recommended that CMS adopt clear and specific policies to ensure consistency in the calculation of AMPs across all manufacturers.

Response: We appreciate this comment and believe we have done so.

Comment: One commenter said that the proposed definition, coupled with the broad definition of wholesaler, is intended to capture transactions with entities that do not pay manufacturers a price established by the manufacturer directly or through distributors. When combined with the proposed inclusions and exclusions from AMP, this definition creates confusion.

Response: We appreciate the comment. As discussed previously, we have revised the definition of AMP in § 447.504(g) to clarify which sales and associated price concessions must be included.

Comment: One commenter said that the proposed rule provided manufacturers a significant amount of latitude and discretion with respect to the final AMP calculation. It is likely that there will be widespread differences in interpretation with respect to those elements that should be included or excluded from AMP. One example of this confusion relates to the treatment of a ''bona fide service fee.'' It remains unclear as to the comparative standard that will be used to establish the determination of ''fair market value.'' The commenter requests that additional clarity be provided to eliminate variation in manufacturer's AMP calculation.

Response: We believe that this final rule provides a clearer, accurate and precise definition of AMP, eliminating much of the confusion and assumptions regarding the entities included and excluded in AMP. For example, we have introduced the concept of bona fide service fees and provided further instructions on how they are to be determined. We expect that manufacturers participating in the Medicaid Drug Rebate Program will be in a much better position to understand our requirements and to determine their AMP calculations consistent with this final regulation. In the absence of specific guidance, manufacturers may make reasonable assumptions consistent with the statute, regulations and general business practices.

Nursing Homes

Comment: Many commenters said that nursing home pharmacies should not be included in AMP because they are not traditional retail pharmacies. Several commenters stated that rebates and discounts to nursing homes are not available to retail pharmacies. Other commenters said that nursing homes sales should be outside the retail pharmacy class of trade as these sales are not accessible to the public. A few commenters supported excluding nursing home pharmacies from the definition of retail pharmacy class of trade and noted that long-term care pharmacies are not retail pharmacies for Part D.

Response: We appreciate the support for this policy and have decided to finalize our proposal to exclude nursing facility pharmacies from the retail

pharmacy class of trade, and, therefore AMP, in this final rule at § 447.504(h)(6).

Comment: One commenter requested that CMS clarify whether contract pharmacies that dispense drugs to nursing home and long-term care residents also should be excluded from the calculation of AMP.

Response: We have clarified in the regulation text at § 447.504(h)(6) that sales to contract pharmacies that dispense drugs through nursing homes and long-term care facilities and other entities such as assisted living facilities which do not serve the general public are excluded from AMP. Since we believe a manufacturer would not know which drugs are dispensed to a nursing facility through an outside contract pharmacy, we have not excluded these sales from AMP unless that manufacturer has reasonable documentation that the drugs were subsequently sold to an excluded entity.

Comment: One commenter stated that to remove nursing home sales from AMP would be inconsistent with CMS guidance issued to date and would be a substantive policy change. The commenter requested that long-term care sales continue to be included in AMP because these transactions are a significant portion of the market for many drugs and the exclusion of those transactions from AMP would yield inaccurate and misleading AMPs. Changing the current policy would require substantial changes in systems, policies, procedures, and data links that would more than offset the benefit from simplifying the AMP calculations. A few commenters encouraged CMS to continue its long-standing policy of including these sales in the calculation of AMP.

Response: We have decided to retain the proposed exclusion at § 447.504(h)(6) in this final rule because we believe that nursing home sales are not in the retail pharmacy class of trade because the general public cannot obtain drugs through this source.

Comment: One commenter said that CMS has not clearly identified those entities that would be considered long-term care (or nursing home) pharmacies. The commenter encouraged CMS to clearly define the attributes of entities that qualify as long-term care pharmacies to avoid disparate treatment by manufacturers as they exclude prices to long-term care pharmacies. In particular, the commenter believed that it is not clear whether the following would be considered a long-term pharmacy: long-term care pharmacies owned by a hospital, infusion centers, and rehabilitation centers. The commenter further recommended that CMS establish a list of long-term care pharmacies similar to the list of eligible 340B covered entities provided by the Office of Pharmacy Affairs in HRSA.

Response: We consider a long-term care pharmacy to be a pharmacy that provides drugs to nursing home patients. Infusion centers and rehabilitation centers that serve patients outside a nursing home would not be included. We do not believe it is administratively feasible for CMS to maintain a list of the entities that fall into this category.

Comment: A commenter asserted that it is often operationally infeasible for manufacturers to identify those sales that are made to a particular type of entity such as a long-term care pharmacy, as opposed to another type of entity that might not satisfy the definition of a long-term care pharmacy. Manufacturer sales data are captured at the contract level, but any included or excluded class of trade customer could purchase products from any wholesaler source contract. Thus, manufacturers have no way of determining whether final sales are made to customers excluded from AMP. Given this inherent difficulty with calculating AMP, it is imperative that CMS provide mechanisms by which manufacturers can calculate AMP as consistently as possible.

Response: The final rule in § 447.504(h)(6) clearly indicates that nursing home sales are excluded from AMP and allows manufacturers to use standards of reasonable documentation to identify such sales.

Hospice and Other Home Health Care Pharmacies

Comment: One commenter suggested that sales to hospice pharmacies should be treated the same as sales to long-term care pharmacies and excluded from AMP and best price.

Response: Hospice pharmacies are outside of the regular retail marketplace, as drugs from these pharmacies are not available to the general public. Therefore, we have clarified in the regulation text at § 447.504(h)(7) that sales to hospices (outpatient and inpatient) are excluded from AMP.

Comment: Several commenters requested that CMS specify in the final rule whether home health care providers meet the retail pharmacy class of trade definition. One commenter asked CMS to clarify whether prices paid by home health care agencies for drugs delivered to home bound patients are included in AMP. Several commenters requested that CMS clarify that home health care providers are included in the retail pharmacy class of trade because such entities provide pharmacy to the general public.

Response: We have clarified in this final rule at § 447.504(g)(12) that sales to home health care providers are included in the retail pharmacy class of trade and AMP unless such drugs are dispensed through nursing facilities. We believe that, unlike nursing facilities, home health care providers operate to provide drugs to the general public.

Physician Offices and Other Provider Settings

Comment: Many commenters requested that CMS specify in the final rule whether sales to physicians are in the retail pharmacy class of trade. Several commenters requested guidance regarding the treatment of the physician class of trade (direct and indirect sales) since it was not addressed in the proposed rule.

Response: We have clarified in the regulation text at § 447.504(g)(13) that sales to physicians fall into the definition of retail pharmacy class of trade and are included in AMP. The definition of retail pharmacy class of trade includes any pharmacy or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, or distributor and subsequently sells or provides the drugs to the general public. We believe that, to the extent that the physician is operating to provide drugs to the general public, they should be included within the definition of retail pharmacy class of trade and AMP.

Comment: One commenter sought clarification concerning whether sales to surgical centers, ambulatory care centers, prisons, and mental health centers are in the retail pharmacy class of trade. Unlike walk-in pharmacies, these providers generally provide drugs incident to providing medical services to persons who are their private patients, although some physician practices sell self-administered products to patients who take the products home.

Response: We appreciate this comment and have clarified in the regulation text at § 447.504(h)(9) that sales to prisons are excluded from AMP. We have further clarified at § 447.504(g)(8) that sales to surgical centers, ambulatory care centers, and mental health centers are included in AMP to the extent that such facilities provide drugs to the general public unless such drugs are provided through a nursing facility pharmacy.

Hospital Pharmacy Sales

Comment: Several commenters stated that hospital prices should be excluded

from AMP because hospital pharmacies receive generous price breaks from wholesalers and manufacturers that are not available to retail pharmacies. Many commenters believe that CMS should exclude all hospital pharmacy sales from AMP because the vast majority of sales are for inpatient use and hospitals do not generally track whether a drug is provided to an individual receiving inpatient services or outpatient services. Another commenter stated that it would be administratively difficult for manufacturers to include sales to walk-in pharmacies located in hospitals because most hospitals buy drugs for inpatient and outpatient use through wholesalers or distributors under agreements negotiated by GPOs. The commenter further suggested that manufacturers be permitted to assume hospital purchases are for their inpatient inventory and exclude them from AMP unless sales to hospital outpatient pharmacies are identifiable. One commenter said that drugs provided through hospital outpatient departments are not available to the general public and should be excluded as they are not in the retail pharmacy class of trade. Another commenter stated that hospital outpatient departments receive drugs at lower prices than retail pharmacies which would result in a lower AMP and unfairly lower reimbursement to retail pharmacies.

Response: We agree that manufacturers often do not know what drugs sold to hospitals are used in the hospital outpatient pharmacies or other hospital facilities, such as clinics. In such an event, we believe that manufacturers should exclude hospital sales from AMP. We have provided in this final rule at § 447.504(g)(3) that drugs sold to hospitals for use in an outpatient pharmacy are included in AMP, except where the manufacturer cannot identify and document hospital sales for outpatient use.

Comment: One commenter stated that it is unclear if pharmacies in physician clinics that dispense prescriptions in such clinics are included in the retail pharmacy class of trade.

Response: We consider physician clinics, to the extent that they provide drugs to the general public, to be in the retail pharmacy class of trade and drugs sold to these clinics should be included in AMP.

Comment: One commenter asked if an outpatient clinic includes hospital surgical centers, ambulatory care centers and outpatient departments in which a patient is admitted to the hospital and released the same day.

Response: The term outpatient clinic was intended to capture all outpatient facilities including hospital surgical centers, ambulatory care centers and outpatient departments because such facilities provide drugs that are available to the general public. We have revised the regulation text in § 447.504(g)(8) to expand the term ''outpatient clinic'' to ''outpatient facilities; for example, outpatient clinic.''

Comment: One commenter requested that CMS define outpatient clinic. The commenter assumed that federally qualified health centers, independent diagnostic facilities, and the like are outpatient clinics.

Response: We have revised the term outpatient clinic in § 447.504(g)(8) to mean ''outpatient facilities; for example, outpatient clinic'' in the regulation text.

Comment: One commenter indicated that it is unclear if the term outpatient clinic was intended to include physician offices. If not, the proposed rule is silent on the handling of sales to physicians in AMP.

Response: The term outpatient clinic was not intended to cover direct physician sales. We have clarified in the final regulation text at § 447.504(g)(13) that the retail pharmacy class of trade may include physicians to the extent that they provide drugs to the general public.

Comment: One commenter requested that CMS clarify that the term ''outpatient clinic'' is not intended to mean hospital outpatient departments since a different sub-paragraph in 42 CFR § 447.504(g) addresses sales to hospitals outpatient pharmacies. Manufacturers may find it difficult to distinguish between hospital-affiliated freestanding outpatient clinics and true hospital-based outpatient departments.

Response: We have clarified in the regulation text at § 447.504(g)(8) that outpatient clinics and facilities, which are not hospital-affiliated entities, are included in AMP. We have further clarified in the regulation text at § 447.504(g)(3) that sales to hospitals, for use by an outpatient pharmacy for a hospital outpatient department, clinic or affiliated entity are included in AMP, except when a manufacturer does not have information to distinguish these sales from sales used for inpatients.

Mail Order Pharmacies

Comment: Many commenters said that though mail order pharmacies have a tendency to decrease AMP, they should be included in AMP because they are licensed pharmacies and provide drugs to the general public. Some commenters support CMS' decision to maintain its existing policy to include sales and price concessions to mail order pharmacies in the AMP calculation. One commenter agreed that mail order should be included in AMP on the basis that it is simply another form of how drugs enter into the retail pharmacy class of trade.

Response: We appreciate the support for this provision and have retained this requirement in this final rule at § 447.504(g)(9).

Comment: One commenter said that mail order pharmacy rebates, chargebacks, and other price concessions should not be included in AMP.

Response: We do not agree. After consideration of all comments received, we continue to believe that mail order pharmacies are part of the retail pharmacy class of trade inasmuch as they are accessible and dispense prescriptions to the general public. The rebate agreement which provides for the inclusions of rebates, discounts, and price concessions associated with drugs provided to the retail pharmacy class of trade be included in AMP. We further believe that we are correct to include mail order pharmacies in AMP, since Congress did not seek to change the policy regarding the inclusion of mail order pharmacy sales and associated price concessions in AMP with the recent DRA (except with respect to customary prompt pay discounts extended to wholesalers). Accordingly, CMS has not changed the policy in this final rule.

Comment: Several commenters said that any closed-door mail order pharmacy, in that it sells only to facilities or plans with which a contractual relationship exists, should be excluded.

Response: As previously discussed, we believe that all sales to mail order pharmacies are within the retail pharmacy marketplace and drugs from these pharmacies are available to the general public. We have clarified in the final regulation at § 447.504(e) the definition of retail pharmacy class of trade.

Comment: Several commenters said that any mail order pharmacy whose rebate and discount arrangements are not available to other pharmacies in the retail pharmacy class of trade should be excluded.

Response: We disagree. The rebate agreement which provides that rebates, discounts, and price concessions associated with drugs provided to the retail pharmacy class of trade be included in AMP. It does not precondition this on whether other

entities within the retail pharmacy class of trade can get these same discounts.

Comment: One commenter expressed the concern that the inclusion of mail order discounts and rebates in the AMP calculation will impact access for a drug when used for the purposed of the FUL process. Several commenters said that to include mail order pharmacies in AMP will skew the price to a lower price at which retail outlets will never be able to purchase medications. Another commenter noted that although mail order pharmacies serve consumers on a retail level their dispensing rate per day is many hundreds of times larger than a community-based retail pharmacy, allowing them to buy at a lower cost that is not available to a community-based retail pharmacy. Another commenter stated that the inclusion of mail order pharmacies will lower reimbursement to the community pharmacies below their cost. Several commenters stated that drug acquisition costs available to mail order pharmacies may not be available to smaller retail pharmacies and that inclusion of mail order pharmacies will serve to drive down pharmacy ingredient costs even further below average acquisition cost. One commenter said that it is self-evident to those in the industry that independent pharmacies do not purchase pharmaceuticals at the same cost as mail order pharmacies or chain pharmacies. This is driven by the inability to collectively negotiate with manufactures and to purchase pharmaceuticals without acquiring the product from a wholesaler or distributor that requires significant additional margins for the distribution of those items from the manufacturers to independent pharmacies. They further noted that the differentials of mail order and chain pharmacies to other pharmacies acquisition cost are very significant. Many commenters said that the proposed rule is flawed by allowing manufacturers to include mail order in AMP on the basis that AMP will not reflect the price paid by traditional retail pharmacies or community pharmacies. A few commenters said that the idea of an AMP is acceptable, but only if hospital and mail order pharmacy pricing is excluded from AMP as mail order and hospital pharmacies receive generous price breaks from wholesalers and manufacturers alike, and thus their AMP should be calculated separately from other traditional retail pharmacies. One commenter further said that mail order pharmacies do not create a level playing field with community pharmacies. Mail order pharmacies have tremendous advantages over community retail pharmacies due to their preferential treatment by pharmaceutical manufacturers. Their special discounts and pricing are not available to the public. Therefore, adding their pricing into the equation will cause an artificially low AMP to be reported. Another commenter stated that community pharmacies are at a loss compared to hospital/clinic organizations, PBMs, and mail order pharmacies because these pharmacies have access to rebates and price concessions that may not be available to community pharmacy.

Response: We disagree. Mail order and other pharmacies are included in the definition retail pharmacy class of trade given that they provide drugs to the general public. Furthermore, the calculation of AMP is based, in part, on the average price received by manufacturers. Some drug prices in AMP will be lower than the average but they will be combined with other sales prices that are higher. The FULs, in turn, are calculated based on the lowest priced drug inflated by 250 percent. In addition, we have taken other measures as described in this regulation to assure that drugs used in the FUL calculation will be available at the FULs price.

Comment: One commenter said that while the proposed rule makes a strong case for the inclusion of prices of sales to mail order pharmacies, it remains extremely vague on operational issues. Because the inclusion of these prices will have a significant impact on the AMP, the operational detail is extremely important.

Response: We are unable to respond to this comment as the commenter did not include enough specific information regarding operational issues to enable us to do so. Prices of sales to mail order pharmacies are currently included in AMP; therefore, we do not believe that the finalization of this provision will present or create new operational issues for manufacturers.

Comment: Many commenters said that mail order pharmacies should be excluded from AMP because mail order pharmacy sales are not traditional retail pharmacies and are a restricted vehicle for the delivery of prescriptions which is not publicly accessible to all patients. They do not provide the expected and needed services a retail pharmacy provides nor do they provide identical medications. Another commenter noted that a traditional retail pharmacy almost without exception pays the highest price. Mail order pharmacies are structurally similar to pharmacies that service nursing homes, which have been excluded in the proposed rule from the retail pharmacy class of trade. They should be considered separate entities.

Response: We disagree. We continue to believe that mail order pharmacies are a segment of the retail pharmacy class of trade and should remain in AMP. We note that in the OIG's report, ''Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program,'' (A–06–91–00092), November 1992 and in the GAO report, ''Medicaid Drug Rebate Program—Inadequate Oversight Raises Concerns about Rebates Paid to States,'' (GAO–05–102), February 2005, retail pharmacy class of trade was defined to mean that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services. We do believe that there are not sufficient similarities between long-term care pharmacies and mail order pharmacies especially given that drugs of long-term care pharmacies are only available to residents of those institutions.

Comment: One commenter said that removing mail order pharmacies from the retail pharmacy class of trade creates consistency in the regulation and conforms the definition to market reality.

Response: We disagree. We have consistently applied the definition of retail pharmacy class of trade to mean that segment of the market accessible to the general public. Given that mail order pharmacies are a segment of the retail marketplace, we continue to believe that their inclusion reflects market reality.

Comment: One commenter stated that mail order pharmacies are owned by PBMs and PBMs are not wholesale distributors; therefore, there is no method for distributing this lower cost to the retail sector. Another commenter said that should CMS decide to include mail order pharmacies in its definition of ''retail pharmacy class of trade'' then PBMs acting as wholesalers and or mail order pharmacies would by default need to have their purchase discounts included in the calculation of AMP.

Response: As discussed previously, we have decided to exclude PBM rebates, discounts and other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies. We understand that PBMs do not generally take possession of pharmaceutical products. Only in their role as mail order pharmacies do PBMs participate directly in the purchase or delivery of prescriptions drugs. However, we

continue to include sales to mail order pharmacies operated by PBMs. We believe that the sale to a mail order pharmacy, regardless of whether such a pharmacy in owned by a PBM, meets the definition of a sale to the retail pharmacy class of trade given that the drugs provided by such pharmacies are generally available to the general public.

Comment: One commenter said that mail order sales should not be included in the calculation of AMP because they are treated by the pharmaceutical manufacturers as a different class of trade.

Response: We disagree. The definition of retail pharmacy class of trade for the purposes of the drug rebate program is governed be the standards in this rule, not by how a manufacturer treats a sale.

Comment: A few commenters stated that mail order pharmacies will have an unfair competitive advantage over retail pharmacy if the final rule permits the inclusion in AMP.

Response: We do not believe the inclusion of mail order pharmacies in AMP in this final rule will significantly affect the competitive advantage one segment of the market has over the other. As we previously noted, the FULs price, which is calculated as an aggregate upper limit based on 250 percent of the AMP, should allow adequate payment to any pharmacy. We believe that States will consider the interests of all pharmacies in the State in setting other pharmacy payment rates and note that such rates will require approval of a State plan amendment.

Comment: One commenter suggests that if mail order pharmacy pricing is not excluded, then it should at least be used only with a diminished weight in the actual equation used to calculate AMP.

Response: We disagree. The legislation does not support a different methodology for mail order pharmacies or any other segment of the retail pharmacy class of trade when calculating AMP.

Comment: One commenter said that including mail order pricing in the determination of AMP is wrong and instead there should be a retail AMP and a mail order AMP.

Response: The current law does not provide for separate AMP calculations.

Comment: One commenter questioned why mail order pharmacies pay less for drugs. The commenter stated that community pharmacy should have the same rebates and pricing to save money.

Response: Such issues regarding the purchase prices of different entities are not covered by this final rule.

Comment: A few commenters stated that if mail order price concessions are included in AMP, the resulting base date AMP will be artificially low.

Response: As elsewhere described in this final rule, we are allowing manufacturers to revise their base date AMPs for the first four calendar quarters following publication of this final rule.

Comment: AMP needs to be defined so that the community pharmacist can continue to serve Medicaid patients.

Response: We believe that this final regulation permits states to provide for adequate reimbursement for FUL drugs subject to the FULs.

Comment: One commenter said that CMS should take into consideration how price concessions are earned by mail order pharmacies. Mail order pharmacies are able to provide manufacturers with increased market share via the use of formularies and incentives, such as copayments. In return for increased market share and profits, manufacturers offer monies and incentives not available to purchasers other than mail order for Medicaid prescriptions. Medicaid requires manufacturers to pay rebates/incentives directly to States. Manufacturers expressly exclude Medicaid prescriptions from incentive programs offered to mail order. The calculation of AMP should exclude discounts or incentives that are not available for Medicaid prescriptions.

Response: We appreciate the comment; however, the methods for earning such price concessions by mail order pharmacies are outside of the scope of the proposed rule. The calculation of AMP is not based on incentives offered to one segment of the market or whether these incentives are offered for Medicaid prescriptions.

Comment: Several commenters stated that because mail order pharmacies do not generally service the Medicaid population, they should not be included in the definition of retail pharmacy class of trade.

Response: We disagree. The definition of retail pharmacy class of trade is not dependent on whether or not Medicaid beneficiaries obtain their services from the pharmacy.

Comment: One commenter said that the inherent variable nature of AMP coupled with the fact that CMS proposed to include the prices paid to mail order pharmacies in the calculation of AMP will not provide for a viable benchmark for the cost of drugs that will allow States to control prescription drugs cost while providing pharmaceutical care for the Medicaid population.

Response: We disagree. We believe that the AMPs will be fully adequate for computing FULs and that States will make their best decisions on the application of these AMPs to the providers in their States.

Comment: One commenter said that providing mail order pharmacy services in rural areas will not suffice because of the inability to do what is required to obtain medicines.

Response: In this final rule, we are addressing the issue of what prices are included in AMP; we are not addressing this issue at this time.

Comment: One commenter said that if mail order pharmacies are in the same class of trade as retail pharmacies, then it is not clear why the MMA, which established Medicare Part D, created separate distinctions for retail pharmacy, nursing home pharmacy and mail order pharmacy. Another commenter stated that CMS specifically excluded mail order pharmacies from the definition of retail pharmacy in the rule implementing the Medicare Part D Program. Therefore, excluding mail order pharmacies from AMP would be consistent with CMS' current Part D definition of retail pharmacy.

Response: The statutory provisions applicable to Medicare Part D and the Medicaid Drug Rebate Program are significantly different. We continue to believe that mail order pharmacies are a segment of the retail pharmacy class of trade accessible to the general public and should remain in AMP.

Comment: One commenter said that the only reason offered by CMS in the proposed rule for including mail order pharmacies in AMP is that the removal would be inconsistent with past policy (71 FR 77178). The commenter further states that this does not apply to the DRA AMP.

Response: We disagree. Our reasons for including mail order pharmacies are clearly enunciated in this final rule and as noted, we do so based on more than consistency with previous policy. We continue to believe that mail order pharmacies are a segment of the retail pharmacy class of trade accessible to the general public and should remain in AMP. The DRA required that we clarify the definition of AMP, but did not mandate a manner in which we do so.

Comment: One commenter stated that if mail order should be included in the definition of retail pharmacy class of trade, a significant additional percentage increase to the FUL or significantly higher dispensing fee should be provided to those entities that provide the more desirable mode of delivery of products and services, such as community pharmacies.

Response: We disagree. The law provides that the FUL should be calculated based on a 250 percent of the

AMP for the lowest price drug. The determination of dispensing fees is left up to each State, with CMS' approval through a State plan amendment. We also disagree that mail order pharmacies do not offer a desirable mode of delivery.

Specialty Pharmacies and Direct Patient Sales

Comment: One commenter stated that direct sales to patients are usually for specialty drugs provided through a direct distribution arrangement and should be excluded from AMP. Several commenters believed that specialty pharmacies should not be included in the definition of retail pharmacy class of trade and therefore, excluded from AMP, because they limit their services to a defined population and do not dispense to the general public. Another commenter requested that CMS provide specific guidance regarding the treatment of discounts and rebates to specialty pharmacies when calculating AMP. Several commenters stated that traditional pharmacies do not have access to the prices provided to specialty pharmacies.

Response: We believe that drugs supplied through specialty pharmacies are within the regular retail marketplace. The fact that the pharmacies serve a client population characterized by specific medical conditions does not mean that their drugs are not sold to the general public, nor does it take them out of the retail pharmacy class of trade. Therefore, we have clarified in the regulation text at § 447.504(g)(11) that sales, rebates, discounts, or other price concessions to specialty pharmacies are included in AMP.

Comment: Several commenters said that sales to specialty pharmacies should be included in AMP.

Response: We appreciate the commenters' support for this provision and have retained this requirement at § 447.504(g)(11) in this final rule.

Comment: One commenter requested that CMS confirm that payments for specialty pharmacy services that satisfy the definition of a bona fide service fee should be excluded from the calculation of AMP.

Response: We concur. Payments for specialty pharmacy services that satisfy the definition of bona fide service fees should be excluded from the determination of AMP.

Comment: A few commenters said that home infusion pharmacies do not clearly fit the definition of retail pharmacy class of trade for the purpose of this regulation because they do not sell or provide drugs to the general public. Unlike retail pharmacies, infusion pharmacies treat only a specialized class of patients who rely on these pharmacies for services that support their therapy regimen as a substitute for hospitalization. In other contexts, infusion pharmacies have been excluded from the retail pharmacy class of trade. For instance, CMS excluded infusion pharmacies from this classification for purposes of Health Insurance Portability and Accountability Act (HIPAA) standards when it established the National Council for Prescription Drugs Program (NCPDP) claim format for retail pharmacy claims. Infusion pharmacies also are distinguished from retail pharmacies under HCPCS. HCPCS provides approximately 80 ''S'' codes for home infusion therapy services that may not be used by retail pharmacies for their drug claims. It is not clear if payment based on AMP would appropriately reimburse home infusion pharmacies for the drugs that they provide.

Response: We believe that even though home infusion therapy pharmacies serve a defined population based on medical condition and are classified differently for the purpose of reimbursement; the drugs from these pharmacies are sold in the retail marketplace and are available to the general public. In accordance with the statute, the AMPs could be used to establish FULs. States may decide to use AMPs for reimbursements subject to our review and approval of a State plan amendment. We further believe that this final regulation provides states with sufficient flexibility to establish adequate reimbursement rates for FULs drugs. Therefore, we have clarified in the regulation text that sales to home infusion therapy pharmacies are included in AMP.

Retail Pharmacy Class of Trade

Comment: One commenter said that the proposed definition of retail pharmacy class of trade does not allow for adequate analysis of the costs related to operating such pharmacy. What normally qualifies as a retail pharmacy is an independently owned grocery, or chain pharmacy locations. Mail service and hospital outpatient pharmacies do not incur the same costs as retail pharmacies. These practice sites are able to purchase drugs at a lower cost than retail pharmacies. Any definition of pharmacy that is used in calculating costs must adequately differentiate between various practices settings so that the reimbursement can properly cover the true cost associated with each setting.

Response: The AMP is the average price received by the manufacturer for the drugs in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade excluding certain customary prompt pay discounts and including certain price concessions, as defined in the regulation. We have defined AMP consistent with our understanding of current law. Since AMP is based on the price received by the manufacturer for the drug, it does not necessarily reflect a particular pharmacy's acquisition cost of a drug.

Comment: One commenter asked whether all community retail entities buy drugs at the same price; if not, what are the differences in purchased drugs for all the retail outlets (HMOs, mail order pharmacies, hospital pharmacies, Federal agency pharmacies, chain pharmacies and independent retail pharmacies). If there is a significant difference, is CMS discriminating against some retail outlets? One commenter said that the definition should reflect the prices at which traditional retail pharmacies purchase medications. Another commenter said that in order to be included in the definition of retail pharmacy class of trade, the prices used should be prices available to community pharmacy and the prescriptions should be publicly accessible.

Response: As we have previously noted, AMP is based on the average price received by the manufacturer for the drug; it does not necessarily reflect the pharmacy's acquisition cost.

Comment: Several commenters agreed that the entities included in the retail pharmacy class of trade must provide public access. Another commenter said that retail pharmacy class of trade describes outlets that dispense drugs to the general public.

Response: We agree.

Comment: One commenter stated that entities should be included in the definition of retail pharmacy class of trade on the basis that they do not conduct a manufacturer-wholesaler transaction. Also, hospitals and nursing homes do not distribute drugs to the general public and should not be included in retail pharmacy class of trade. Only traditional retail pharmacies (chains and independents) should be included. The retail pharmacy class of trade should be defined as those pharmacies that provide face-to-face service to patients, offer timely delivery, can provide 24/7 availability and response to patient needs, and are available to patients in the event of a disaster.

Response: We do not agree that the retail pharmacy class of trade is limited

to those entities proposed by the commenter. As stated in response to prior comments, we define retail pharmacy class of trade more broadly to include, for example, direct sales to physicians and outpatient hospital sales, to the extent that they provide drugs to the general public.

Comment: Many commenters stated that the retail pharmacy class of trade should include any independent pharmacy, independent pharmacy franchise, independent chains, independent compounding pharmacy, and traditional chain pharmacy—including each traditional chain pharmacy location, mass merchant pharmacy and supermarket pharmacy.

Response: We agree, but note that we do not believe this list of pharmacies to be inclusive of all entities in the retail pharmacy class of trade.

Comment: Another commenter said that the proposed definition of retail pharmacy class of trade includes entities such as mail-service pharmacies, hospital outpatient pharmacies, and outpatient clinics that may have access to rebates and price concessions that are not accessible to community pharmacies. One commenter further said that these entities fall clearly outside of the statutory definition of AMP. Some commenters said that if AMP is to represent the price of drugs bound to the retail pharmacy class of trade then it should include and exclude components (including discounts, rebates, and other price concessions) according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.

Response: We disagree. We believe the statute requires that rebates, discounts, and price concessions associated with drugs to the retail pharmacy class of trade be included in AMP. The definition does not precondition the inclusion of such discounts or other price concessions on whether other entities within the retail pharmacy class of trade can access these same discounts. We believe there are variety of circumstances in which an entity within the retail pharmacy class of trade might receive a rebate or discount not available to other entities in that class.

Comment: One commenter said that manufacturers should be instructed to exclude from AMP sales to entities that do not meet the definition of the retail pharmacy class of trade.

Response: We have clarified at § 447.504(g)–(h) which sales are included and excluded in this final regulation.

Comment: A few commenters said that independent pharmacy owners should have a level playing field. It is not fair to include rebates and discounts to PBMs, insurance companies and government agencies and exclude rebates to independent business owners. One commenter said that only if complete access to all discounts offered at every level, mail order, government, HMO and PPOs are offered to any willing buyer will this system be fair.

Response: We disagree. The rebate agreement provides for the inclusion of rebates, discounts, and price concessions associated with drugs provided to the retail pharmacy class of trade in AMP. It does not condition the inclusion of such price concessions on whether other entities within the retail pharmacy class of trade can receive these same discounts. We agree with the comments concerning the PBMs and certain government purchasers, and have decided to exclude certain Federal and state sales, and PBM rebates, discounts, or other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies. As noted previously, we believe there may be circumstances in which an entity within the retail pharmacy class of trade might receive a rebate or discount not available to other entities in that class of trade.

Comment: One commenter stated that there is no basis in the statute or in the congressional discussion surrounding the legislation to include sales to mail order pharmacies and rebates, discounts, or other price concessions associated with sales of drugs provided to the retail pharmacy class of trade in AMP. Had Congress wanted to do so, it would have expressly provided for these items to be included in AMP, as it had done in establishing the ASP-based reimbursement system for Medicare Part B drugs.

Response: We do not agree. After consideration of all comments received, we continue to believe that mail order pharmacies are part of the retail pharmacy class of trade in as much as they dispense prescriptions to the general public. The rebate agreement has consistently provided for the inclusion of rebates, discounts, and price concessions associated with drugs provided to the retail pharmacy class of trade be included in AMP. We see no reason to change that policy in this rule.

Comment: One commenter requested that CMS clarify what it means to sell or provide covered drugs to the general public.

Response: We believe that the term sell or provide covered drugs to the general public as discussed previously in the OIG reports is consistent with our definition of the retail pharmacy class of trade. As discussed previously, we have defined retail pharmacy class of trade to include the sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which include all price concessions related to such goods and services.

Treatment of Medicaid Sales

Comment: One commenter stated that price concessions associated with the sales to Medicaid should be included in AMP but Medicaid rebates should be excluded because no portion of these rebates is shared with the retail pharmacy community. One commenter agreed that prices paid by Medicaid programs should be included in AMP.

Response: We appreciate the support for this provision and have clarified in the regulation text at § 447.504(h)(23) that discounts and other price concessions to third party payers, including Medicaid, are excluded from AMP.

Comment: One commenter stated that if CMS requires Medicaid sales and units to be included in AMP, then CMS should require that the applicable Medicaid rebates are included in AMP. Requiring the inclusion of Medicaid units in AMP without including the applicable Medicaid rebates will skew the AMP calculation and make the resulting AMP inaccurate.

Response: We disagree. We do not believe that including Medicaid sales and units without the respective rebate in AMP results in an inaccurate AMP. AMP is calculated by dividing net sales by total number of units sold, less free goods. This has been CMS' policy since the inception of the Medicaid Drug Rebate Program. While AMP and best price include discounts or other price concessions, we do not believe that Medicaid rebates should be subtracted from sales. As a practical matter, we do not know how this could be done with accuracy because manufacturers often do not know which of their sales are dispensed to Medicaid beneficiaries.

Comment: Many commenters stated that Medicaid sales should not be included in AMP, similar to other Federal payers.

Response: We disagree. Medicaid sales are included in AMP, as are the sales in other Federal programs (except for those excluded as identified in the regulation), because Medicaid sales are part of the chain of sales to retail pharmacies. Therefore, we believe that it is appropriate to include Medicaid sales in AMP. Furthermore, manufacturers often do not know which

of their sales are dispensed to Medicaid beneficiaries, making it impossible to remove these sales from AMP.

Comment: One commenter stated that AMP should reflect rebates paid by manufacturers to third party payers such as Medicaid which are unavailable to retail pharmacies.

Response: AMP generally reflects rebates provided by the manufacturer for drugs distributed to the retail pharmacy class of trade. However, the rebate agreement specifically state that rebates paid to States under the Medicaid Drug Rebate Program are excluded from AMP calculations. We see no reason to change that policy in this rule.

Comment: One commenter requested that CMS explain what sales and associated rebates are paid under the Medicaid Program other than those paid under section 1927 of the Act.

Response: Rebates paid to State Medicaid Agencies for covered outpatient drugs dispensed to Medicaid beneficiaries, including CMS-authorized State supplemental rebates, are excluded from AMP.

Comment: One commenter requested that CMS clarify what we mean in the proposed by the statement, ''Therefore, we would clarify that rebates paid to the States under the Medicaid Drug Rebate Program should be excluded from AMP calculations but that the price concessions associated with the sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients should be included'' (71 FR 77180).

Response: This statement was intended to clarify how price concessions provided to wholesalers for drugs for which Medicaid is the payer differ from Medicaid rebates paid directly by manufacturers to Medicaid agencies. It would be virtually impossible for a manufacturer to separate these price concessions out from its AMP calculation because Medicaid does not purchase drugs directly, but reimburses pharmacies for drugs. Rebates, however, are paid based on state utilization data by manufacturers to States. These are clearly identifiable and are not taken into account in the calculation of AMP.

Comment: One commenter requested that CMS clarify how rebates paid to State Medicaid agencies under either the national rebate agreement or a CMS-authorized supplemental rebate agreement are treated in the calculation of AMP. The commenter asked whether manufacturers are expected to perform some level of diligence to trace Medicaid sales to the retail pharmacy class of trade.

Response: Rebates paid to State Medicaid Agencies under either the national rebate agreement or CMS-authorized State supplemental rebate agreements are excluded from AMP.

Comment: Several commenters stated that including Medicaid data in AMP is ''bootstrapping'' the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the State and Federal Government. The commenters believed that the inclusion of Medicaid data would have an artificial impact on market prices, and that Medicaid should be excluded from the AMP calculation. Other commenters stated that including Medicaid sales data would likely create a circular loop, negating the validity of AMP.

Response: We disagree. The AMP is not intended to represent the prices paid by retail pharmacies for medications; rather, it is the average unit price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. We do not believe that the inclusion of Medicaid sales will have an impact on market prices because they are subsumed in the total sales from manufacturers to wholesalers.

Treatment of Supplemental Rebates

Comment: One commenter stated that supplemental rebates paid to the Medicaid agency are not disclosed, never shared with pharmacy vendors and may be significant in their negative impact on those vendors participating in the Medicaid Program.

Response: Medicaid supplemental rebates paid to the Medicaid agency are not included in AMP. We see no reason why supplemental rebates paid to the State that do not impact the payment rate to pharmacies would affect their participation in the Medicaid Program.

Comment: A few commenters stated that because community pharmacies do not receive State supplemental rebates, the rebates should be excluded from AMP. Another commenter requested that CMS clarify that any supplemental rebates manufacturers pay to State Medicaid programs are to be considered ''other price concessions'' for the purposes of this section; thus, these rebates should be included in AMP calculations.

Response: Supplemental rebates paid under a CMS-authorized State supplemental rebate agreement are excluded from AMP and not considered as ''other price concessions'' for the purposes of this section. We have clarified in the regulation text at § 447.504(h)(24) that such supplemental drug rebates are excluded from AMP.

Comment: One commenter requested that CMS clarify that rebates paid to States under the Medicaid Drug Rebate Program should be excluded from AMP calculations but that price concessions associated with the sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients should be included.

Response: Rebates paid to States under the Medicaid Drug Rebate Program are excluded from AMP, but the units and price concessions associated with the sales of drugs in the retail pharmacy class of trade, regardless of whether such drugs are provided to Medicaid patients, are included.

Comment: A commenter requested that CMS clarify whether supplemental state rebates (for example, those associated with a preferred drug list) are included as well.

Response: All supplemental rebates paid under a CMS-authorized State supplemental rebate agreement are excluded from AMP regardless of whether the agreement is associated with a preferred drug list.

Treatment of Medicare Part D Sales

Comment: Several commenters expressed support for CMS' treatment of Medicare Part D.

Response: We appreciate the support for this provision and have clarified in the regulation text at § 447.504(h)(23) that associated discounts, rebates, or other price concessions to third party payers such as a PDP or an MA–PD are not included in the calculation of AMP on the basis that such price concessions are essentially third party discounts and not discounts which adjust the price actually realized at the retail pharmacy. We retained in the regulation text that the sales of drugs in the retail pharmacy class of trade which are provided to a PDP or an MA–PD are included in AMP.

Comment: Several commenters stated that sales and rebates to a Medicare Part D PDP and an MA–PD should not be included in AMP. One commenter recommended that CMS exclude price concessions under Medicare Part D, as these price discounts are PBM discounts of those PBMs that administer the Part D Program. One commenter further stated that the rebates paid by the manufacturer to a PDP or an MA–PD are not considered by wholesalers when determining the purchase price to a retail community pharmacy and should not be included in any calculation to reimburse the pharmacy. A few commenters stated that Medicare Part D rebates are similar to Medicaid rebates, which are excluded from AMP, and that Medicare Part D rebates should be treated similarly. One commenter

requested that CMS confirm and provide guidance regarding whether rebates paid to Medicare Part D are excluded from AMP. Another commenter stated that including the prices of sales and rebates through a PDP, MA–PD, or a qualified retiree prescription drug plan would result in a windfall to manufacturers and an additional burden for retail pharmacies. The commenter stated that while prices charged to Part D plans cannot create a new best price for the Medicaid Program, including Part D prices that are lower than typical commercial prices in AMP calculations could further reduce the reported AMPs below the actual cost to retail pharmacies.

Response: We have clarified in the regulation text at § 447.504(h)(23) that associated discounts, rebates, or other price concessions to third party payers such as to a PDP or an MA–PD are not included in AMP. Such price concessions are essentially third party discounts and not discounts which adjust the price actually realized. We retained in the regulation text that the sale of the drugs reimbursed by these programs and units associated with the sales of drugs in the retail pharmacy class of trade which are reimbursed by a PDP or an MA–PD should remain in AMP. We do not believe that this will be a burden for retail pharmacy because the manufacturer would not necessarily know the ultimate destination or whether the discount or price concession to the third party payer is passed on to the retail pharmacy class of trade such that it would result in an adjustment of the price actually realized.

Comment: One commenter requested that CMS clarify whether a manufacturer discount provided to a PBM in connection with Part D mail order business should be included in AMP.

Response: We have clarified in the final rule at § 447.504(g)(6) that sales and discounts to mail order pharmacies operated by PBMs are included in AMP.

Comment: One commenter requested that CMS clarify the treatment of qualified retiree prescription drug plans for purposes of AMP.

Response: We have clarified in the regulation text at § 447.504(h)(23) that associated discounts, rebates, or other price concessions paid to third party payers such as rebates paid by the manufacturer to a qualified retiree prescription drug plan under section 1860D–22(a)(2) of the Act are not included in AMP. Such price concessions are essentially third party discounts and not discounts which adjust the price actually realized. We retained in the regulation text that the sale of the drugs reimbursed by these programs and units associated with the sales of drugs in the retail pharmacy class of trade which are reimbursed by a qualified retiree prescription drug plan under section 1860D–22(a)(2) of the Act should remain included in AMP.

Comment: One commenter stated that the proposed rule excludes from AMP rebates to Medicaid, the DoD, the IHS, and the DVA because prices to these entities are not available to the retail pharmacy class of trade. Rebates offered to SCHIP, Medicare Part D Plans, and SPAPs are also not available to the retail pharmacy class of trade but are required to be included in AMP. The commenter asserted that assumptions in the proposed rule regarding these programs are definitely flawed and should be revisited.

Response: We revised the regulation text at § 447.504(h)(23) to state that associated discounts, rebates, or other price concessions to third party payers such as a PDP, MA–PD, SCHIP, or an SPAP are not included in the calculation of AMP. Such price concessions are essentially third party discounts and not discounts which adjust the price actually realized.

Comment: One commenter stated that including Part D in AMP may change manufacturer discounting behavior for Part D.

Response: We do not believe that a change in manufacturer discounting behavior is likely, as the manufacturer would not necessarily know the ultimate destination when initially sold. Furthermore, as discussed previously, we have revised the regulation to exclude discounts, rebates, or other price concessions to third party payers, such as a PDP or MA–PD. Such price concessions are essentially third party discounts and not discounts which adjust the price actually realized.

Comment: A few commenters said that the proposed rule directs manufacturers to consider sales and associated price concession extended to Part D. However, manufacturers do not have access to this information until they receive quarterly invoices from the States. CMS should include in the final rule instructions for addressing lagged data.

Response: We appreciate these comments and have clarified in the regulation text at § 447.504(h)(23) that associated discounts, rebates, or other price concessions paid to third party payers such as rebates paid by the manufacturer to a qualified retiree prescription drug plan under section 1860D–22(a)(2) of the Act are not included in AMP. As discussed previously, such price concessions are essentially third party discounts and not discounts which adjust the price actually realized.

Comment: One commenter said that CMS should recognize in the final rule the operational challenges manufacturers face in collecting data. Based on those challenges, the commenter urged CMS to allow manufacturers to make and rely upon appropriate reasonable assumptions when including Part D sales in AMP.

Response: We recognized the operational challenges manufacturers face in collecting data and have clarified in the final regulation text the submission of lagged price concessions and the use of manufacturer assumptions.

SPAP Price Concessions

Comment: Many commenters suggested that CMS exclude manufacturer rebates to SPAPs from AMP calculations as it does with Medicaid rebates. Another commenter expressed appreciation for CMS' specific guidance regarding the treatment of discounts/rebates to SPAPs, but disagreed with including discounts/rebates to SPAPs in AMP. This commenter argued that SPAPs are government-run programs, and discounts offered to them are often statutorily driven (sometimes tied to Medicaid rebates) or otherwise not determined by market factors. Another commenter stated that SPAPs are similar to the Medicaid Program in that SPAPs represent third-party government payers; therefore, rebates for these programs should be treated the same as Medicaid rebates. One commenter stated that the proposal to include all SPAP sales and rebates in AMP to the extent that these sales are made to the retail pharmacy class of trade conflicts with Manufacturer Release 68, which states that only SPAPs that meet specified criteria are excluded from AMP. Another commenter requested that CMS clarify that all SPAP sales and rebates are included regardless of the administrative structure of the SPAP. Other commenters supported the inclusion of SPAP sales and rebates in AMP.

Response: We recognize that SPAPs are typically third-party governmental payers that do not directly purchase drugs from manufacturers. After considering the comments received, we agree that SPAP sales, as well as sales to PDPs and MA–PDs under the Medicare Part D Program should be treated in the same manner as Medicaid sales. That is, sales of drugs that are

paid by these programs to pharmacies are included in AMP, but we have revised our policy and provide in this final rule at § 447.504(h)(23) that associated discounts, rebates, or other price concessions to the extent that they do not adjust prices at the retail pharmacy class of trade are excluded from AMP. As discussed previously, we believe that such price concessions are essentially third party discounts and not discounts which adjust the price actually realized. Other State payments for drugs, such as State employee benefit programs or medical programs for inmates or patients of State prisons or hospitals, do not meet the criteria of an SPAP. We also agree with the commenter regarding Manufacturer Release 68 and have clarified that SPAP sales should be included in AMP and SPAP discounts should be excluded. Therefore, all SPAP sales will be treated the same for AMP, regardless of whether they meet the criteria in Manufacturer Release 68.

Comment: Several commenters stated that community pharmacies do not receive State-only and SPAP prices and rebates; therefore, these should be excluded from AMP. One commenter believed it is inconsistent with the legislative intent of the DRA for CMS to include sales reimbursed by SPAPs for non-Medicare Part D covered prescriptions in the calculation of the AMP because no Federal money is involved, making it outside CMS' purview in determining what to include in AMP. One commenter stated that the inclusion of SPAPs seems inconsistent with legislative intent.

Response: CMS believes that SPAP sales should be included in AMP given our understanding of the statute. We also find that SPAP sales, like Medicaid and Medicare Part D sales, are part of the broader chain of sales from manufacturers to wholesalers or pharmacies that are indistinguishable from other market sales. We believe that SPAP sales are within the scope of AMP because AMP is intended to capture sales to the retail pharmacy class of trade.

Comment: One commenter requested that CMS post on its Web site a complete and accurate list of qualified SPAPs which is updated on a frequent and regular basis.

Response: We appreciate this comment and will continue to post a current list of SPAPs designated as exempt from best price on the CMS Web site at *http://www.cms.hhs.gov/MedicaidDrugRebateProgram/Downloads/SPAPBestPriceList.pdf.*

Comment: Another commenter asked that CMS treat SPAP sales consistently for AMP and best price purposes and exclude them from both. AMP should reflect prices in the commercial marketplace and including prices set by statute in the AMP calculation undermines this purpose. Likewise, excluding prices from best price encourages manufacturers to provide concessions that do not reflect commercial considerations, as is the case with SPAPs, where prices or rebates are generally the result of State law rather than market negotiations.

Response: We disagree. While the statute specifically excludes SPAPs from the determination of best price, CMS believes that SPAP sales should be included in AMP because they are subsumed in the overall chain of sales from the manufacturers through wholesalers to the pharmacies in the retail pharmacy class of trade.

Comment: One commenter asked CMS to provide guidance regarding how SPAP sales and rebates should be included. Specifically, the commenter asked CMS to specify what ratio of sales manufacturers should apply to SPAP rebates, since the data available to manufacturers do not indicate the particular sales to which the rebates apply.

Response: We have clarified in the regulation text at § 447.504(h)(23) that associated discounts, rebates, or other price concessions paid to third party payers such as rebates paid by the manufacturer to a SPAP are not included in AMP. Such price concessions are essentially third party discounts and not discounts which adjust the price actually realized.

Comment: One commenter noted that the proposed rule directs manufacturers to consider sales and associated price concession extended to SPAPs. However, manufacturers do not have access to this information until they receive quarterly invoices from the states. CMS should include in the final rule instructions for addressing lagged data.

Response: We have in § 447.504(h)(23) excluded the associated discounts, rebates, or other price concessions provided by the manufacturer to SPAPs from AMP in this final rule.

Comment: One commenter requested that CMS define SPAP.

Response: We have decided not to define SPAP in this regulation at this time. The current guidance for the definition of SPAP has been set forth in Manufacturer Release 68.

Comment: One commenter requested that we share with SPAPs the quarterly unit rebate amount (URA) on the basis that the data is already being furnished to State Medicaid Agencies.

Response: The URAs for brand name drugs are based on best price, which we consider confidential. The URAs for generic drugs are 11 percent of AMP, which will be posted on our Web site.

Treatment of SCHIP

Comment: One commenter noted that the proposed rule directs manufacturers to consider sales and associated price concession extended to SCHIP. However, manufacturers do not have access to this information until they receive quarterly invoices from the States. CMS should include in the final rule instructions for addressing lagged price concessions.

Response: We have modified the regulation text regarding the submission of lagged price concessions to allow manufacturers to submit such information.

Comment: One commenter asked that we clarify the meaning of the term ''associated with sales of drugs provided to the retail pharmacy class of trade'' in regard to Part D, SCHIP, and SPAP.

Response: We have clarified in the regulation text at § 447.504(h)(23) that associated discounts, rebates, or other price concessions paid to third party payers such as rebates paid by the manufacturer to Medicare Part D, SCHIP, and SPAP are not included in AMP. However, we continue to believe that the respective sales are included in AMP to the extent that such sales have occurred through the retail pharmacy class of trade. However, the associated discounts, rebates, or other price concessions for these sales are not included in AMP because we understand such price concessions are essentially third party discounts and not discounts which adjust the price actually realized.

Comment: One commenter stated that SCHIP should be excluded from AMP and another commenter expressed support for the inclusion of SCHIP.

Response: We agree that the treatment of SCHIP sales is determined by the entities that are actually in the sales chain for drugs for SCHIP beneficiaries. We recognize that SCHIP sales are similar to Medicaid sales and should be treated as such. Therefore, we have clarified in the regulation text at § 447.504(h)(23) that the associated discounts, rebates, or other price concessions for these sales are not included in AMP. We understand that such price concessions are essentially third party discounts and not discounts which adjust the price actually realized. We retained in the regulation text at § 447.504(g)(15) that the sale and units

associated with the sales of drugs in the retail pharmacy class of trade which are provided to SCHIP are included in AMP.

Prices to Other Federal Programs

Comment: One commenter endorsed CMS' position to exclude from AMP the prices provided to government programs on the basis that such purchases are outside the retail pharmacy class of trade. Other commenters stated that community pharmacies do not receive FSS/depot prices and should be excluded from AMP.

Response: We appreciate the support for this provision and have retained this requirement at § 447.504(h) in the final rule.

Comment: Several commenters stated that CMS rightly excluded from AMP, manufacturer rebates paid to the DoD under TRICARE. One commenter requested that the classification of the retail TRICARE pharmacies as a depot should be avoided until the issue between manufacturers and the DVA has been resolved. Several commenters requested that CMS provide clarification regarding which TRICARE prices, if any, are considered depot prices and are excludable. Several commenters requested that CMS provide clarification in the treatment of TRICARE utilization when the manufacturer has not paid rebates on the utilization and does not receive utilization data.

Response: We appreciate the comment regarding the litigation concerning TRICARE and DVA program. See *The Coalition for Common Sense in Government Procurement v. Secretary of Veteran Affairs*, 464 F.3d 1306 (Fed. Cir. 2006). However, we recognize that TRICARE, like the Medicaid Program, is a third-party governmental payer that does not directly purchase drugs from manufacturers. After considering the comments received, we agree that TRICARE sales, as well as sales to SPAPS, PDPs and MA–PDs under the Medicare Part D Program should be treated in the same manner as Medicaid sales to the extent that such sale has occurred through the retail pharmacy class of trade. That is, sales of drugs to pharmacies that are reimbursed by these programs are included in AMP, but we have revised our policy and provide in this final rule at § 447.504(h)(23) that associated discounts, rebates, or other price concessions to these programs are excluded from AMP.

Comment: One commenter requested that CMS clarify whether the exclusion for depot prices applies both to mandatory rebates and voluntary rebates paid to the DoD. Additionally, if voluntary rebates paid to DoD are to be excluded from AMP, the final rule must specify whether the units are to be left in the calculation, as with Medicaid rebates, or, if the units are to be excluded, the value at which the excluded units should be removed from the AMP calculation.

Response: We have clarified in this final regulation at § 447.504(g)(15) that sales of drugs to pharmacies that are reimbursed by TRICARE are included in AMP, but we have revised our policy and provide in this final rule at § 447.504(h)(23) that associated discounts, rebates, or other price concessions, whether mandatory or voluntary, are excluded from AMP.

Comment: One commenter requested that CMS clarify whether payment of rebates by a manufacturer on TRICARE utilization is a prerequisite for concluding that such utilization is a depot sale.

Response: We have clarified in the final regulation at § 447.504(h)(23) that associated discounts, rebates, or other price concessions to TRICARE are excluded from AMP.

Comment: Several commenters stated that CMS rightly excluded manufacturer rebates paid to the DVA and the DoD from AMP.

Response: We appreciate the support for this provision and have retained this requirement at § 447.504(h)(1) in the final rule.

HMOs and MCOs

Comment: A few commenters stated that it is unclear whether the HMO/MCO exclusion from AMP applies only to purchases by MCOs that have their own facilities, or whether it also excludes transactions of health plans that reimburse network providers. The commenters further stated that only transactions with clearly identifiable HMOs and health plans should be treated as excluded from AMP. Many commenters asked that CMS clarify that HMOs that simply reimburse enrollees for their drug purchases at retail pharmacies (without themselves purchasing or taking possession of the drugs) are included in the calculation of AMP.

Response: We recognize that many HMOs that act as third party payers, like SPAPs and PBMs, do not generally take possession of pharmaceutical products. Sales of these drugs flow through the regular retail chain of sales and are not distinguishable to manufacturers. Accordingly, similar to a third party payer, when an HMO does not purchase or take possession of drugs, we consider those sales to be within the retail sales chain and not the HMOS. Because as with other third party payers, the discounts, rebates, or price concessions are not available to the wholesaler, we have clarified that the associated rebates, discounts, or other price concessions are not included in AMP. We retained in the regulation text at § 447.504(h)(23) that the sales of the drug reimbursed by the HMO/MCO should remain in AMP, but sales directly to the HMO/MCO should be excluded. However, when drugs are dispensed by HMOs, including managed care organizations, those drugs are not subject to the requirements of the Medicaid drugs rebate program.

Comment: One commenter noted that in some places in the proposed rule CMS uses the terms MCO and HMO interchangeably, but in others, it refers to ''health maintenance organizations (HMOs), including managed care organizations (MCOs).'' The commenter noted that MCO is usually an umbrella term for a number of different entities, one of which is an HMO. The commenter requested that CMS clarify the definition of MCO for purposes of the final rule. Another commenter stated that neither HMO nor MCO is defined in the proposed rule.

Response: We acknowledge that the terminology used for these entities varies. Our intent is that sales to HMOs and MCOs that purchase and take possession of drugs are excluded from AMP. We have clarified in § 447.504(h)(23) that the associated rebates, discounts, or other price concessions for an HMO does not purchase or take possession of drugs are not included in AMP. We retained in the regulation text at § 447.504(g)(15) that the sales of the drug reimbursed by the HMO/MCO should remain in AMP.

Comment: One commenter requested that CMS clarify whether HMO-operated pharmacies that provide drugs only to their enrollees are excluded from AMP. The commenter noted that these pharmacies do not serve the general public in the way that other retail pharmacies do.

Response: HMO-operated pharmacies that purchase drugs and provide these drugs only to their enrollees are excluded from AMP. We have clarified in the regulation text at § 447.504(h)(5) that direct sales to HMO-operated pharmacies are excluded from AMP.

Comment: One commenter asked that we clarify whether the reference to HMOs and MCOs are limited to so-called ''staff model'' HMOs and MCOs that purchases pharmaceuticals for dispensing to their members, or whether they include so-called ''IPA-model'' HMOs and MCOs that arrange for pharmacy discounts but do not actually purchase drugs.

Response: As explained above, direct sales to HMOs that purchase and take possession of drugs, such as many staff model HMOs, would be excluded from AMP.

Comment: One commenter was pleased that CMS included MCOs in its definition of HMOs, which the statute specifically excludes in section 1927 of the Act. Another commenter expressed support for the treatment of HMOs/MCOs.

Response: As discussed in the preceding responses, we distinguish between HMOs and MCOs that purchase and take possession of drugs, which are excluded from AMP, from those that reimburse for drugs through retail pharmacies, which are included in AMP.

Comment: One commenter requested that CMS exclude direct and identifiable indirect sales to HMOs that operate their own pharmacy.

Response: As noted in the preceding responses, these sales are excluded from AMP.

Administrative and Service Fees

Comment: Several commenters agreed with CMS that ''bona fide service fees'' should not be taken into account for the purpose of AMP. These commenters noted that this is consistent with Congress's intent and consistent with the treatment of bona fide services fees for the calculation of ASP for Medicare Part B.

Response: We appreciate the support for this provision and have retained this provision at § 447.504(h)(19) in the final regulation.

ASP

Comment: Many commenters requested that CMS explicitly adopt all guidance related to the definition of bona fide service fee contained in the preamble to the 2007 Physician Fee Schedule (PFS) final rule published on December 1, 2006 (71 FR 69624). Another commenter supported the same approach for AMP in Medicaid. CMS defined these fees as ''expenses that generally would have been paid for by the manufacturer at the same rate had these services been performed by other or similarly situated entities.'' CMS should continue to permit manufacturers, depending on the circumstances and the nature of the services involved, to calculate the fair market value for a set of itemized bona fide services, rather than for each service individually. Moreover, as the method for determining fair market value may vary based on the terms of the contract at issue, CMS should refrain from requiring manufacturers to follow a particular method for evaluating whether a fee equals fair market value. The commenter further said that the bona fide service fee definition requires these fees to ''not be passed on, in whole or in part, to a client or customer of an entity.'' The commenter urged CMS to replicate its interpretation of this clause in the ASP context for AMP. Another commenter stated that CMS should clarify that the explanations applicable to the definition of bona fide service fees when manufacturers are calculating ASP also apply when they are determining AMP and best price because many manufacturers do not make products subject to ASP reporting and may not be familiar with the discussion of service fees in the preamble to the 2007 PFS final rule. The commenter requested CMS to expressly reference the discussion of bona fide service fees in the preamble to the 2007 PFS final rule, as well as make clear that CMS is adopting the principles and positions applicable to bona fide service fees outlined in the 2007 PFS final rule in the ASP context for purposes of AMP and best price.

Response: We agree. In light of the many comments received, we are adopting the 2007 final ASP reporting rule's (71 FR 69668, December 1, 2006) interpretation of the definition of bona fide service fees and how manufacturers may apply the definition for the purposes of AMP and best price. We appreciate these comments and have further clarified in § 447.502 that bona fide service fees mean fees for an expense that would have been paid by the manufacturer at the same rate had these services been performed by the manufacturer or another entity.

Comment: One commenter believes CMS should apply the definition of bona fide service fees to the term ''distribution services'' on the basis that the ASP final rule has clearly articulated a standard for exclusion. Furthermore, incorporating the term ''distribution services'' into the definition of AMP does not reflect the fact that many core distribution services—such as packaging, shipping and handling—may meet the test of bona fide service fee and should be excluded from AMP.

Response: We appreciate this comment and have clarified at § 447.504(h) that distribution services which meet the definition of bona fide services fees are excluded from AMP.

Comment: Several commenters expressed support for the exclusion of legitimate service fees from AMP, since by definition, these fees are paid for services, not the drug. However, the exclusion only recognizes one of the two standard methods by which manufacturers have paid service fees and recommended that CMS create an additional explicit exclusion for administrative fee arrangements that meet the OIG safe harbor under the anti-kickback statute.

Response: We believe that it is outside the scope of our authority to propose exclusions regarding the OIG safe harbor under the anti-kickback statute since only the IG of the U.S. Department of Health and Human Services has been authorized to issue advisory opinions related to health care fraud and abuse under section 1128D(b) of the Act.

Comment: Several commenters recommended that CMS eliminate the condition that the services would be required ''in the absence of the service arrangement'' or otherwise clarify that fees paid for bona fide administrative services related to the administration of a rebate contract will qualify as ''bona fide service fees'' as long as they are: (i) for legitimate services, (ii) for services that the manufacturer would otherwise have to perform or have others perform for it, and (iii) represent fair market value.

Response: We disagree. We do not believe that for the purposes of the Medicaid drug rebate program, administrative services related to the administration of a rebate contract would qualify as bona fide service fees because these fees are not associated with the efficient distribution of drugs or our interpretation of the bona fide service fee guidance.

Comment: A commenter further said that bona fide service fees should explicitly include all fees paid by manufacturers to non-terminal retail providers.

Response: We disagree. We believe that the definition and additional guidance clearly defines what constitutes a bona fide service fee and distinguishes these fees from other fees that may reduce the price of a drug.

Comment: One commenter strongly supports CMS' proposed definition of bona fide services and believes that the decision to adopt the same definition of these fees for both ASP and AMP will enhance uniformity in reporting across the Medicare and Medicaid Programs. However, the commenter encourages CMS to confirm several points by replicating portions of the narrative of the PFS final rule and (1) deleting the specific reference to ''distribution fees'' in the definition of AMP, (2) confirm that the terms ''bona fide,'' ''itemized,'' and ''actually performed on behalf of the manufacturer or otherwise performed'' include ''any reasonably necessary or useful services of value to

the manufacturer that are associated with the efficient distribution of drugs.'' CMS should reiterate that AMP will incorporate the ASP definition's reference to services that are performed ''on behalf of'' a manufacturer as including both those services that a manufacturer possesses the capacity to perform and those that only another entity can perform.

Response: We appreciate the support for this provision and have incorporated the final ASP reporting rule's interpretation of the definition of bona fide service fees at § 447.502 and how manufacturers may apply the definition for the purposes of AMP in its entirety.

Group Purchasing Organizations

Comment: Many commenters requested that CMS specify that administrative fees paid to GPOs be specifically excluded from AMP. A few commenters requested that CMS clarify an issue in the preamble to the final ASP rule regarding whether fees paid to GPOs would come within the definition of bona fide service fees. The commenters stated that these fees should receive the same treatment as other administrative and service fees for the purpose of AMP and best price. Also, CMS should clarify in the final rule that such arrangements do not constitute price concessions or discounts to purchasers and should require the manufacturer to ascertain if the fee is passed on. One commenter requested that CMS clarify that fees paid to GPOs are excluded and revise the definition of bona fide service fee to read, ''For purposes of 42 CFR §§ 447.504(h) and 447.505(e), fees paid by a manufacturer to a bona fide group purchasing organization, as defined at 42 CFR § 100.952(j)(2), will not constitute a price concession by the manufacturer unless the fees (or any portion thereof) are passed on to the group purchasing organization's members or customers as part of an agreement between the manufacturer and the GPO.''

Response: We have clarified in § 447.504(h)(19) that to the extent that fees, including service fees, distribution fees, and administrative fees and other fees to GPOs meet the definition of ''bona fide service fee,'' such fees are excluded from the calculation of AMP and are not considered price concessions. If the manufacturer has an agreement with the GPO that any of these monies are passed on to the group purchasing organization's members or customers, they would not be excluded as a bona fide service fee. We believe there must be no evidence or arrangement that the fee is passed on to the member pharmacy, client or customer of any entity included in the calculation of AMP in order for the manufacturer to exclude these fees from the determination of AMP.

Comment: Several commenters said that unlike the ''safe harbor'' regulations, the proposed rule should not differentiate between administrative fees paid to entities, such as GPOs and PBMs, and fees for other services, such as distribution and inventory management. The commenter further supported the exclusion of both types of fees from AMP, if they satisfy the criteria for itemized bona fide services performed on behalf of a manufacturer for fair market value not passed through to a customer or client of the recipient, regardless of whether it takes title to the drugs, because such fees are necessary business expenditures. However, the commenters urge CMS to allow categorical exclusion of administrative fees of three percent or less if they fall within the GPO administrative fee safe harbor, including its limitation with ownership of members. Such a categorical exclusion would be consistent with the purpose of the statutory exemption and safe harbor, which encourage group purchasing arrangements, and alleviate the necessity to evaluate each GPO agreement to determine if it is fair market value for bona fide services received by the manufacturer.

Response: We appreciate these comments and have clarified at § 447.504(h)(19) that to the extent that fees to GPOs meet the definition of ''bona fide service fee,'' they are excluded from the calculation of AMP. We believe that to propose a categorical exclusion of administrative fees of 3 percent or less if they fall within the GPO safe harbor provisions would be inconsistent with our guidance regarding an actual determination of the amount of bona fide service fees.

Comment: One commenter requested that CMS clarify that the guidance provided in the preamble to the final rule on the ASP calculation is equally applicable in the Medicaid context, except with regard to those circumstances in which a GPO is passing on fees to members.

Response: As we have previously stated, we have incorporated the policy in the ASP rule into this final regulation in § 447.502.

Comment: One commenter further requested that CMS clarify that GPO fees do not affect AMP calculations when the GPO negotiates prices for member hospitals for drugs used in the inpatient setting, since the underlying sales to hospitals would be excluded from AMP in this circumstance.

Response: We agree that these fees should be excluded to the extent that the sales are not recognized as outpatient hospital sales as elsewhere discussed in this final rule.

Comment: One commenter expressed support for the comment provided by an entity within the industry which suggested that fees to GPOs should not be treated as price concessions ''unless the fees (or any portion thereof) are passed on to the group purchasing organization's members or customers as part of an agreement between the manufacturer and GPO.''

Response: We have incorporated the 2007 final ASP reporting rule's interpretation of the definition of bona fide service fees at § 447.502 and how manufacturers may apply these definitions for purposes of AMP. We believe that it is necessary to retain consistency regarding bona fide service fees and clarify that to the extent that fees to GPOs meet the definition of ''bona fide service fees'' the fees are excluded from the calculation of AMP.

Comment: One commenter stated that the proposed rule treats fees, discounts and other concessions offered to purchasers of drugs the same as payments made to third parties like PBMs and GPOs that do not purchase or take possession of drugs (and for GPOs, do not even pay for drugs). The commenter requested that CMS limit the provision to price reductions and other payments that flow to purchasers, and expressly exclude payments that flow to third parties not involved in the purchase transactions. The commenter recommended that CMS clarify this to state that all fees that manufacturers pay to customers or third parties meeting the definition of a bona fide service fee are excluded from the calculation of AMP. The commenter contended that the provision clouds the issue of proper handling of bona fide service fees and appears to create distinctions between administrative fees, service fees and distribution fees that do not always exist.

Response: We appreciate this comment and have clarified at § 447.502 that to the extent that fees to any entity included in the retail pharmacy class of trade meet the definition of bona fide fees, they are excluded from the calculation.

Comment: One commenter recommended that CMS remove the bona fide service fees provision because this term is not well defined and is open for interpretation, abuse, and fraud. The commenter believed that if this term reduces AMP, it should be eliminated.

Response: We disagree. We believe that the excluding bona fide service fee results in an appropriate measure of AMP. We also believe that it provides the appropriate safeguard against potential fraud and abuse. The Federal Government, however, will continue to monitor these calculations to assure they are not done improperly.

Comment: One commenter said that the final rule should provide an overview of the types of payments that are bona fide service fees but not identify an exclusive list. This would allow for manufacturers and contracting entities to make future interpretations based on the practices of the marketplace. The commenter did not see the need for future guidance or rulemaking to add to this list and believes that doing so may reduce the level of innovation and impede the delivery of new products to patients. Other commenters requested that CMS provide more guidance as to what constitutes a bona fide service fee, as well as provide additional parameters and/or specific examples to assist manufacturers in making this determination. Another commenter supported excluding bona fide service fees from AMP, especially when those fees are not passed through to the product's ultimate purchaser, but did not support any attempt to list specific bona fide service fees in the final regulation. The commenter further noted that the preamble should provide examples of types of bona fide service fee payments that would be acceptable for exclusion from the AMP calculation at this time.

Response: We believe that the definition defines what constitutes a bona fide service fee. Providing a list of types of bona fide service fee payments could limit the scope of what constitutes a bona fide service and, because of the complexities of the marketplace, raises further questions as to why some examples were included and some excluded from that list.

Other Fees

Comment: Commenters requested that CMS provide guidance regarding the treatment of payments from manufacturers for performing certain patient care programs, such as patient education and compliance and persistency programs. These payments should be omitted from the AMP calculation because they do not reflect prices paid by wholesalers for drug products or reduce the retail pharmacy's cost of purchasing the drugs.

Response: We are providing no further policy on these arrangements in this final rule and will continue to review such arrangements individually.

Fair Market Value

Comment: One commenter disagrees with the adoption of Medicare Part B's definition of fair market value. The commenter said that AMP should not exclude bona fide service fees set at the fair market value because Part B drugs cannot be purchased by the pharmacy community at the prices set using ASP. The commenter further stated that excluding bona fide service fees from AMP would transform chain pharmacy stores into variety stores and independent pharmacies would cease to exist. Access to prescription drugs would be unavailable and hospital emergency rooms would become understaffed clinics.

Response: We disagree. We do not believe that allowing manufacturers to exclude bona fide service fees that represent the fair market value of the service will have any impact on the operations of chain and independent pharmacies.

Comment: One commenter stated that to be truly fair and appropriate, the definition of fair market value of drugs must be in some way related to the purchasing power of the pharmacy involved. If all pharmacies are to be included in the calculation, then it must be the cost at which the least powerful purchaser can obtain the product. Alternatively the markets could be separated in a fair manner and the average acquisition cost for each market could be considered to be the fair market value of that particular segment.

Response: We believe that the commenter misunderstood the context of fair market value as it relates to a manufacturer's payment of bona fide service fees. We do not believe that allowing manufacturers to determine the fair market value of drug distribution services as it relates to bona fide service fees impacts the average acquisition cost.

Comment: One commenter supported the exclusion of bona fide service fees from AMP but stated that an unnecessarily narrow reading of what constitutes ''fair market value'' remuneration for legitimate services performed on behalf of a manufacturer may disrupt normal and legitimate business transactions between PBMs and manufacturers.

Response: Elsewhere in this final rule, we have excluded rebates, discounts and price concessions provided to PBMs from the determination AMP, except for purchases through PBM mail order pharmacies eliminating an effect on these transactions between manufacturers and PBMs. We have not further defined ''fair market value'' so that manufacturers have the flexibility to determine fair market value consistent with industry accepted methods. This is consistent with our adoption of the discussion in the 2007 final ASP reporting rule (see 71 FR 69668, December 1, 2006).

Comment: One commenter recommended that CMS not provide that a fee must not be passed on in order for it to be considered a bona fide service fee. If the fee is for a legitimate service performed for the manufacturer, it should not matter if it is passed on. Moreover, the administrative burden for manufacturers to gather confidential information from PBMs and others in the drug channel would be significant and may cause manufacturers to forgo any service arrangements.

Response: We disagree. We believe that a fee which is passed on is not a bona fide service fee but rather a price concession. Price concessions reduce the price realized by the manufacturer for drugs distributed to the retail pharmacy class of trade. We understand that manufacturers may face administrative burdens regarding the collection of data to determine whether a fee is passed on and have incorporated the discussion in the 2007 final ASP reporting rule (see 71 FR 69669, December 1, 2006). Finally, elsewhere in this final rule, we have excluded rebates, discounts and price concession to PBMs so there is no longer the administrative burden associated with PBM adjustments.

Commenter: One commenter asked that CMS allow manufacturers discretion in selecting methodologies for determining fair market value and in identifying the types of services that can qualify as bona fide services.

Response: We have not further defined ''fair market value'' so that manufacturers have the flexibility to determine fair market value consistent with generally recognized standards. This is consistent with our adoption of the discussion in the 2006 final ASP reporting rule (see 71 FR 69668, December 1, 2006).

Comment: One commenter requested that CMS amend the definition of bona fide service fee to reflect that a fee paid by a manufacturer to a group purchasing organization, as that term is defined in 42 CFR § 1001.952(j), represents ''fair market value'' if the fee results from arms-length, bona fide bargaining between the manufacturer and the GPO.

Response: We believe that the proposed definition and additional guidance incorporated from the final ASP reporting rule clarifies that fees,

including service fees, administrative fees and other fees paid to GPOs are not considered price concessions to the extent that they satisfy the definition of a bona fide service fee.

Comment: A commenter said that CMS should amend the definition of ''bona fide service fee'' to allow that a payment need not represent fair market value in order to qualify as a bona fide services fee.

Response: We do not agree. As previously discussed, we have not further defined ''fair market value'' so that manufacturers have the flexibility to determine fair market value consistent with generally recognized standards. This is consistent with our adoption of the discussion in the 2006 final ASP reporting rule (see 71 FR 69668, December 1, 2006).

Comment: Other commenters stated that CMS should allow a manufacturer to exclude from AMP any payment to any entity other than a purchaser, where this payment is not passed on in whole or in part by the entity to a purchaser of the manufacturer's drugs as a price concession by the manufacturer.

Response: We disagree. We believe that the proposed definition and additional guidance incorporated from the final ASP reporting rule clearly define what constitutes a bona fide service fee to an entity included in the retail pharmacy class of trade, which is excluded from AMP.

Comment: One commenter requested that CMS clarify whether a service fee determined not to be ''bona fide,'' should be prorated to include only that portion related to sales included in AMP.

Response: A manufacturer's AMP should include administrative fees, service fees (except bona fide service fees) and distribution fees for those entities and units of drugs included in the determination of AMP.

Comment: One commenter agreed that certain service fees should be included in the calculation of AMP on the basis that some wholesalers charge inventory service or stocking fees to certain manufacturer for carrying their products. Fees such as inventory service or stocking fees should not be considered bona fide service fees as they do not fall under the proposed definition and effectively result in a discount that should be considered when calculating AMP. The commenter further expressed concern that inventory service or stocking fees charged to manufactures by wholesalers are not imposed uniformly and agreed that these should be excluded from AMP to ensure consistency between manufacturers.

Response: We believe that the definition and additional guidance clearly defines what constitutes a bona fide service fee and distinguishes these fees from other fees that may reduce the price of a drug.

Retail Impact

Comment: One commenter said that community pharmacies do not receive administrative service agreements from wholesalers and should be excluded from AMP. Another commenter stated that administrative fees and service fees paid to wholesalers, PBMs or HMOs should not be excluded from the calculation of AMP because these fees are not available to the retail pharmacy of trade. The commenter further stated that the fees are kept by the above entities and have no effect on invoice pricing to the retail pharmacy. If CMS feels that these fees are more than nominal, then this should be addressed in the future through further legislation.

Response: We disagree. A manufacturer's AMP should include administrative fees, service fees (except bona fide service fees) and distribution fees for those entities and units of drugs included in the determination of AMP.

Direct Patient Sales

Comment: One commenter supported the inclusion of direct patient sales in AMP on the basis that when drugs are provided to patients through distributors, the distributor is acting as a wholesaler and the transaction is a sale to the retail pharmacy class of trade.

Response: We appreciate the support for this provision and have retained this requirement in the final rule at § 447.504(g)(7). However, as discussed below, we did not intend to include patient assistance programs.

Comment: A few commenters stated that CMS should reconsider the rationale used to include direct sales to patients in AMP because the statute does not contemplate those patients within the classes of purchasers used to determine AMP. One commenter said that sales directly to patients should be excluded from AMP. Several commenters said that sales and rebates associated with direct sales programs should not be included in AMP for pharmacy reimbursement. Many commenters said that the retail pharmacy class of trade does not have access to direct to patient sales and that they should not be included in AMP. One commenter requested that CMS explain how drugs distributed directly to patients fall within the definition of drugs distributed to the retail pharmacy class of trade when patients do not resell or provide drugs to the general public. A few commenters said that there is no support for CMS to expand ''wholesaler'' and ''retail pharmacy class of trade'' to include direct-to-patient sales by a manufacturer. CMS has not provided an analysis as to why it believes patients are within the retail pharmacy class of trade.

Response: We appreciate the comment and have clarified that where the distributor is acting as a wholesaler, such sales should be included in AMP. We believe such sales are usually for specialty drugs through a direct distribution arrangement, where the manufacturer may retain ownership of the drug and pay either an administrative or service fee to a third party for functions such as the storage, delivery and billing of the drug. In this case, where the distributor is acting as a wholesaler, such sales should be included in AMP.

Comment: A few commenters said that direct-to-patient programs are an efficient, cost-effective means to provide much needed therapies. Federal policy should encourage such programs rather than discourage their development and use. However, requiring manufacturers to include such sales in AMP many have an unintended effect of discouraging manufacturers from implementing such programs. The commenter urged CMS to revise its proposed rule so that direct sales to patients are excluded from AMP. Another commenter said that including these sales and, presumably, discounts, in the AMP calculation may potentially serve as a disincentive for manufacturers to offer patient assistance programs or other subsidies to patients. If the intent of the AMP calculation is to determine the net price paid by wholesalers for drugs to the retail pharmacy class of trade, including sales and discounts directly to patients may improperly lower AMP.

Response: The inclusion of direct patient sales in AMP is not intended to discourage manufacturers from implementing these programs. However, we believe that the inclusion of such direct patient sales in AMP (where the distributor is acting as a wholesaler) is consistent with our understanding of the statute and our definition of wholesaler. The policy with respect to patient assistance programs is addressed elsewhere in this final rule.

Comment: One commenter said that the inclusion of direct patient sales in AMP is inconsistent with CMS' position on patient coupons, which are excluded from AMP.

Response: We disagree. Direct patient sales (where the distributor is acting as

a wholesaler) are like other sales included in AMP where the manufacturer sells a drug to a wholesaler/distributor which then sells/transfers the drug to a pharmacy or dispenses the drug itself. Our policy is based on our understanding of the transaction and on the pharmacy or wholesaler not being involved in the patient coupon transaction given that there is no adjustment of price at the wholesaler or pharmacy level.

Comment: One commenter requested that CMS clarify whether products which are sold directly to patients through company stores that sell only to the company's employees are included in AMP.

Response: We are unable to respond to this comment as the commenter did not include enough specific information to enable us to do so. However, we have defined retail pharmacy class of trade at § 447.504(e) to mean any independent pharmacy, chain pharmacy, mail order pharmacy or other outlet that purchase drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public. We will continue to respond to such questions via the website or informal guidance when additional information can be obtained.

Comment: One commenter requested that CMS clarify the meaning of ''direct sales'' as it used in the calculation of AMP.

Response: As we understand this term, it means sales for which the manufacturer exerts control over the distribution of the drug through either an exclusive wholesaler/distributor or pharmacy. While this is the general definition we used to respond to these comments, we note that the underlying basis for our policy on these sales' inclusion in AMP is based on our broader policy concerning the type of sales that are included in our definition of the retail pharmacy class of trade.

Returned Goods

Comment: Some commenters expressed support for CMS' proposal to exclude returned goods from the calculation of AMP pursuant to manufacturer policies that are not designed to manipulate or artificially inflate or deflate AMP. The commenters believed that manufacturers should be able to design their return policies and exclude such returns from AMP, provided the policies do not represent a covert means of manipulating AMP. As they understood it, CMS' proposal permits manufacturers the operational freedom to define and accept returned goods, while eliminating administrative burdens, preserving the integrity of the Medicaid drug rebate program, and harmonizing the AMP calculation with that of ASP. Thus, they asked that CMS finalize its proposed rule on returned goods.

Response: We appreciate this support and have retained this requirement in the final rule at § 447.504(h)(21).

Comment: Several commenters requested that CMS clarify the standards for determining when a return is made in good faith. The commenters asked whether a manufacturer may assume that goods are returned in good faith if a manufacturer has no evidence to the contrary. Alternatively, they requested that CMS delete the ''good faith'' requirement as this requirement addresses the intentions of those returning the drugs and not the manufacturer.

Response: We intend that ''good faith'' must be demonstrated on the part of the manufacturer, not the returning entity. We believe that returns made in good faith should be made in accordance with pre-existing manufacturer policies that comply with customary acceptable business practices; and applicable laws and regulations.

Comment: One commenter stated that these negotiated return goods policies should take into consideration the unique burdens which retail pharmacies must absorb in order to efficiently return expired pharmaceutical products to manufacturers. By mandating that only returns made pursuant to manufacturers' policies be excluded from AMP, CMS could be voiding these negotiated return goods policies (which were negotiated in good faith between manufacturers and retailers) and are forcing retailers to accept manufacturers' policies and their inherent deficiencies. The commenter asserted that such action ignores that retailers absorb considerable cost through replacement value of returns, inventory carry cost, reverse logistic costs, and administrative expense. In order to remedy this inequity, the commenter believes that goods returned in good faith pursuant to a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, should also be excluded from AMP. The commenter further recommended that CMS adopt a policy regarding returned goods that define them as the result of a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, which are designed to reimburse pharmacies for the replacement cost of products returned in good faith.

Response: The returned goods policy in this regulation pertains to when payments for these goods are to be excluded from AMP. It should not affect negotiated agreements between pharmacies and manufacturers regarding returned goods. While the proposed rule did not address the treatment of replacement products, in the final rule at § 447.504(h)(21), we clarify that replacement products should not be included in AMP.

Comment: One commenter said that the language regarding handling returned goods in ''good faith'' leaves too much opportunity for interpretation by various manufacturers. The commenter stated that CMS should clearly state whether or not returned goods are to be included in pricing calculations rather than providing a method for some manufacturers to pick and choose when they will exclude returns.

Response: We do not agree that we should provide a standard definition at this time. As previously stated, we believe that returns made in ''good faith'' should be made in accordance with manufacturer policies that comply with customary business practices; and applicable laws and regulations.

Comment: The commenter recommended that we eliminate the reference to ''manufacturers' policies'' as it is unfair and could result in additional changes by manufacturers in their policies that would compromise community retail pharmacy.

Response: We disagree. Historically, manufacturers have had the flexibility to determine whether returns were to be credited to the quarter of sales or quarter of receipt. This has caused difficulty for some manufacturers when returns have substantially reduced AMP in a quarter or resulted in a negative AMP. In light of these concerns, we proposed to exclude returned goods from the calculation of AMP. The intent of this revision is not to cause or encourage manufacturers to change their current policies regarding returns. On the contrary, the exclusion of returned goods will allow the manufacturer to calculate and report an AMP that is more reflective of its true pricing policies to the retail pharmacy class of trade in the reporting period. It eliminates artificially low, zero or negative AMPs that may result from these adjustments.

Comment: One commenter expressed support for the proposal to exclude returned goods from AMP. The commenter further requested that CMS clarify that manufacturers may exclude

returned goods based on the good faith of the manufacturer in accepting the return, because manufacturers do not have a basis to determine the good faith of the returning purchaser.

Response: We intend that the ''good faith'' be shown on the part of the manufacturer, not the pharmacy returning the goods. In order to exclude returned goods from the AMP calculation, the manufacturer must exercise good faith, in accordance with the manufacturers return policy.

Comment: One commenter requested that CMS clarify that goods that are returned in accordance with the manufacturer's written return policies will be deemed to have been made in good faith.

Response: We agree to the extent it meets the criteria specified in this final rule.

Comment: One commenter said that a manufacturer's payment to a pharmacy or wholesaler for expired or recalled merchandise as well as fees associated with those services should be excluded from the manufacturer's AMP calculation of the basis that the level of credit provided is not enough to cover the replacement values, the cost of carrying the product to expiration, the cost of returning the product and the administrative cost associated with tracking the return.

Response: We would consider these payments acceptable provided that this payment is in lieu of a credit for the returned good and meet the other criteria in this final rule for such returns.

Comment: One commenter requested that CMS clarify that products destroyed by purchasers (and thus, not returned to the manufacturer) should be excluded from AMP.

Response: We agree. Products that are destroyed with no replacement product issued can be treated as a return.

Comment: One commenter recommended that recalls be treated the same as returned goods and excluded from AMP and urged CMS to clarify the treatment for AMP calculation of any return fees or reasonable recall fees paid by manufacturers.

Response: We agree to the extent that these recalls meet the other criteria in this final rule.

Comment: One commenter requested that CMS clarify whether a manufacturer may treat all chargeback reversals as returns if data is not available to the manufacturer to indicate otherwise.

Response: Only returns within the criteria in this final rule are to be excluded from AMP.

Comment: One commenter expressed concern regarding the exclusion of returned goods because of the effect that excluding these goods may have on AMP. The commenter believed that a significant increase or decrease in the AMP as a result of a returned good could lead to inaccuracies in FULs and potential future payment methodologies based on AMP to be used by third party programs.

Response: We disagree. We believe that the exclusion of returns will stabilize AMP and allow the manufacturer to calculate and report an AMP that is reflective of its pricing to the retail pharmacy class of trade in the reporting period. It eliminates artificially low, zero or negative AMPs that may result from these adjustments.

Manufacturer Coupons

Comment: One commenter stated that the final rule should clarify that manufacturer coupons redeemed by consumers, either directly to the manufacturer or at point of sale through pharmacies, are excluded from AMP as long as manufacturer payments to pharmacies are limited to administrative fees, charged at fair market rates, to compensate the pharmacies for their services; and, the prices paid by such pharmacies for the drugs are not affected by the coupon. Several commenters stated that if CMS decides that coupons redeemed by entities other than the consumer are to be included in AMP, additional guidance would be needed regarding the valuation of such transactions in AMP (for example, at wholesale acquisition cost (WAC), retail cost, or some other method). Another commenter requested that CMS clarify that coupons should not be included in AMP if, the benefit provided to the patient was set by the manufacturer without any negotiation between the manufacturer and a third party; the entire amount of the benefit was made available to an individual patient, without any opportunity for the retail pharmacy or other third party (such as an insurer or PBM) to reduce that benefit or take a portion of it for its own purposes; and the pharmacy collected no additional payment, other than the benefit amount, from the drug discount program. Coupons redeemed directly by patients with the manufacturer should be treated the same as coupons redeemed through other parties. The commenter proposed that CMS adopt as a definition of manufacturer coupon any certificate provided to a consumer that provides by its terms that the consumer is entitled to a discount on his or her purchase of drugs, either at the point-of-purchase, through a reduction equal to the face value of the coupon up to the amount the consumer is required to pay the entity that dispense the drugs, or subsequent to the purchase, through receipt of a cash reimbursement from the manufacturer (or a vendor under contract to the manufacturer to administer the coupon program) where the reimbursement amount is equal to the lesser of the amount the consumer paid to the dispensing entity or the face value of the coupon. The commenter further requested that CMS clarify that manufacturers should exclude from AMP any fee paid to an entity other than a consumer that redeems a manufacturer coupon where the fee satisfies the definition of ''bona fide service fee'' adopted by the final rule.

Response: In light of the comments received, we believe that manufacturer coupons redeemed by any entity other than the consumer where full value of the coupon is passed on to the consumer, and the pharmacy does not receive any price concessions, should be excluded from AMP. We also agree with the comment regarding the need to clarify criteria regarding coupons and are codifying our prior guidance in this final rule with respect to manufacturer coupons at § 447.504(g)(15) to state that manufacturer coupons redeemed by any entity other than the consumer are excluded from AMP as long as the following provisions are met:

1. The manufacturer coupon is not contingent upon any purchase requirement to individuals.

2. The manufacturer establishes a benefit amount of the coupon to be given to individual patients, without any negotiation between the manufacturer and any other third party (such as an insurer or PBM) as to that amount.

3. The entire amount of the free product or coupon amount is made available to the individual patient, without any opportunity for the retail pharmacy or any third party (such as an insurer or PBM), to reduce the benefit amount, or take a portion of it, for its own purposes.

4. The pharmacy collects no additional payment, other than the benefit amount and a bona fide service fee, from the coupon.

Comment: Many commenters requested that CMS clarify that it does not matter who or which type of entity provides the benefit to the patient. Another commenter requested that CMS make clear that manufacturer coupons redeemed by a consumer, whether directly or indirectly to the manufacturer should be excluded from AMP. One commenter stated that in instances where a third party vendor is

used by the manufacturer to administer a coupon program on its behalf, that the coupon be considered redeemed directly to the manufacturer by the consumer. One commenter requested that CMS affirm that, when the only party receiving an economic benefit from the program is the patient, the value of the coupon will not be included in AMP. The commenter further requested that CMS confirm that the delegation of the operations of a coupon program to a fulfillment house or other agent does not by itself cause the coupon to be included in AMP. One commenter requested that CMS abandon its focus on redemption mechanics, as that focus will yield arbitrary results on the basis that the coupons would require disparate treatment for transactions that are indistinguishable in their substance.

Response: We appreciate these comments and have provided in the final regulation at § 447.504(h)(15) that manufacturer coupons redeemed by any entity other than the consumer which meet the previously discussed criteria may be excluded from AMP.

Comment: One commenter said that although coupon and voucher programs may appear similar, they are different in purpose and function. The commenter was concerned that ''vouchers'' may also be included in potential interpretations of the term coupon, whether or not this was CMS' intent. The commenter used the term, coupons as certificates provided to patients that entitle them to discounts on their prescription drug purchases, either at the point of sale (through a reduction in the amount that consumer is required to pay the dispensing pharmacy) or subsequent to the purchase (by sending the coupon to the manufacturer or a clearinghouse with proof of purchase to receive a cash reimbursement from the manufacturer). In either case, the amount of the discount provides a dollar for dollar reduction in the amount paid out of pocket by the patient. In point-of-sale coupons, the dispensing pharmacy receives reimbursement for the discount passed on to the patient plus a small handling fee for administering the transaction. Vouchers are certificates provided to patient that entitle the patient to receive a specified number of units of a drug free of charge. The vouchers function similarly to product samples. The pharmacy dispenses the drug free-of-charge to the patient and is then reimbursed by the vendor according to a formula negotiated between the vendor and the pharmacy, plus a dispensing fee. The vendor bills the manufacturer for this reimbursement expense, plus a bona fide service fee. The commenter further stated that CMS should require manufacturers to exclude from AMP any manufacturer coupon redeemed by a consumer either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the coupon program; or alternately, any manufacturer coupon redeemed by an entity other than a consumer (after being presented by the consumer and honored by such entity) either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the coupon program. If CMS does decide to treat manufacturer vouchers separately from, or as part of, manufacturer coupons, CMS should define manufacturer voucher to mean any certificate provided to a consumer that provides by its terms that the consumer is entitled to a specified number of units of a drug free of charge, without any co-payment from the consumer, or reimbursement to the entity that dispenses the drug from any insurance program of which the consumer may be a beneficiary. Furthermore, the commenter requested that CMS instruct manufacturers to exclude from their AMP: (i) any manufacturer voucher redeemed by a consumer either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the voucher program; and (ii) any manufacturer voucher redeemed by an entity other than a consumer (after being presented by the consumer and honored by such entity) either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the program; and specify that manufacturers should also exclude from AMP; (i) the reimbursement amount paid for any manufacturer vouchers; and (ii) any fees paid to an entity other than a consumer that redeems a manufacturer voucher where the fee satisfies the definition of ''bona fide services fee.'' If CMS does not adopt the approach to treating coupon and voucher programs, clear guidance from CMS as to how manufacturers should account for the value of point-of-sale coupons and vouchers in the calculation of AMP is needed, including specific mathematical examples as to how the value of such coupon and voucher should be accounted for in AMP.

Response: We believe that vouchers for free sample products should be excluded from AMP in instances that the, voucher is not contingent on other purchase requirements and is redeemed by any entity other than the consumer, where the full value of the coupon is passed on to the consumer and the pharmacy does not receive any price concessions, it should be excluded from AMP. We have amended the final rule at § 447.504(h)(16) to incorporate these comments.

Comment: One commenter said that no distinction should be made between manufacturer coupons and other manufacturer-sponsored point-of-sale discounts.

Response: This policy only applies to manufacturer coupons and vouchers, as discussed in the previous response.

Comment: A commenter said that CMS should provide further guidance concerning what arrangements it considers to constitute ''coupons directly redeemable to the manufacturer.'' It is unclear whether CMS intends for the term ''coupon'' only to cover coupon arrangements in their traditional sense or whether the term also is intended to cover other types of consumer subsidies. Another commenter requested that CMS provide an explanation of what arrangements CMS considers to be patient coupons and guidance regarding how such arrangements should be incorporated in AMP.

Response: We have clarified in the final regulation at § 447.504(h)(15) the criteria that must be met for manufacturer coupons redeemed by the consumer to be excluded from AMP.

Comment: One commenter requested that CMS explain how coupons other than those redeemed by the manufacturer are to be accounted for in those calculations. The commenter further stated that the proposed rule does not account for a variety of coupon arrangements that exist.

Response: We have clarified in the final regulation at § 447.504(h)(15) that manufacturer coupons redeemed by the consumer that meet the criteria in this final rule are excluded from AMP.

Comment: One commenter asked if patient assistance continue to be excluded from AMP. Another commenter requested that CMS provide guidance regarding how a manufacturer may properly structure a patient assistance program utilizing coupons.

Response: In light of the comments received, we believe that patient assistance programs which extend free products to consumers without purchase contingencies and which do not provide any price concessions to the pharmacy, should be excluded from AMP. We are codifying guidance in this final rule at § 447.504(h)(12) to clarify that patient assistance programs should be excluded from AMP as long as the following criteria are met.

1. The program is focused on extending free products not contingent

upon any purchase requirement or extending financial assistance to low-income individuals and families, as determined by CMS.

2. Each manufacturer establishes an amount of the subsidy to be given to individual patients, without any negotiation between the manufacturer and any other third party (such as an insurer or PBM) as to that amount.

3. The entire amount of the free product or subsidy is made available to the individual patient, without any opportunity for the retail pharmacy or any third party (such as an insurer or PBM), to reduce that subsidy, or take a portion of it, for its own purposes.

4. The pharmacy collects no additional payment, other than the benefit amount and a bona fide service fee, from the patient assistance program.

Comment: One commenter said that CMS should provide in the final rule that any type of consumer program, be it a patient assistance, coupon, or debit card program, be exempted from AMP, and so as long as such program does not affect the price paid by the pharmacist to acquire the product. The commenter further said that CMS should clarify that programs should be excluded from AMP to the extent that the full amount of the discount goes to the consumer and does not affect the price realized by the pharmacist, or any end user other than a patient.

Response: We have clarified in the final regulation at § 447.504(h) the types of programs; for example, patient assistance programs and manufacturer coupons that provide free goods which are not contingent upon future purchases to patients, that should be excluded from AMP.

Comment: Many commenters said that coupons redeemed by pharmacists, just as those redeemed directly by manufacturers, should be excluded from AMP. In such cases the pharmacist is merely a pass-through entity as the pharmacist does not realize any monetary gain. Another commenter noted that patient coupons do not have an impact on prices for entities included in AMP and any requirement to include such arrangements in those calculations could impact the continued viability of the patient access programs. Other commenters stated that CMS should clarify that patient coupons transactions should not be included in AMP. Another commenter said that CMS incorrectly assumed that all indirect redemption arrangements necessarily affect the price realized by the redeeming pharmacy and that CMS should revise its proposed policy on manufacturer coupons to make clear that only arrangements that affect the price realized must be included in AMP. To count these coupons in AMP would distort those price figures and create a disincentive for manufacturers to continue offering these valuable programs. Several commenters said that manufacturer coupons should be excluded from AMP because these are not sales to traditional pharmacies.

Response: We appreciate these comments and have clarified in § 447.504(h)(15) that manufacturer coupons redeemed by any entity other than the consumer which meet the previously discussed criteria are excluded from AMP.

Comment: A few commenters requested that CMS clarify the definition of ''coupon.'' A commenter further asked if CMS intended the term to refer only to paper coupons or to include patient assistance discount cards and other media provided to consumers.

Response: We have not specified that coupons must be printed on paper so as not to limit these in the future. We have clarified in the final regulation the treatment of other patient assistance programs.

Comment: One commenter urged CMS to expand the patient assistance program exception to cover those programs as a category, regardless of whether they provide goods free of charge or at limited cost to patients.

Response: We appreciate this comment and have clarified in § 447.504(h)(12) that patient assistance programs which met the previously discussed criteria are excluded from AMP.

Comment: One commenter said that CMS should exclude all patient transactions; for example, direct patient sales, patient coupons, and patient assistance programs from AMP on the basis that patients are not part of the retail pharmacy class of trade.

Response: We appreciate this comment and have clarified the treatment of these transactions in this final rule at § 447.504.

Copayment Assistance Programs

Comment: One commenter requested that CMS clarify the treatment of copayment assistance coupons.

Response: We have clarified that copayment assistance programs are another form of patient assistance programs and should receive similar treatment provided they otherwise qualify for exclusion from AMP under this final rule at § 447.504(h)(12).

Drug Discount Card Programs

Comment: Some commenters stated that if the manufacturer drug discount program exclusion from best price is retained in the final rule, then the final rule should also provide a similar exclusion from AMP. The commenter further stated that a drug discount card program involving the pass-through of a manufacturer discount of 100 percent to the consumer and does not affect the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

Response: We have clarified at § 447.504(h)(17) that manufacturer-sponsored discount card programs which meet the previously discussed criteria for patient assistance programs are excluded from AMP.

Other Entities

Comment: A few commenters requested that CMS provide clarification regarding the treatment of dialysis centers, surgical centers, ambulatory care centers, and mental health centers. Unlike walk-in pharmacies, these providers generally provide drugs incident to providing medical services to persons who are their private patients, although some physician practices sell self-administered products to patients who take the products home.

Response: Sales to outpatient facilities such as dialysis centers, surgical centers, ambulatory care centers and mental health centers that are not hospital-affiliated entities are included in AMP. We have clarified at § 447.504(g)(8) in the regulation text the treatment of outpatient facilities.

Comment: A few commenters requested that CMS clarify whether sales to prisons are included in AMP.

Response: We have clarified at § 447.504(h)(9) in the regulation text that sales to prisons are not included in AMP.

Comment: One commenter stated that examples of non-retail entities should be included in final rule; that is sold to other manufacturers, academic medical centers and physician investigators for research purposes.

Response: We have provided clarification at § 447.504(g)–(h) regarding which sales are included and excluded in this final regulation.

Comment: One commenter requested that CMS clarify whether sales to veterinary offices are within the definition of retail pharmacy class of trade. In the commenter's view, veterinary offices are not licensed to provide drugs to people and thus could not provide them to the general public.

Response: We have clarified in the regulation text at § 447.504(h)(8) that sales to veterinarians are excluded from AMP.

Comment: One commenter requested that CMS clarify whether State, county, and municipal entities are excluded from the retail pharmacy class of trade.

Response: We have clarified in the regulation text at § 447.504(h)(11) that sales to State, county, and municipal entities are excluded from the retail pharmacy class of trade and, therefore, are excluded from AMP.

Comment: One commenter requested that CMS explicitly state that the retail pharmacy class of trade does not include physician-administered drugs. The preamble to the proposed rule did not address whether to include prices to physicians in the retail pharmacy class of trade. In the same way that CMS excluded sales to long-term care pharmacies from the AMP calculation because they typically are closed operations that serve only residents of a specific long-term care facility, a physician's office is not a retail location open to the general public.

Response: In light of the definition of wholesaler set forth in the rule, physician-administered drugs are included in AMP because physicians operate to provide such drugs to the general public. Specifically, the sales to physicians for these drugs are included in AMP as well.

Comment: One commenter requested that CMS provide clarification regarding the treatment of sales to facilities that may operate both a closed-door long-term care pharmacy (excluded from AMP in the proposed rule) and a retail pharmacy (included in AMP). For such a facility, it is impossible for the manufacturer to identify which units were sold through the long-term care pharmacy and which units were sold through the retail pharmacy, since their orders do not distinguish between the two.

Response: Where a manufacturer does not have adequate documentation to substantiate whether these drugs are dispensed to a long-term care facility or to the general population, the manufacturer should include all of these sales in AMP.

Comment: One commenter requested that CMS specify that closed-wall pharmacies which do not sell to the general public are not included in the retail pharmacy class of trade.

Response: We are not familiar with the term ''closed-wall pharmacy,'' but we have clarified the definition of retail pharmacy class of trade. If a pharmacy meets this definition, sales to it would be including in AMP.

Comment: A commenter asked that CMS provide guidance regarding price concessions offered by generic companies. The commenter recommended that CMS specify that all discounts, rebates, payments and fees (other than bona fide service fees) provided to entities in the retail pharmacy class of trade or related sales flowing through the retail pharmacy class of trade be included in the calculation of AMP. This would include off-invoice discounts, rebates, and payments of preferred product positioning, payments for the number of products carried or preferred, floor stock adjustments, new store credits, ''meet the competition'' price adjustments, and the like.

Response: We have clarified at § 447.504(g) those sales that are included in AMP in this final rule. We do not agree that price concessions offered by generic manufacturers are to be included in AMP if they do not relate to the sale of the drug and do not otherwise meet the criteria in this final rule.

Discounts and Rebates

Comment: One commenter said that rebates, kickbacks, allowances, discounts and all other schemes should be declared illegal or not counted in AMP.

Response: Issues regarding health care fraud and abuse are not addressed in the proposed rule. Concerns regarding health care fraud and abuse should be addressed to the IG of the U.S. Department of Health and Human Services.

Comment: One commenter said that the calculation of AMP for the purpose of establishing FULs should exclude discounts or incentives that are not available for Medicaid prescriptions.

Response: We disagree. Under the law, AMP has the same definition for purposes of rebates and the FULs program.

Comment: One commenter stated that it is inappropriate to include cash discounts and price reductions in AMP.

Response: The rebate agreement provides that AMP includes cash discounts and price concessions which reduce the price amount received by the manufacturer with respect to drugs distributed to the retail pharmacy class of trade.

Comment: One commenter said that discounts included in the retail pharmacy class of trade should reflect only those prices that are provided to wholesalers for drugs distributed to retail pharmacies.

Response: AMP includes cash discounts, free goods that are contingent on any purchase requirement, volume discounts, chargebacks, incentives, administrative fees, service fees, distribution fees (except bona fide service fees), other fees, and any other discounts or price reduction and rebates, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

Free Goods

Comment: Several commenters stated that non-contingent free goods should be excluded from AMP because community pharmacies do not receive them. Exclusion of free goods from the AMP calculation effectively penalizes the manufacturer for engaging in this type of marketing by not lowering the AMP which bases the Federal rebate on a higher value and by not reducing the difference between AMP and best price. However, another commenter supported the exclusion of free goods from the calculation of AMP.

Response: When a free good is non-contingent on any other purchase requirement, there is no sale of this drug and it is appropriately excluded from AMP. We have retained in the final rule at § 447.504(h)(18) the requirement that free goods not contingent upon any purchase requirement are excluded from AMP.

Comment: One commenter asked CMS to make clear in the final rule that a free goods coupon that is redeemed through a pharmacy that either used consigned product or its own product but receives replacement product, plus a bona fide service fee, is excluded from AMP. A few commenters said that CMS should clarify that coupons for free drugs, such as starter prescriptions, that are not contingent on the purchase of the same or any other drugs, should be excluded from AMP.

Response: As previously discussed, we believe that vouchers for free samples should be excluded from AMP in instances that the pharmacy receives a replacement product or collects no payment greater than the cost of the sample and a bona fide service fee. We have amended the final rule at § 447.504(h)(21) to incorporate these comments.

Nominal Price

Comment: One commenter stated that nominal prices are not available to the retail pharmacy class of trade and should be excluded from AMP.

Response: In order to be included in AMP, nominal prices must be available to the retail pharmacy class of trade. As we explain elsewhere in this final rule, we consider the retail pharmacy class of trade to encompass more than walk-in pharmacies.

Future Clarification of AMP Calculation

Comment: One commenter said that CMS should commit to updating the Medicaid regulations and/or guidance on a regular basis so that manufacturers have clear guidance with regard to the treatment of new and evolving classes of trade within the retail channel. Such regular updating will prevent a recurrence of the situation where ambiguity of the AMP definition leads to different practices across manufacturers.

Response: We appreciate this comment. We believe that the final rule clarifies the determination of AMP. We are unable to commit to a schedule for the issuance of Medicaid regulations at this time. We expect to continue to issue subregulatory guidance regarding these regulations and other policy clarification, as appropriate, in a timely manner. In addition, given some of the revisions, we have decided that this final rule with comment period should allow for further public comment on AMP.

Comment: One commenter believed that any future clarifications by CMS should be prospectively effective, providing manufacturers with a reasonable period of time to implement necessary changes in order to ensure accuracy.

Response: We appreciate this comment and will address this concern when we issue the subregulatory guidance.

Comment: One commenter expressed concern that other new classes of trade which receive prices not available to community pharmacy should not be included in AMP.

Response: We disagree. New classes of trade which provide sales to the general public are by definition included in the retail pharmacy class of trade and AMP.

Comment: One commenter expressed the concern that some areas of clarification will likely reflect policy choices, as opposed to being technical clarifications. For those more substantive areas, a regulatory, due process method of proposing and receiving comments on proposed rulemaking should be used. Another commenter requested that CMS reconsider the strategy to address future clarifications of AMP and to publish a proposed rule for public comment.

Response: We appreciate this comment. We believe that the final rule clarifies the determination of AMP, thereby eliminating ambiguity, confusion and need for additional clarification. However, we do not believe that rulemaking is the most appropriate or efficient mechanism to provide interpretations or additional guidance as may be necessary.

Other Issues

Comment: One commenter stated that CMS should provide more explanation for ''reasonable assumptions'' manufacturers are to use when data are insufficient or not available to calculate prices.

Response: We believe that reasonable assumptions are those made by manufacturers consistent with Medicaid drug rebate statute, regulation, and general business practice.

Comment: One commenter said that should CMS provide clarification regarding whether FFP is available for drugs included in a package with a non-drug item and if so, how is pricing to be reported.

Response: These issues are not addressed in the proposed rule and are outside the scope of this rulemaking document. Therefore, we cannot consider these comments as we consider revisions to the final rule.

Comment: One commenter recommended that a formal appeals and adjudication process is needed at CMS to provide a forum in which retailers can bring forth concerns regarding the method by which AMP is calculated, as well as which products are included in the determination of AMP.

Response: We appreciate this comment. The proposed rule was designed to provide the public with an opportunity to provide meaningful comments; however, retailers and manufacturers have the option of raising additional concerns directly to CMS to the extent necessary. Retailers can also raise concerns to the states as may be necessary.

Comment: One commenter said that CMS should specify a timeframe for review of manufacturer methodology change requests so that manufacturers can resolve their financial liability for past quarters.

Response: We cannot specify a timeframe; however, in the absence of guidance, manufacturers may make reasonable assumptions consistent with the statute, regulations, and reasonable business practices.

Comment: One commenter said that CMS should avoid including in the calculation of AMP data that is not readily available to manufacturers, or that would significantly increase the number of calculations and assumptions to be made.

Response: The provision of the DRA does not provide for the exclusion of AMP data that is not readily available to manufacturers. To the extent that we were able to do so within the law, we have considered the impact this calculation will have on manufacturers. We believe that this final rule provides a clear, precise and adequate definition of AMP consistent with the provisions of the DRA and helps resolve ambiguities and confusion associated with the pre-DRA definition.

Comment: One commenter suggested that CMS consider implementing a tolerance level for quarterly AMP variation, within which an AMP restatement (positive or negative) would not be permitted. This would reduce the burden on States, CMS and manufacturers to comply with the requirement that a manufacturer must adjust the AMP if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized.

Response: We disagree. The calculation of AMP is based on actual sales data, and the AMP must be revised when errors or omissions are found, consistent with the regulations.

Comment: A few commenters requested that CMS define the terms ''include'' and ''exclude'' with respect to the dollars and units components of the AMP calculation. The proposed rule is not clear as to how to treat such terms for purposes of performing the AMP calculation. The commenter requested that CMS include a sample AMP calculation and a chart indicating each of the various entities that may affect the AMP and best price calculation whether sales, discounts, and/or units are deducted from the gross (for example, factor dollar and unit numbers) for purposes of AMP. The commenter suggested that the list of excluded entities should have an identifier such as a Drug Enforcement Administration (DEA) number or Health Industry Number and updated as frequently as AMP reports are filed.

Response: We have provided clarification in § 447.504(g)–(h) regarding which sales are included and excluded in this final regulation. We have not provided a sample calculation or chart of included AMP and best price sales here but will consider doing so in subregulatory guidance, depending on whether we get more specific questions.

Comment: One commenter cautioned CMS to carefully weigh the OIG's recommendation against the Agency's own significant expertise in the area. Because the OIG lacked a working understanding of the history of many of these issues, the commenter feared that its recommendation could lead to the inconsistent treatment of important issues related to the program.

Response: The DRA required the OIG to review how AMP is determined and recommend changes to the Secretary of the Department of Health and Human Services by June 1, 2006. It also required CMS to consider the IG's recommendations and promulgate a regulation that clarifies the requirements for and the manner in which AMP is determined no later than July 1, 2007. We have evaluated the OIG's recommendations and have incorporated them where we believe they are appropriate.

Comment: One commenter requested that CMS confirm and provide guidance regarding whether rebates paid to Medicaid as a secondary payer under this title and the national rebate agreement on outpatient drugs are excluded from AMP.

Response: Rebates paid under this title are excluded from AMP, including those rebates paid for Medicare claims where Medicaid is the secondary payer.

PBMs

Comment: Many commenters requested that PBM rebates, discounts, or other price concessions be excluded from the calculation of AMP because PBMs receive discounts, rebates, or other price concessions that are not available to community retail pharmacies. Commenters stated that the fact that these discounts, rebates, or other price concessions are not paid to community retail pharmacies clearly indicates that they should not be included in a cost-based benchmark that may become the determining factor associated with reimbursement for community retail pharmacies. The commenters contended that PBMs are not included within the retail pharmacy class of trade. They argued that, in light of the rationale used by CMS to exclude nursing facility sales from the definition of retail pharmacy class of trade, CMS should similarly exclude PBM sales, discounts, rebates, and other price concessions.

Other commenters stated that excluding PBM pharmacies from the definition of retail pharmacy class of trade offers numerous benefits, including reduced recordkeeping requirements, reduced risk of price fluctuations, and limiting the need for additional regulatory burdens. In addition, commenters argued that PBMs do not dispense to the public, and that patients have to belong to a specific health plan in order to access drugs through a particular PBM. Consequently, commenters stated that PBM rebates, discounts, or other price concessions are not typically available to the public. Commenters argued that for PBMs to purchase prescription drugs from a manufacturer or wholesaler, or to dispense drugs to the public, PBMs generally need to be licensed as pharmacies under the applicable State's law. Commenters stated that they were not aware of any State that licenses PBMs as pharmacies to purchase, receive, or dispense drugs to the public.

Response: We have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies in § 447.504(h)(22). We believe this is consistent with previous guidance issued in manufacturer releases and to the extent that PBM discount rebates and price concessions did not meet these criteria, the impact on the calculation of AMP is likely to be minor.

Furthermore, we understand that PBMs do not generally take possession of pharmaceutical products. Only in their role as mail order pharmacies do PBMs participate directly in the purchase or delivery of prescription drugs. Accordingly, except with respect to such mail order activities, we have decided that PBM sales and associated rebates, discounts, or other price concessions fall outside of our definition of AMP.

Comment: Many commenters requested that PBM rebates, discounts, or other price concessions be excluded from the calculation of AMP because they believe that PBMs are not wholesalers; therefore, transactions with them should not fall within the definition of AMP. The commenters argued that the proposed definition is contrary to how the term wholesaler is defined in the national rebate agreement and that Manufacturer Releases 28 and 29 support that PBMs do not meet the definition of a wholesaler in that they do not purchase, or take delivery of drugs or redistribute drugs to retail and institutional pharmacies. Commenters indicated that they were not aware of any PBM arrangements currently in existence where PBMs are acting as wholesalers, as they do not buy pharmaceuticals directly from the manufacturers and resell them to pharmacies, which then dispense to the public. Commenters suggested that we define the term wholesaler to be consistent with its traditional meaning and the definition in the national rebate agreement to mean any entity that purchases drugs from a manufacturer for purposes of resale.

Response: We agree with the commenters that many of the sales to PBMs do not flow through wholesalers so the discounts received by PBMs generally do not affect the price actually realized. The distribution functions typically performed by wholesalers are different from the functions performed by PBMs. Furthermore, because rebates, discounts, or other price concessions obtained by PBMs are not passed on to the retail pharmacy class of trade, including PBMs in the definition of wholesalers would permit the inclusion of price concessions to which community retail pharmacies do not have access. Therefore, in § 447.504(g), we are not classifying PBMs as wholesalers.

Comment: Some commenters requested that PBM rebates, discounts, or other price concessions (except for mail order sales) be excluded from the calculation of AMP because to include them in the calculation of AMP could increase drug costs for Medicare Part D and lower Medicaid rebate payments.

Response: As discussed elsewhere in this regulation, we have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies in § 447.504(h)(22).

Comment: Some commenters stated that reporting PBM rebates, discounts, or price concessions can cause operational difficulties and competitive concerns. The degree to which manufacturer rebates are passed through or shared with PBM clients is privately held, competitively sensitive information that can differ from contract to contract. Drug manufactures are not privy to this information and would need to review thousands of rebate arrangements to require PBMs to share this information.

Response: We agree with the commenters that the administrative burden for manufacturers to gather confidential information from PBMs and others in the drug chain regarding rebates, discounts, or other price concessions is significant. Therefore, as discussed above and in § 447.504(h)(22), we have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies.

Comment: One commenter stated that CMS should clarify that there is no automatic requirement that manufacturers affirmatively obtain information concerning transactions between downstream entities. The commenter believes that such a requirement would create serious administrative difficulties. Manufacturers have no authority to require recipients of these payments to disclose to the manufacturers whether

they have shared the payment with their customers or clients, and there is no guarantee that payment recipients would agree to such disclosure.

Response: As discussed previously, we have decided to exclude PBM rebates, discounts, or other price concessions from the calculation of AMP, except for purchases by PBM mail order pharmacies in § 447.504(h)(22). Therefore, manufacturers do not have to collect rebate data with respect to such transactions between such downstream entities.

Comment: Many commenters raised other concerns about PBMs, such as that there is a need for PBM transparency, that PBMs should be regulated, that PBMs continue to impose non-negotiable contracts on independent pharmacies, or that PBMs are making too much profit.

Response: These issues are not addressed in the proposed rule and are outside the scope of this rulemaking document. Therefore, we cannot consider these comments as we consider revisions to this final rule.

Comment: Some commenters stated that the proposed rule included confusing language about how to treat price concessions to PBMs in the AMP calculation. The commenters requested that CMS clarify that the AMP calculation includes all PBM rebates, discounts, or other price concessions in the AMP calculations. The commenters believed that such a requirement would be administratively less burdensome to implement and would not affect the overall value of manufacturer AMP calculations. While manufacturers can track price concessions provided to PBMs, the commenters stated that it is neither realistic nor appropriate for them to track which price concessions PBMs pass through to the retail pharmacy class of trade. To include all PBM rebates, discounts, or other price concessions would also help promote greater uniformity in AMP calculations and preclude the possibility of confusion regarding the treatment of PBM price concessions. Conversely, requiring additional granularity in allocating PBM rebates could require manufacturers to make significant modifications to existing systems and could result in inaccurate and inconsistent AMP calculations. Commenters also stated that if CMS include discounts for products that flow through the retail pharmacy class of trade in AMP, CMS also should include rebates paid directly to health plans by manufacturers, unless the health plan is a staff model HMO.

Response: As discussed previously, we have decided to exclude PBM rebates, discounts, or other price concessions from the calculation of AMP, except for purchases through PBM mail order pharmacies in § 447.504(h)(22). We believe this will alleviate some of the administrative burden associated with the calculation of AMP and result in more accurate and consistent AMPs across manufacturers.

Comment: While some commenters supported CMS' proposal to include PBM rebates and discounts in the AMP calculation, they and other commenters stated that there would be operational difficulties if manufacturers were required to segregate price concessions provided on mail order utilization from that provided on other PBM utilization as such detail is not available from the PBMs to quantify these two figures. The commenters stated that it is often impractical, if not impossible, for a manufacturer to obtain precise retail and non-retail analysis on a PBM's non-mail order sales. The commenters also stated that some PBMs may provide data that may allow some manufacturers to segregate their non-mail order sales data into retail and non-retail sales under some circumstances. However, the commenters argued this is not always the case. The commenters contended that many PBMs are unwilling or unable to provide this data to manufacturers and that some PBMs do not compile such data. Due to the lack of PBM data, commenters argued that manufacturers should be able to make reasonable assumptions with respect to PBM sales and discounts.

Response: We have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP except for purchases through PBM mail order pharmacies in § 447.504(h)(22). Therefore, manufacturers will not need to obtain retail and non-retail analysis with respect to PBM non-mail order sales.

Comment: Some commenters supported the inclusion of PBM rebates, discounts, or other price concessions in the determination of AMP. However, the commenters stated that CMS needs to clarify what factors are included and excluded in PBM price concessions and be more direct and specific as to what types of PBM rebates and discounts should be included in AMP. If CMS fails to define the term PBM for the purpose of AMP calculations, manufacturers would include sales from any entity that a manufacturer considers to be a PBM, including sales to MCOs, which are specifically excluded from AMP under the national rebate agreement. The commenters believed that CMS needs to clearly define the attributes of entities qualifying as PBMs for purposes of including price concessions from such entities and/or establish a list of excluded entities. This would allow manufacturers to use uniform criteria to distinguish between PBMs and non-PBMs for purposes of incorporating rebates and fees into AMP calculations. The commenters argued that if CMS fails to set forth guidance regarding PBMs, manufacturers would continue to treat PBM price concessions disparately, resulting in inconsistent AMP calculations across manufacturers.

Response: We have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies in § 447.504(h)(22). Therefore, we do not need to define the attributes of entities qualifying as PBMs for purposes of including price concessions from such entities and/or establish a list of excluded entities.

Comment: One commenter agreed that PBM discounts should be included in the calculation of AMP since most Americans, including dual eligible beneficiaries enrolled in the Medicare prescription drug program, benefit from these discounts.

Response: We appreciate the comment, but we have decided to exclude PBM discounts from AMP calculations, except in certain situations where the PBM is operating a mail order pharmacy. The issue regarding the benefits associated with PBM arrangements is outside the scope of this rulemaking document.

Comment: One commenter supported the inclusion of Medicare Part D PDPs and PBM rebates, discounts, or other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP. However, the commenter asked that CMS clarify the treatment of sales associated with PBMs and how these differ from payments to PDPs. The commenter believes that PDPs are functioning as PBMs for Medicare Part D beneficiaries. Another commenter also argued that it seems inconsistent that prices to PDPs, which are PBMs, be excluded from best price calculations but included in AMP calculations.

Response: We appreciate the comment and have decided to exclude PBM rebates, discounts, or other price concessions from the calculation of AMP, except for purchases through PBM mail order pharmacies in § 447.504(h)(22).

Comment: A few commenters agreed that the exclusion of PBM rebates, discounts, or other price concessions would cause AMP to be higher than it

would be if these discounts were included. However, the commenters disagreed with the characterization of this higher amount as artificial inflation. Instead, the commenters believed that the exclusion of these amounts results in a more accurate reflection of AMP, and that their inclusion artificially depresses AMP because PBMs are not wholesalers nor are PBM rebates reflected in the prices paid by community retail pharmacies.

Response: As discussed previously, we agree with the commenters that excluding PBM rebates, discounts, or other price concessions would result in a more accurate reflection of AMP. Therefore, in § 447.504(h)(22) we have excluded them from the determination of AMP in this final rule, except for purchases through PBM mail order pharmacies.

Comment: Some commenters argued that because CMS excluded manufacturer rebates paid to State Medicaid programs, to the DoD under TRICARE, and to the DVA from the AMP calculation, CMS should also exclude rebates paid to PBMs from the AMP calculation. The commenters reasoned that these rebates are not available to the retail pharmacy class of trade, and none of the funds are ever received by community retail pharmacies. They also argued that the retail pharmacy class of trade does not have access to these direct-to-patient sale prices and thus these transactions should also be excluded from the AMP calculation.

Response: We agree that these PBM rebates, discounts, or other price concessions are not generally available to the retail pharmacy class of trade and should be excluded from AMP. We have excluded them from the determination of AMP in this final rule in § 447.504(h)(22), except for purchases through PBM mail order pharmacies.

Comment: Some commenters said best price was included as a factor in the rebate calculation so that States receive a rebate that more closely matches pricing in the marketplace. Manufacturers must pay States the greater of a percentage of AMP or the difference between AMP and best price. In this context, the commenters suggested that best price is the most appropriate place to include PBM rebates, discounts, or other price concessions as well as direct-to-patient sales and manufacturer coupons.

Response: We appreciate the commenters' suggestion to include PBM rebates, discounts, or other price concessions in best price; however, we have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP in § 447.504(h)(22) and best price in § 447.505(d)(13), except for purchases through PBM mail order pharmacies.

Comment: A few commenters stated that rebates and discounts offered to PBMs typically are based on relationships between the PBM and HMO or Medicaid MCO. Given that CMS proposed to exclude rebates and discounts to HMOs and Medicaid MCOs from the calculation of AMP, the commenter believed that rebates and discounts to their associated PBMs should be excluded as well.

Response: As discussed previously, we have decided to exclude PBM rebates, discounts, or other price concessions from the determination of AMP, except for purchases through PBM mail order pharmacies in § 447.504(h)(22).

Reimbursement Based on AMP

We received numerous comments regarding the option for State Medicaid Agencies to use AMP as a benchmark to calculate pharmacy payment rates, as discussed below:

Comment: Many commenters opposed the proposal to permit States to use AMP as a benchmark for pharmacy reimbursement because the commenters believed that AMP is not representative of pharmacy providers' acquisition costs and does not consider the markup applied within the distribution chain between the manufacturer and the purchasing pharmacy. Other commenters expressed concern that the proposal to permit States to use AMP to calculate pharmacy payment rates would result in a decrease in reimbursement to retail pharmacies. Many commenters stated that using AMP for reimbursement targets independent pharmacies because AMP does not adequately address the costs incurred by independent pharmacies. These commenters predicted that the proposal will result in decreased pharmacy reimbursement and decreased profits on the dispensing of generic medications and may drive independent pharmacies out of business. Many commenters estimated that retail pharmacy profit margins are less than ten percent of gross sales and pharmacists will be unable to dispense drugs to Medicaid patients if reimbursement rates are set by using the proposed definition of AMP. One commenter said that the proposed AMP-based reimbursement is unfair to retail pharmacies as their profit margins are being set by insurers when other entities, such as manufacturers and wholesalers, are able to set their prices and determine their profit margins. Another commenter opposed using AMP as a benchmark for Medicaid reimbursement stating that pharmacies save money for State Medicaid agencies, have provided many hours of free counseling services to Medicaid patients, spent uncompensated hours resolving Medicare Part D issues and deserve actual acquisition costs for dispensed medications.

Response: The DRA does not require States to use AMP as a benchmark to calculate pharmacy payment rates. To the extent that States opt to use AMP in their payment methodologies, they will be required to submit SPAs. We will review the amendments to ensure that proposed payment methodologies are consistent with State plan requirements, and will allow for fair and reasonable payments to providers for drugs to protect beneficiaries' access to quality pharmacy services.

Comment: Several commenters requested that CMS clarify how AMP will be balanced to benefit all entities within the pharmaceutical industry and the retail pharmacy class of trade since lower AMPs will benefit manufacturers in lower rebate payments to States and higher AMPs will allow pharmacies to receive increased reimbursement rates but may not reflect all market pricing.

Response: As discussed elsewhere in this rule, we have decided to exclude rebates, discounts and price concessions to PBMs (except those to PBMs' mail order pharmacies) while maintaining our position that prices to mail order pharmacies should be included in the determination of AMP. We believe that we have carefully considered the impact that our decisions made in this final rule will have on AMP and all of the entities that may be affected by it.

Comment: A few commenters stated that there is a conflict in using AMP as a baseline for reimbursement and an index for rebates that manufacturers pay to States.

Response: The law does not require that AMP be used for reimbursement. Rather, the law provides that AMP be used as a basis for the calculation of rebates and the FULs (based on 250 percent of the relevant AMP) and that States may also use AMP data when determining pharmacy reimbursement.

Comment: One commenter stated that a publicly reported, widely available AMP that includes all supply chain discounts will lead to higher prices for the entire pharmaceutical market, as the AMP will become the benchmark below which manufacturers will not lower their prices. In addition, an AMP that includes all supply chain discounts will reduce competition, particularly in the generic market, as manufacturers make

the decision to stop the production of certain products. The commenter believed that these factors together will raise pharmaceutical prices.

Response: The DRA provides for the public release of AMP data. We have no reason to believe the market will not adjust to the availability of this information.

Comment: A few commenters stated that AWP better reflects true costs to independent retail pharmacies as it has allowed payment to exceed the estimated acquisition costs of generic drugs, compensating pharmacies for counseling services and medical advice offered to Medicaid patients. Another commenter suggested that AWP would be a better benchmark for reimbursement than AMP because it is a publicly available list price and it is easily accessible. One commenter stated that the proposal to allow States to use AMP as a benchmark for pharmacy reimbursement eliminates pharmacists' ability to cover their costs as opposed to using AWP as a benchmark, in that pharmacies benefit from the difference between the actual cost of the drug and AWP. One commenter stated that AMP may offer a closer estimate of ingredient cost than AWP but recommended that CMS consider both the cost of the drug and the cost of dispensing in the final rule as dispensing fees in most States are far below the actual cost pharmacies incur to dispense prescriptions. One commenter expressed concern that not only will pharmacy reimbursement for generic drugs be reduced but that the President's Fiscal Year 2008 budget proposes to further reduce reimbursement to pharmacists to 150 percent of AMP and urged CMS to oppose any further cuts to pharmacy reimbursement.

Response: We do not believe that AWP reflects acquisition cost. In the OIG report, ''Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005'' (A–06–06–0063), it was noted that Medicaid pharmacy reimbursement based on AWP often exceeds pharmacies' actual acquisition costs. GAO also stated in its report, ''Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared With Retail Pharmacy Acquisition Costs'' (*GAO–07–239R*), that the AMP-based FUL is preferable to an AWP-based FUL as long as States ensure adequate pharmacy reimbursement. As discussed previously, we believe that States who opt to use AMP, as opposed to AWP, to determine pharmacy payment rates will ensure that such payment rates have greater transparency, as consistent with the DRA amendments. Elsewhere in this regulation, we have encouraged States to examine their dispensing fees to determine whether they reasonably cover the cost of dispensing the drug.

Comment: Several commenters stated that using AMP to set reimbursement is flawed and would not be an appropriate indicator of community pharmacy costs because it does not include wholesaler costs to pharmacies. One commenter stated that the proposal requires manufacturers to calculate AMP using prices that are inaccessible to community retail pharmacies and will result in skewed calculations and misinterpretation that could negatively affect provider reimbursement. Another commenter noted the importance of accurately incorporating the acquisition costs of providers and suppliers in the AMP calculation if AMP is to be used as a benchmark for pharmacy reimbursement.

Response: There is no requirement that States use AMPs to set payment rates for pharmacy providers. The DRA amended section 1927 of the Act to require that CMS use AMP, as opposed to AWP, in the FUL calculation. States may continue to use methodologies that they believe will accurately reflect pharmacy acquisition costs. We believe that we have made States aware in our discussions of AMP in this rule of what AMP represents and that States will use this as a factor when determining a reasonable reimbursement methodology for pharmacy providers.

Comment: One commenter suggested that CMS consider a definition of AMP that differentiates between various practice settings so that reimbursement will adequately address true costs associated with each setting. Another commenter recommended that CMS consider using one AMP such as the monthly AMP for the calculation of the FUL (and a benchmark for reimbursement) and the quarterly AMP for use as the basis for Medicaid rebates.

Response: We disagree that AMP should be calculated separately for each entity within the retail pharmacy class of trade or that monthly and quarterly AMPs should be defined and used differently. The law makes no distinction in AMP by entity or use.

Comment: A few commenters suggested that setting reimbursement rates based on AMP is complicated and would result in States reimbursing pharmacy providers below the acquisition costs of generic drugs. For this reason, the commenters requested that CMS not implement this portion of the proposed rule. A few commenters expressed concern that AMP is not a true indicator of market prices because business transactions may cause periodic changes in AMP from month-to-month. Therefore, the AMP may fluctuate depending on the timing of the original sale and transactions that occur after the original sale that could span across multiple periods.

Response: The DRA amended the statute to require that, effective January 1, 2007, the Secretary calculate FULs based on 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers). The statute also provides that, by July 1, 2007, the Secretary promulgate a regulation clarifying the requirements for AMP calculations. AMPs are based on the average prices paid to manufacturers, net of discounts and price concessions, and will be more useful than prices reported to drug pricing compendia that have been shown to often have no relationship to market prices.

Comment: One commenter expressed concern that drug rebates and other complicated payment arrangements account for high costs for prescription drugs. The commenter cited a report by the McKinsey Global Institute, ''Accounting for The Cost of Healthcare in the United States (January 2007),'' that found that although Americans use fewer drugs per capita, they pay about 70 percent more for prescription drugs than citizens of peer nations. This commenter recommended that CMS bring greater transparency and accuracy by exposing hidden rebates and discounts and determining the true cost of prescription drugs to enable more purchasers to obtain lower prices for drugs.

Response: The law only provides for making AMPs publicly available. However, we believe that the public availability of monthly and quarterly AMPs will bring greater transparency and accuracy to manufacturer pricing.

Comment: Several commenters recommended alternatives to States' use of AMP as a benchmark for reimbursement. One commenter recommended that AMP not be used to set pharmacy reimbursement rates and recommended that CMS instruct States to use actual net acquisition costs, allowing for a reasonable profit and dispensing fee. One commenter recommended that CMS urge States to consider the markup applied within the distribution chain between the manufacturer and the purchasing pharmacy when setting pharmacy payment rates. A few commenters recommended that CMS consider a reimbursement formula that pays pharmacies actual acquisition costs for drugs plus a fair retail markup and

incorporates a dispensing fee and an education fee to compensate pharmacists for Drug Utilization Review services, including checking for interactions with medicine and food and educating patients regarding their medications. One commenter suggested that CMS refocus efforts to save Medicaid dollars on brand name drugs by mandating an additional rebate on brand name drugs and stated that this would result in far greater savings for the Medicaid Program than reducing payment for generic drugs. One commenter recommended that CMS require States to include a minimum profit margin for low-cost generic drugs in their reimbursement methodologies for independent pharmacies that at least covers the cost of dispensing that drug. Several commenters expressed concern that the proposal that States use AMP as a benchmark for reimbursement does not address dispensing fees and suggests that the lack of guidance allows States to continue to underpay pharmacists for dispensing-related services. One commenter recommended that CMS consider an alternate proposal that would cap the cost of medications from the pharmaceutical companies, charge all pharmacies the same price without preferential treatment or pricing for one type of pharmacy over another, and set all Medicaid dispensing fees at the same rate for all pharmacies based on the Grant Thornton LLP National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies, prepared for the CCPA, published in January 2007, and accessible at *http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=7641&TEMPLATE=/CM/ContentDisplay.cfm.* Another commenter recommended that CMS require reimbursement to be based on the WAC plus a professional fee of $10 for brands and $15 for generics to more accurately account for pharmacy acquisition costs and ensure that pharmacy providers are reimbursed fairly. One commenter recommended that CMS set a standard reimbursement methodology for pharmacy providers based on AWP or the average price per unit that a pharmacy pays for a drug. Another commenter recommended that CMS offer guidance to the States to establish a meaningful percentage differential to be applied to all FULs (AMPs) for all small pharmacies that meet the definition of ''small business'' as defined by the Small Business Administration (SBA). Other commenters stated that pharmacy provider acquisition costs surveys should be used to estimate pharmacy acquisition costs. Another commenter recommended that CMS instruct States to use the monthly Retail Price Survey (RPS) data as a benchmark for pharmacy reimbursement as this data represents the weighted average reimbursement received by independent community pharmacies for each drug. One commenter requested that CMS define the pharmacy reimbursement methodology for States and set the dispensing fee in a manner that adequately compensates independent retail pharmacies, as independent pharmacies will not be offered drug products from their suppliers at AMP or near the AMP. One commenter agreed with CMS that States should be allowed to use AMPs as a benchmark for pharmacy reimbursement and suggested that CMS conduct studies to identify manufacturers whose products consistently have atypically large spreads between AMP and AWP or WAC. The commenter suggested that States may then implement alternative payment rates on products distributed by these manufacturers, thus preventing revenue enhancing schemes and retaining the usefulness of their current reimbursement techniques. Another commenter stated that AMP should be considered by States as the minimum allowable reimbursement.

Response: We do not agree with these proposals that CMS should establish dispensing fees or reimbursement methodologies as the States are in a better position to determine such payment amounts. The statute does not give CMS the authority to assess higher rebates on certain brand name drugs or to regulate the price charged by manufacturers for drugs.

Comment: One commenter noted that State MAC lists currently are significantly lower than the FUL for some products and that AMP-based reimbursement will not adequately cover pharmacy operating costs. The commenter suggested that CMS complete a study to evaluate whether States are currently reimbursing providers below 250 percent of AMP.

Response: Since the FULs methodology is established in the DRA, we see no benefit at this time in completing a study to determine whether States are already paying less than this amount. We note that States continue to be able to establish their own MACs as well as adjust the individual prices of drugs provided they do not exceed the FULs in the aggregate.

Comment: One commenter recommended that CMS review the price disparity between retail pharmacy class of trade and mail order pharmacies.

Response: We appreciate the comment; however, as our definition of AMP is based on what we have defined as the retail pharmacy class of trade, we believe it is unnecessary for CMS to conduct the recommended review. As previously discussed in this final rule, we have decided that the retail pharmacy class of trade includes mail order pharmacies. We believe that, as with traditional pharmacies, mail order drugs are available to the general public.

Comment: One commenter recommended that CMS offer grants to the States to (1) develop separate, differentiated payment to pharmacies for clinical services provided to Medicaid beneficiaries beyond OBRA 90 mandates and (2) develop differential payments based on quality measures and implementation of patient safety measures. Other commenters requested that CMS encourage the use of incentives to support efforts of pharmacists to improve patient outcomes through patient education and medication compliance instead of reducing costs to States by decreasing reimbursement to pharmacies.

Response: While we appreciate these comments, they are beyond the scope of this final rule.

Comment: A few commenters expressed concern that AMP may serve as a benchmark for reimbursement by other third party payers. Other commenters stated that although the rule proposes that States may use AMP as a benchmark for reimbursement of generic drugs, it will also have implications for the reimbursement of single source products.

Response: The use of AMPs by other payers is beyond the scope of this rule.

Comment: One commenter requested that CMS use its authority to review and approve SPAs to prevent States from modifying pharmacy reimbursement methodologies before the final rule has been implemented and the new AMP data has been assessed.

Response: We do not agree. While we will review SPAs to ensure compliance with the dictates of section 1902(a) of the Act, we do not have the authority to prevent States from submitting SPAs to modify pharmacy reimbursement methodologies before this final rule has been implemented and the new AMP data assessed.

Comment: A few commenters recommended that CMS instruct States to provide appropriate reimbursement for clinical services provided by specialty pharmacies, including long-term care pharmacies and other pharmacies that specialize in unit dose packaging as these services help ensure the effectiveness of patients' treatment

regimens, are not provided in the retail pharmacy setting and ultimately reduce costs to the Medicaid Program. One commenter requested that CMS consider the financial impact of the proposed AMP-based reimbursement methodology on specialty pharmacies as the average cost to dispense prescriptions in the specialty pharmacies is ten times greater than that of traditional retail pharmacies. Some commenters expressed concern that pharmacies' cost of serving mentally ill Medicaid patients, particularly those whose drugs require pharmacies to provide special packaging, would not be covered by the FULs, resulting in many special needs patients being institutionalized at Medicaid's expense.

Response: States may differentiate dispensing fees for specialty pharmacies and other classes of providers to ensure appropriate reimbursement.

Comment: One commenter stated that the proposal to permit States to use AMP as a benchmark for pharmacy reimbursement does not address a separate furnishing fee for anti-hemophilic clotting factors as set forth in section 303(e)(1) of the MMA. The commenter has requested that CMS consider a separate furnishing fee, a separate payment added into the payment rates, to allow Medicaid patients who are affected by bleeding disorders to maintain access to care and access to anti-hemophilic clotting factor medications.

Response: Medicaid already has other service categories that can be used to appropriately reimburse providers for these other services. States are also able to establish a dispensing fee that is appropriate for the dispensing of anti-hemophilic clotting factor medications.

Comment: One commenter expressed concern that CMS will not consider expert advice from pharmacists, pharmacy organizations and Congress regarding the proposal that States may use AMP as a basis for reimbursement.

Response: We have considered and appreciate the advice that we received from all interested parties including the comments received on the proposed rule.

Comment: Another commenter recommended that CMS require the use of therapeutic alternatives when an alternate product in the same class has a generic available in order to control the use of expensive brand name medications and save Medicaid dollars.

Response: Since many States already require generic substitution and have other measures in effect to encourage the dispensing of generic drugs, we do not agree that there needs to be a further CMS requirement here.

Determination of Best Price (§ 447.505)

Comment: One commenter asked that if a manufacturer offers a price that is lower than any actual price paid, is best price set on the lowest price paid or the lowest price available.

Response: The best price is the price from the manufacturer which is calculated to include all applicable sales and discounts; it is the price actually realized. Best price includes prices available to any purchaser, inclusive of cash discounts, free goods contingent on any purchase requirement, volume discounts, and rebates (other than rebates under section 1927 of the Act).

Comment: One commenter stated that the proposed rule defines best price as ''* * * the lowest price available from the manufacturer during the rebate period to any entity in the United States * * *.'' However, the national rebate agreement defines best price as ''* * * the lowest price at which the manufacturer sells the covered outpatient drug to any purchaser in the United States * * *.'' The commenter asked if CMS intends to materially change the definition of best price by using ''entity'' rather than ''purchaser.'' If CMS is not changing the definition, the commenter asked that we use the language from the national rebate agreement in the final rule.

Response: We used the term ''entity'' in the proposed rule because this is the term used in the DRA. We are retaining this term in the final rule. We do not intend any material change, except that given the DRA amendments, the term entity may include sales to other manufacturers.

Comment: One commenter questioned if all SPAPs are excluded from the determination of best price in the proposed rule or only SPAPs that qualify under the criteria set out in Manufacturer Release 68.

Response: SPAPs should continue to meet the qualifications in program guidance, which is currently set out in Manufacturer Release 68, which can be found on the CMS Web site at *http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp.* A list of designated Medicaid SPAPs can be found on the CMS Web site at *http://www.cms.hhs.gov/MedicaidDrugRebateProgram/Downloads/SPAPBestPriceList.pdf.* Price concessions to SPAPs that do not meet these standards would not be exempt from best price. We have added language to this final rule to clarify this point.

Comment: One commenter stated that SPAPs are generally third-party payers and do not typically purchase drugs directly. The commenter recommended that the exclusion from best price be expanded to include price concessions received by SPAPs including rebates.

Response: We agree. SPAPs operate their programs similar to PBMs whose rebates, discounts, or other price concessions have been excluded from AMP and best price. These PBM rebates, discounts or price concessions are not available to the retail pharmacy class of trade and, therefore, are not passed on to community pharmacies. SPAPs, as with PBMs, are treated by pharmaceutical manufacturers as a different class of trade and are not accessible to the public. Therefore, in accordance with section 1927(c)(1)(C)(i) of the Act, we are excluding rebates obtained from designated SPAPs from manufacturers from the best price.

Comment: One commenter noted that in § 447.505(b) of the proposed rule, CMS defined providers as ''a hospital, HMO, including an MCO or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provisions of health care''. In § 447.505(c)(3), CMS noted that ''prices to providers (for example, hospitals, HMOs/MCOs, physicians, nursing facilities, and home health agencies)'' are included in best price. The commenter asked if it is the intent of CMS to define home health providers as retail providers or non-retail providers.

Response: We consider home health providers to be retail providers. Home health agencies (as well as hospices, hospitals, and skilled nursing facilities) are providers for purposes of Medicare (see section 1861(u) of the Act). Accordingly, we have decided, in light of section 1927(c)(1)(C) of the Act, that CMS should include sales to home health agencies within best price.

Comment: One commenter expressed concern with the exemption from best price of payments made by PDPs and MA–PDs to manufacturers. With the advent of the Medicare Part D program, there are substantial sales attributable to PDPs and MA–PDs. If included in best price, the commenter believed these sales arrangements would result in more accurate pricing information and enhance the Medicaid Drug Rebate Program.

Response: Section 1927(c)(1)(C)(i)(VI) of the Act provides that prices negotiated by a PDP under Part D and an MA–PD under Part C, both of Title XVIII of the Act, are excluded from best price.

Comment: Several commenters agreed with the statement in the preamble to the proposed rule that to the extent that

an entity is not included in the best price calculation, both sales and associated discounts or other price concessions provided to such an entity should be excluded from the calculation.

Response: We agree and have retained this policy in the final rule.

Comment: One commenter recommended that CMS publish a proposed rule for public comment when significant changes related to best price are being considered rather than issue program releases and post clarifications on the CMS Web site as proposed in the rule. Another commenter noted that clarifications to the definition of AMP should be made through formal notice and comment rather than through program releases and Web site postings.

Response: We agree that substantive changes in policy should be made through the rulemaking process. We note, however, that policy established through regulation may need to be clarified to explain how it applies in specific situations or to new situations in the marketplace. CMS will continue to issue subregulatory guidance when we find this to be necessary or appropriate.

Comment: Several commenters disagreed with limiting the exemption from best price for manufacturer coupons to those redeemed by the consumer with the manufacturer. The commenters believe that coupons redeemed by a pharmacy or other third party should also be exempt from best price when the pharmacy or other party passes through the full value of the coupon to the consumer and does not receive any price concession on acquisition cost from the manufacturer other than the coupon amount and the handling fee.

Response: We concur. We are exempting coupons redeemed through a pharmacy from best price as long as the exact value of the coupon is paid to the pharmacy from the manufacturer or its agent, the full value of the coupon is passed on to the consumer, and the pharmacy does not receive any price concessions.

Comment: One commenter requested that CMS reaffirm that multi-manufacturer patient assistance programs continue to be exempt from the best price determination.

Response: We agree, and as discussed previously with respect to AMP, we have decided to codify our existing policy in this rule. Accordingly, patient assistance programs are exempt from the best price determination under 1927(c)(1)(C) of the Act as long as the following provisions are met:

1. The program is focused on extending financial assistance to low-income individuals and families, as determined by CMS, who are not otherwise eligible for Medicare and do not have public or private prescription drug coverage.

2. Each manufacturer establishes an amount of the subsidy to be given to individual patients, without any negotiation between the manufacturer and any other third party (such as an insurer or PBM) as to that amount.

3. The entire amount of the subsidy is made available to the individual patient, without any opportunity for the retail pharmacy or any third party (such as an insurer or PBM), to reduce that subsidy, or take a portion of it, for its own purposes.

4. The pharmacy collects no additional payment, other than the benefit amount, from the patient assistance program.

Comment: Several commenters stated that to include PBM rebates in best price poses significant operational issues because manufacturers often do not know the amount a PBM receives as rebates for retail mail order and non-mail order sales. The commenters suggested that the final rule should allow manufacturers to use reasonable assumptions to estimate PBM rebates. This would be similar to Medicare Part B ASP reporting requirements (71 FR 69623 and 69676, Dec. 1, 2006).

Response: We recognize the commenters' concerns and have decided that, except in those situations where PBM rebates are designed to provide price concessions, discounts, or rebates, or to adjust prices recognized by providers or retailers, PBM rebates should not be included in best price calculations.

Comment: Several commenters stated that some industry analysts appeared to misread the proposed rule to suggest that manufacturers may be obligated to add concessions paid to PBMs to the concessions paid to customers of the PBMs in calculating best price. This would effectively call for the combining of two separate prices, one offered to a PBM and the other to a customer of a PBM. The commenter stated that the statute is quite clear in defining best price as the lowest price to ''any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or government entity * * *.'' The commenters argued that if Congress had intended anything other than a customer-by-customer analysis of separate prices, the statute would have combined each customer with the word ''and'' instead of the disjunctive ''or.'' The commenters requested that CMS reaffirm that best price is the lowest price available from the manufacturers reflecting concessions provided by the manufacturers.

Response: We do not agree with the commenters. Although we have deleted the requirement that manufacturers include PBM rebates and discounts and other price concessions in best price, there are instances where some PBM rebates and discounts may be designed to adjust prices at the retail or provider level. Best price is designed to reflect the lowest price available from the manufacturer to any purchaser, inclusive of rebates, discounts, or price concessions that adjust the price realized. Where PBM rebates, discounts, or price concessions do not operate to adjust prices, they should not be included in the best price calculation.

Comment: Several commenters suggested that PBM rebates should be included in the best price calculation but not in the calculation of AMP because including these prices would reduce the FUL to an amount below available market price. The commenter stated that this would undermine the FUL and shrink rebates paid to States.

Response: We appreciate the recommendation of the commenters. We believe that, as a general matter, PBM rebates, discounts, and price concessions obtained from manufacturers (except for PBM mail order purchases) should be excluded from both best price and AMP. We have concluded that we should not consider PBMs as falling within the retail pharmacy class of trade as they are not directly involved in the supply chain of pharmaceuticals. PBMs are treated by the pharmaceutical manufacturers as a different class of trade and the public does not necessarily have access to drugs supplied through PBMs. Therefore, we do not believe that it is appropriate to include PBM rebates, discounts, and prices in either AMP or best price, except for mail order purchases.

Comment: One commenter requested that PBM price concessions should not be used in the best price calculation because they are not shared with pharmacies.

Response: We have excluded PBM price concessions except for mail order purchases where rebates or price concessions are designed to adjust prices at the retail or provider level.

Comment: One commenter disagreed with the proposed rule that prices of sales directly to patients should be included in best price because direct-to-patient sales are not specified in the statute. Rather, the commenter believed that the statutory definition is intended

to capture prices to commercial entities, and that CMS' interpretation goes beyond, and is inconsistent with, the plain language of the statute.

Response: The statute clearly specifies at sections 1927(c)(i)(I)–(VI) of the Act those sales, including, for example, sales provided to patients through the endorsed discount card program, that are excluded from best price. As we discussed previously, we believe that sales directly to patients are included, except as specifically excluded by statute, as this is an alternate channel for sales that normally flow through included entities.

Comment: One commenter requested that discounts negotiated on behalf of retirees enrolled in retiree prescription plans which are excluded from best price be extended to their dependents. The commenter stated that rebate agreements for retirees for qualified retiree prescription drug utilization apply the same price structure to all of the individuals covered by the plan and do not distinguish between utilization by retirees and of their dependents.

Response: We proposed to exempt from best price any prices charged which are negotiated by a qualified retiree prescription drug plan under section 1860D–22(a)(2) of the Act. To the extent the prices are negotiated by a qualified retiree prescription drug plan under section 1860D–22(a), they are exempt from best price.

Comment: Several commenters requested that CMS not include customary prompt pay discounts in the determination of best price to the extent that such discounts are excluded from AMP. They stated that Congress recognized that discounts serve an important role in providing a revenue stream for distributors to ensure the safe and effective distribution of drugs to patients.

Response: We do not agree. Congress did not exclude customary prompt pay discounts from the determination of best price. Therefore, customary prompt pay discounts remain included in the determination of best price.

Comment: One commenter requested that when best price is determined, customary prompt pay discounts extended to wholesalers should not be aggregated with price concessions available to an end-customer under a contract administered through a wholesaler chargeback arrangement, regardless of whether the manufacturer negotiated the contract directly with the end-customer or with a third party.

Response: We do not agree. As we have previously stated, there is no basis to exclude these discounts. Both the customary prompt pay discounts and other price concessions available to the end-customer are to be included in the determination of best price.

Comment: One commenter requested that the regulation not define fair market value for administrative and service fees that are excluded from best price. The commenter suggested that CMS mirror Medicare's position on ASP which permits manufacturers to determine the most appropriate industry-accepted method to determine fair market value of the drug distribution services they receive.

Response: We concur that manufacturers should be permitted to determine the fair market value of drug distribution services using industry-accepted methods and have not defined these terms in this final rule.

Comment: One commenter requested that further guidance be given on when GPOs should be excluded from best price. The commenter suggested that fees to GPOs should not be treated as price concessions unless the fees (or any portion thereof) are passed on to the GPO's members or customers.

Response: GPOs may function as negotiators for price concessions on behalf of member pharmacies with GPOs receiving service fees for their services or they may function as a distributor to their member pharmacies of price concessions from manufacturers after volume sales benchmarks have been attained. If the service fees paid to GPOs are bona fide service fees, and there is no evidence or arrangement that the fee is passed on to the member pharmacy, client or customer of any entity, the manufacturer can exclude the fees from the determination of best price.

Comment: One commenter stated that in 2004, the DoD restructured its pharmaceutical benefit plan TRICARE and placed the pharmacy benefit under contract with PBMs. DoD determined, and CMS agreed, that the TRICARE transactions, known as TRICARE Retail Pharmacy Program or TRRx, amounted to depot sales that qualified for Federal ceiling prices (FCP). Manufacturers paid rebates, called refunds on TRRx utilization, and those rebates were calculated in a manner intended to provide DoD with FCP for that utilization. In Manufacturer Release 69, CMS directed that both TRRx sales and refunds be excluded from AMP and best price because they qualified as depot sales. In September 2006, the Federal Circuit Court of Appeals raised significant concerns with the TRRx drug program holding that DoD could not require manufacturers to pay refunds without issuing a regulation through formal notice and comment rulemaking (464 F.3d 1306 (Fed. Cir. 2006)). It is our understanding that DoD has ceased the TRRx program and is refunding any rebates previously paid. The commenter requested that any voluntary price concessions provided to DoD by manufacturers on direct purchases, sales to TRICARE mail order pharmacy, or through rebates on TRICARE be exempt from best price even though the prices are not obtained from depot purchasing.

Response: We recognize the Federal Circuit Court of Appeals remanded the DVA's Dear Manufacturer Letter (October 24, 2004) for substantive rulemaking. However, to the extent section 1927(c)(1)(C)(i)(I) of the Act includes the DoD as an exclusion from best price, TRRx prices are excluded from best price.

Comment: One commenter requested that if the final rule changes the AMP NDC reporting from 9 digits to 11 digits, CMS should also require that best price be reported for each package size. This would allow for more consistent, transparent, and accurate calculations between AMP and best price.

Response: This final rule maintains that AMP reporting remain at nine digits.

Authorized Generic Drugs (§ 447.506)

Summary of Comments

The DRA requires drug manufacturers to include drugs sold under an NDA approved under section 505(c) of the FFDCA in their AMPs and best prices.

In the proposed rule, we would require the manufacturer holding title to the NDA of the authorized generic drug to include the direct and indirect sales of this drug in its AMP and to include in the computation of best price the price of the innovator multiple source drug as well as the single source drug.

We received numerous and detailed comments concerning these proposed requirements that led us to agree with commenters that these requirements would be unduly burdensome on manufacturers, call into question the veracity of manufacturer pricing information reported to CMS, and potentially violate anti-trust statutes because they would require manufacturers to share pricing information and engage in anti-competitive practices.

In the final rule, we limit the application of the requirement to the sale of an authorized generic product from the primary manufacturer; that is, the manufacturer that holds the NDA, to the secondary manufacturer; that is, the manufacturer that markets and sells the authorized generic drug. This eliminates the need for manufacturers to share

information on sales to other entities and potential competitors. We believe that the sale price of the drug from the primary to the secondary manufacturer will generally be lower than the lowest price paid for the authorized generic drug by subsequent purchasers. We have further supported this by stating that all price concessions, discounts and fees other than bona fide service fees must be reflected in the primary manufacturer's calculations of best price. This will prevent the primary manufacturer from circumventing its rebate liability, impact the rebate owed by the primary manufacturer, and result in the savings contemplated by the provision.

At this time, we do not require that subsequent sales of an authorized generic product by the secondary manufacturer be included in the AMP calculation of the primary manufacturer. We note that this is consistent with our reading of the DRA in that, unlike the best price amendment, the DRA did not amend the definition of AMP, which continues to require that AMP be calculated with respect to the covered outpatient drug of a manufacturer based on the price paid to the manufacturer ''by wholesalers for drugs distributed to the retail pharmacy class of trade.'' The DRA did not amend the AMP definition to include prices paid to the manufacturer by other manufacturers. Furthermore, in light of the comments we have received with respect to the proposed rule, we believe that to require the primary manufacturer to include sales of the secondary manufacturer within its calculation would be problematic from an administrative accounting and anti-trust perspective. We also note that to include the sales of the authorized generic drug in the AMP of the primary manufacturer's drug could lower the AMP and rebate liability, and present additional concerns with respect to the FUL calculation, contrary to our reading of the provision.

In light of the comments received and our concerns given the statutory amendment, at this time we have decided not to include authorized generic products marketed by the secondary manufacturer in the AMP calculation. We will continue to review this issue, but we believe this interpretation best implements the DRA amendments.

General Comments

Comment: One commenter expressed general support for the authorized generic provisions in the proposed rule.

Response: We appreciate the support the commenter expressed.

Definition of Authorized Generic

Comment: One commenter urged CMS to clarify that the term ''authorized generic'' is limited to those products for which the title passes to an authorized generic entity.

Response: We disagree. We do not interpret the DRA amendment as necessarily limiting the application of this provision to drugs for which the secondary manufacturer holds title.

Comment: One commenter suggested that CMS exclude from the definition of ''authorized generic,'' drugs that are repackaged for use in institutions. The commenter requested that CMS clarify that private label arrangements involving distinct packaging due to variations in package size from the branded product do not constitute ''authorized generics'' where the private label product is used in an institution. Another commenter recommended that CMS preserve its current policy of exempting manufacturers who repackage products (for sale) from reporting best price. The commenter recommended that CMS classify the secondary manufacturer of authorized generic products as a repackager.

Response: The definition of authorized generic drugs excludes drugs that have been repackaged for use in institutions. Thus, any sales of the repackaged drug by the repackager would not be included in the primary manufacturer's rebate calculation if it were simply repackaged in an institutional package size with the primary manufacturer's NDC; however, the sale to the institution would be included in the primary manufacturer's best price.

AMP and Best Price Reporting Requirements

Comment: Many commenters expressed concern regarding the proposed policy to require the price or sales of the authorized generic drug to be included in the AMP and the best price of the branded drug. Many commenters requested further guidance to clarify how the price or sales of authorized generic products should be gathered, shared and incorporated into the AMP and best price of the branded drug. One commenter stated that the proposed rule did not address whether the primary manufacturer must incorporate raw sales data into the brand drug calculations in order to derive a blended AMP and best price or whether the primary manufacturer can rely on the secondary manufacturer to provide the authorized generic AMP-eligible units and dollars to derive the AMP. Several commenters recommended that CMS allow the primary manufacturer to calculate a blended AMP and determine the best price based on the pricing data provided by the secondary manufacturer. One commenter suggested two methods for blending authorized generic sales data with the sales data of the primary manufacturer. Several commenters suggested that CMS require the primary manufacturer to obtain from the secondary manufacturer either the AMP and best price or underlying authorized generic sales data. The primary manufacturer would then combine its own sales data with the sales data provided by the secondary manufacturer to calculate the AMP and determine the best price for the brand drug. One commenter asked for guidance regarding a method for calculating a weighted AMP value for authorized generic drugs. Several commenters recommended that CMS require manufacturers to use a weighted average to calculate the AMP for authorized generic drugs.

Response: This final rule provides the requirements for manufacturers to use in calculating the AMP for covered outpatient drugs. Specific calculation methods are left up to the manufacturer consistent with this rule.

In light of the comments, we have decided to reconsider our proposal that primary manufacturers include the authorized generic product pricing data of a secondary manufacturer in their best price and AMP calculations. At this time, we have revised the authorized generics provision to require the primary manufacturer to include in best price the authorized generic sales from the primary manufacturer to a secondary manufacturer or subsidiary of the brand company.

At this time, based on concerns raised by the commenters, primary manufacturers would not be required to incorporate the sales of the authorized generic in the AMP of the brand drug. The primary manufacturer and the secondary manufacturer would be responsible for separately calculating their own AMP. The method for determining the AMP, as described elsewhere in this final rule, is the same for all covered outpatient drugs, including authorized generics.

Comment: A few commenters expressed concern that a blended AMP and best price would distort the AMP and the best price of authorized generic drugs which in turn may cause pharmacies to receive substantially lower reimbursements for such drugs. One commenter stated that a blended AMP for the brand drug may be lower than a pharmacy's acquisition cost for the product. A few commenters stated

that while CMS may allow the primary manufacturer to pay its rebate based on a blended AMP, it is not fair to use this blended AMP to potentially underpay pharmacies for dispensing the brand drug when prescribed by a physician. One commenter stated that this final rule would result in new AMP-based calculations that would apply to more medications, thereby compounding concerns regarding decreased reimbursement to pharmacies for authorized generic products. The commenter further stated that the broadened definition of authorized generic could create a disincentive for generic utilization, thereby increasing costs to the Medicaid Program. A few commenters suggested that separate AMPs should be posted on CMS' website for the brand drug and the authorized generic drug.

Response: We agree with these comments. The primary manufacturer should not include within its AMP calculation any pricing data concerning the sale by the secondary manufacturer regarding the authorized generic product.

Comment: A few commenters requested further clarification on how to handle incomplete or inaccurate data reported by the secondary manufacturer. In addition, commenters wanted to know what should be done when information is not received from the secondary manufacturer in a timely manner. One commenter recommended that CMS allow the use of the prior month's data to calculate the blended AMP to ensure compliance with reporting deadlines. Many commenters requested that CMS confirm that the primary manufacturer may rely on the AMP and sales data provided by the secondary manufacturer without having to review the underlying data and methodologies for accuracy. Several commenters also requested that the primary manufacturer not be held responsible for certifying (in accordance with the certification requirements set forth in this rule) the accuracy and completeness of the AMP and best price data provided by the secondary manufacturer. Another commenter requested that CMS allow the primary manufacturer to incorporate the AMP and best price of the authorized generic product into the AMP and the best price of the brand drug.

Response: We appreciate the comments and have revised the authorized generics provision to require the primary manufacturer to include in best price the authorized generic sales from the primary manufacturer to a secondary manufacturer or subsidiary of the primary manufacturer. As discussed previously, based on the comments received, we have decided that the primary manufacturer should not incorporate the sales of authorized generic products by the secondary manufacturer in the AMP of the brand drug. At this time, we have decided that the primary manufacturer and the secondary manufacturer would separately calculate their own AMP.

Comment: One commenter requested that CMS clarify whether the sales by the primary manufacturer of an authorized generic to a secondary manufacturer should be included in the primary manufacturer's AMP and best price. The commenter indicated that inclusion of such manufacturer-to-manufacturer sales in the AMP would result in double-counting in AMP of every authorized generic unit; once when the unit is sold by the primary manufacturer to the secondary manufacturer, and again when the unit is sold by the secondary manufacturer to its customers, thereby resulting in a distortion of the AMP. A few commenters urged CMS to clarify that manufacturer-to-manufacturer sales are non-retail sales and, therefore, excluded from AMP. Another commenter stated that including inter-company transfer prices in the AMP for every unit of a drug would deflate the market price and skew the AMP to an inappropriately low level. The commenter suggested that the final rule clarify that inter-company transfer prices will be excluded from AMP or best price regardless of the circumstances surrounding the transfer of product within the same corporate company, even if the product is provided at a lower price from one member of the company to another member of the company. Another commenter recommended that CMS define the term ''any entity'' in the best price definition to exclude the sales price of authorized generics from the primary manufacturer to the secondary manufacturer so that this sales price would not set the best price. The commenter further explained that failure to exclude the sale price from the primary manufacturer to the secondary manufacturer would result in increased costs that will shift to payors and consumers because both the primary manufacturer and the secondary manufacturer will raise their prices in order to recoup reduced profit margins resulting from an inaccurate best price.

Response: We appreciate the comments but have not revised our definition of ''any entity'' as we believe, in light of the DRA amendments, that any sales of covered outpatient drugs between manufacturers must be included in the best price. The DRA amended the definition of best price, in part, to specifically provide that the best price should be inclusive of the lowest price available from the primary manufacturer to ''any manufacturer.'' In accordance with the best price provisions in section 1927(c)(1)(C)(i) of the Act, we believe that all price discounts, except for bona fide service fees, should be included in the best price of the brand drug unless the discount is specifically excluded by statute or regulation. Therefore, the primary manufacturer will be required to include in the best price of its drug any price concession provided by the manufacturer to any entity (including the secondary manufacturer) that reduces the price of the authorized generic drug sold by the primary manufacturer and actually realized by the primary manufacturer, unless the price concession is specifically excluded by statute or regulation or falls within the definition of a bona fide service fee.

Comment: Several commenters expressed concern that our proposed policy would require the primary manufacturer and the secondary manufacturer to share confidential pricing information that may result in anti-trust violations. Commenters strongly urged CMS to consult with the FTC before implementing the new reporting requirements outlined in the DRA. One commenter recommended that CMS consider eliminating or delaying implementation of the authorized generic reporting requirements until a later date.

Response: We appreciate the comments and have revised the authorized generics provision to require the primary manufacturer, that is, is the NDA holder, to include its sales of the authorized generic to the secondary manufacturer in best price. We have revised the best price provision to provide, at this time, that best price should only include authorized generic sales from the primary manufacturer to a secondary manufacturer or subsidiary of the primary manufacturer and shall be the lowest price at which the primary manufacturer sells the drug.

At this time, we believe this revision will avoid any anti-trust concerns that could potentially arise as a result of pricing data being exchanged between manufacturers. In light of the DRA amendments, we are not eliminating or delaying the implementation of this provision but we will continue to consider this issue as we receive AMP and best price data.

Comment: Several commenters requested that CMS require the primary manufacturer and the secondary

manufacturer to separately report and calculate the AMP and determine the best price for their own products, using only the sales data based on the products' NDCs, and include in each of their own AMP reports the number of units sold during the rebate period. Other commenters recommended that CMS allow the primary manufacturer and secondary manufacturer to submit separate pricing data regarding their own sales so that CMS may calculate the AMP and best price.

Response: We have revised the provision to no longer require the primary manufacturer to include authorized generic sales of the secondary manufacturer in the AMP. The best price shall include authorized generic sales from the primary manufacturer to a secondary manufacturer or to a subsidiary of the primary manufacturer and shall be the lowest price at which the drug is sold by the primary manufacturer.

Comment: A few commenters expressed concern that there are a number of transactions that may not have been intended to fall within the scope of the authorized generic provision. Several commenters requested that CMS clarify that inter-company transactions between the primary manufacturer and the secondary manufacturer will not be included in the primary manufacturer's pricing calculations. Several commenters recommended that inter-company transactions such as transfer price, royalties and/or license payments made by the secondary manufacturer to the primary manufacturer should not be included in pricing calculations. A few commenters indicated support of CMS' decision not to require manufacturers to include the transfer price of the authorized generic drug in best price. One commenter requested that CMS clarify how manufacturers should account for transfer prices when the product is sold from the primary manufacturer to the secondary manufacturer. Other commenters were concerned that transfer fees, licensing fees and manufacturer contracting fees would be inappropriately included in the best price and AMP for authorized generic sales. Several commenters stated that such fees should not be taken into account in the authorized generic provision and only the sales of the authorized generic products in the marketplace should be considered. One commenter requested that CMS clarify that the term ''price'' used in § 447.506(c) would be considered to be either (1) the adjusted transfer price after the value of all profit-sharing, royalties, license fees and other adjustments to the contracted transfer price have been added; or (2) the lowest price at which the secondary manufacturer sells the authorized generic in the marketplace. The commenter stated that either clarification of the term ''price'' would help ensure a true and accurate reflection of the best price of the authorized generic in the marketplace. The commenter indicated that the sales of the authorized generic drugs by the secondary manufacturer to its own customers should be included in the best price, not the primary manufacturer's sales price to the secondary manufacturer. Several commenters requested that the transfer price at which the primary manufacturer sells the drug to the secondary manufacturer not be taken into account or included in the best price or the AMP. One commenter stated that the transfer price should not be included in the best price even if this price would otherwise be the lowest price at which the drug is sold. The commenter stated that transfer prices involve complex royalty or profit-sharing arrangements that would be difficult for the primary manufacturer to incorporate into its best price and difficult for CMS to evaluate. Another commenter recommended that CMS require manufacturers to include the transfer price from the primary manufacturer to the secondary manufacturer in the best price.

Response: We believe that transfer prices and all fees paid by the secondary manufacturer to the primary manufacturer for the authorized generic product, other than bona fide service fees or other discounts excluded by statute or regulation, are price discounts which should be included in the best price of the primary manufacturer. The inclusion of such price reductions or fees ensures that the amount recognized by the primary manufacturer for the authorized generic product reflects all discounts and price concessions that are meant to be included in the best price. Therefore, we have revised the authorized generic provision to include in the best price of the brand drug, transfer prices and other fees paid for authorized generics by the secondary manufacturer to the primary manufacturer, unless such prices or fees are excluded by statute or regulation or fall within the definition of a bona fide service fee as defined in § 447.505 of this final rule.

Comment: One commenter requested that CMS confirm that the best price for authorized generic products is the lowest price charged for the drug by the primary manufacturer in a best price-eligible sale. In addition, the best price for the secondary manufacturer is the lowest price charged for the drug by the secondary manufacturer in a best price-eligible sale. Another commenter requested that CMS allow the primary manufacturer to obtain from the secondary manufacturer the best price for the authorized generic and compare the secondary manufacturer's best price to its own best price and then submit the lowest price of the two drugs.

Response: In this final rule, we state that the best price includes authorized generic sales from the primary manufacturer to the secondary manufacturer or subsidiary of the primary manufacturer, and the best price is the lowest price at which that product is sold.

Comment: One commenter recommended that CMS clarify that the proposed authorized generic provisions do not apply to situations in which a product is sold to a secondary manufacturer for purposes of incorporating the product into a ''kit'' consisting of multiple products.

Response: The authorized generic provisions apply to the transaction between the primary and secondary manufacturers. Therefore, the price for any authorized generic product sold for the purpose of incorporating the product into a kit consisting of multiple products must be included in the best price of the primary manufacturer.

Comment: One commenter stated that the authorized generic provisions negatively impact manufacturers and penalize them for entering into authorized generic arrangements. The commenter stated that CMS has prematurely taken a negative position on authorized generics before receiving results from an FTC study that is currently analyzing the impact of authorized generics in the marketplace. The commenter further indicated that it would be premature and unwise of CMS to adopt any policy that would impose a penalty on the authorized generic industry before conclusions of the FTC study are in hand.

Response: We appreciate the comments, but the statute does not condition this policy on the results of the FTC study or its findings. The policy concerning authorized generics is intended to implement our understanding of the provisions of the DRA. The purpose of the authorized generic provisions is to ensure that prices for such drugs are accounted for in prices reported by manufacturers participating in the Medicaid Drug Rebate Program.

Comment: One commenter recommended that CMS treat authorized

generic drugs as noninnovator multiple source drugs unless the manufacturer has licensed the drug to another labeler and has no control over pricing, marketing or distribution.

Response: We disagree. Authorized generic drugs are single source or innovator multiple source drugs. In accordance with our understanding of the statute, drugs sold, marketed or distributed under an NDA must be treated as single source or innovator multiple source drugs for purposes of the Medicaid Drug Rebate Program.

Comment: Several commenters requested further guidance regarding the inclusion of authorized generics in the AMP and best price when the drug is being sold by the primary manufacturer and a secondary manufacturer at the same time. The commenter suggested that all sales of the authorized generic product should be considered when calculating the AMP and best price and requested that CMS provide guidance in order to confirm this interpretation. Another commenter requested that CMS clarify in the final rule that the authorized generic provision applies to sales of the brand drug under a new labeler code. A few commenters asked if the authorized generic provision would apply to situations where the primary manufacturer has completely sold the drug to another manufacturer (including all rights to sell the authorized generic drug). Other commenters asked how sales should be treated when the primary manufacturer is no longer manufacturing the authorized generic product but is selling off existing inventory. One commenter requested that CMS confirm its interpretation that the licensed drug would meet the definition of a single source drug because the primary manufacturer is not a source of the drug. Another commenter recommended that the primary manufacturer not be required to take into account authorized generic sales after the date the primary manufacturer stops marketing the brand product.

Response: The manufacturer that holds the title to the labeler code and whose NDC appears on the product when a Medicaid prescription is dispensed is responsible for reporting pricing and paying rebates. We have revised this final rule to state that the primary manufacturer will no longer be required to include the sales of authorized generics by the secondary company in the AMP or best price of the brand drug. Each manufacturer will be responsible for determining the AMP or best price for its own products consistent with the methodology described elsewhere in this rule. If the primary manufacturer no longer sells the brand drug and the secondary manufacturer buys an authorized generic version of the drug and changes the NDC, the primary manufacturer is responsible for paying rebates on its drugs still in the supply chain and must supply a termination date equal to the shelf life of the last lot/stock sold under the previous NDC. It must also supply pricing data for four quarters beyond the shelf life of the drug. The secondary manufacturer would be responsible for supplying pricing data starting with the quarter the authorized generic is for sale under its own NDC.

Comment: A few commenters requested clarification regarding whether the secondary manufacturer or licensee should include the combined sales of two separate NDCs in its price reporting data where the licensee is selling both the brand and authorized generic version of the licensed innovator multiple source drug, or should the licensee continue to report data for two separate NDCs as is currently done under existing policy.

Response: If the secondary company markets two drugs that have the same nine-digit NDC numbers, the pricing data with respect to both products should be used in AMP and best price calculations.

Comment: One commenter recommended that CMS redefine the rebate period following the initial launch of an authorized generic by dividing the first quarter in which the authorized generic is launched into two separate rebate periods: (1) One period prior to the launch of the authorized generic; and (2) one period starting at the date of the launch. The commenter indicated that this change would allow the manufacturer to apply an AMP and weighted best price for the first quarter of the authorized generic entry. The commenter also mentioned a second option that would allow manufacturers to report, for the first quarter of the authorized generic entry, an AMP and weighted best price based on the number of days the authorized generic is available in the quarter. Additionally, the commenter suggested a third option, in which the incorporation of the authorized generic would begin with the first full quarter the authorized generic is available. Another commenter recommended that for authorized generic agreements effective during the middle of a quarter, CMS should not begin to apply the blending of AMP data until the following quarter. One commenter recommended that CMS require the brand manufacturer to incorporate authorized generic products into pricing calculations the first full quarter after the authorized generic product is launched. The commenter suggested CMS clarify that authorized generic products will not be taken into account in monthly AMP calculations until the first month of the first full quarter following the launch of the authorized generic.

Response: We are not redefining the rebate period or adjusting the monthly and quarterly reporting requirements as they are currently defined under the law and this regulation. Like other manufacturer programs that start in the middle of a quarter or a month, the appropriate authorized generic sales must be reported for whatever part of the reporting period they occur.

Comment: Several commenters indicated that there are several operational issues that may prevent the primary manufacturer from incorporating authorized generic AMP and best price data from the secondary manufacturer within the required 30-day timeframe. A few commenters stated that it would be infeasible for the primary manufacturer to calculate the AMP and best price for the brand drug within 30 days if the primary manufacturer is unable to rely on the information provided by the secondary manufacturer. In addition, a few commenters stated that the primary manufacturer would not have access to the proprietary data and records of the secondary manufacturer, who may be a competitor, and there may be intersystem incompatibility between the reporting systems of the primary manufacturer and the secondary manufacturer. Another commenter suggested that allowing the primary manufacturer to calculate a weighted AMP and determine the best price based on sales data provided by the secondary manufacturer would allow primary manufacturers to avoid the administrative burden and complexity of incorporating raw sales data of authorized generic products into the pricing calculations of the brand drug. Another commenter recommended that CMS allow the manufacturers to use aggregate data at the 11-digit NDC level (supplied by the secondary manufacturer to the primary manufacturer) to minimize operational and legal issues. Another commenter requested that CMS allow manufacturers flexibility in reporting in order to minimize operational issues.

Response: We have revised this final rule to no longer require the primary manufacturer to include the sales of the secondary manufacturer or subsidiary in the AMP. The primary manufacturer will be required to include in best price its sales to the secondary manufacturer

or subsidiary of the primary manufacturer and the best price shall be the lowest price at which the drug is sold.

Comment: One commenter expressed support for CMS' assertion that the secondary manufacturer would continue to calculate AMP and best price and pay rebates for the authorized generic drug based on its own NDC according to its own utilization of the drug, as is done under current policy.

Response: We appreciate the support this commenter expressed.

Comment: One commenter recommended that CMS clarify that for store brand versions of the brand drug, the primary manufacturer must include in its AMP and best price the sales of such authorized generics to the secondary manufacturer, not sales to consumers by the secondary manufacturer. The commenter indicated that the sales of store brand products to retailers are commercial prices and are not subject to transfer pricing or other similar profit-sharing arrangements. The commenter mentioned that in many cases the primary manufacturer labels the store brand products under the retailer's labeler code, thereby making the retailer a secondary manufacturer of those drugs. The commenter stated that unlike secondary manufacturers of prescription authorized generic products, a secondary manufacturer of an OTC authorized generic sells the authorized generic directly to consumers and typically does not participate in the Medicaid Drug Rebate Program. The commenter stated that the most appropriate sales data to include in the branded product's AMP and best price calculations would be the primary manufacturer's sales transactions with the retailer. The commenter further suggested that in calculating the blended AMP and best price figures for authorized generics sales, the primary manufacturer should incorporate the direct and indirect sales to secondary manufacturers of the store brand authorized generic. The commenter requested that CMS confirm that the primary manufacturer may comply with the authorized generics provisions by including its sales of the authorized generic to the secondary manufacturer when the primary manufacturer calculates the blended AMP and best price figures for the brand product.

Response: The primary manufacturer would be responsible for including prices to the secondary manufacturer, but further sales from the secondary manufacturer to the consumer would not be included.

Exclusion From Best Price of Certain Sales at a Nominal Price (§ 447.508)

Comment: Several commenters did not agree with the statement in the preamble that using the nominal price exception as a marketing tool was not within the spirit and letter of the law and requested CMS to issue further guidance through the formal rulemaking process. Another commenter requested that until such guidance is forthcoming, manufacturers should be permitted to continue to exclude nominal price sales from best price.

Response: CMS does not believe that further guidance is needed on this subject. We believe, in light of the DRA amendments, that the final regulation is clear concerning what sales at nominal price may be excluded from best price.

Comment: Numerous commenters expressed concern that the proposed rule explicitly declined to exercise the Secretary's statutory discretion to identify additional safety net providers that could receive nominal pricing on drugs that would be excluded from best price. They stated that CMS' failure to define a fourth category to include other charitable health care providers is contrary to congressional intent, ill-advised and unfair to providers that are the mainstay of the nation's health care safety net. Many of these commenters suggested that a fourth category of safety net providers include non-profit entities that serve the uninsured and underinsured, regardless of their ability to pay and for whom a majority of their patients have income at less than 200 percent of the Federal Poverty Level (FPL). Many commenters disagreed with the limited entities that qualify to purchase drugs under the proposed nominal price exclusion. These commenters suggested that other safety net providers who offer low-cost oral contraceptive drugs to their low-income, uninsured or underinsured patients should continue to be eligible for nominal pricing exceptions. Commenters requested that nominal pricing exceptions should continue to be extended to such reproductive health care centers, including college and university health centers, which have traditionally purchased contraceptive drugs from manufacturers at nominal prices. Commenters contended that the impact of the rule is significant because it would require the reproductive health care centers to close their doors or to charge the patients who are unable to pay and, therefore, eliminate access to oral contraceptives. These patients would be at risk for unplanned pregnancies and increased reliance on abortion.

Response: The statute allows the Secretary to determine other entities to which sales of drugs at a nominal price would be excluded from best price. However, the statute does not mandate that the Secretary do so. This final rule exercises the Secretary's authority to choose not to expand that list of entities. We believe the entities listed in the statute to be sufficiently inclusive. In addition, commenters indicated that many manufacturers routinely used the nominal price exclusion for other than charitable purposes. Furthermore, manufacturers who have chosen to make drugs available to indigent patients often do so through patient assistance programs, which are excluded from best price (as discussed previously in this rule), and not through nominal pricing.

Comment: One commenter stated that sales of contraceptive drugs at a nominal price are not contingent on market share agreements or the purchase of other products, which were the concerns that prompted Congress to restrict the nominal price exemption. A few commenters stated that nominal pricing predated Medicaid best price and rebates and that keeping family planning providers as entities that can receive nominal prices would not suddenly have an adverse effect on the Medicaid Drug Rebate Program. Another commenter stated that family planning is a cost-effective public health strategy that saves money by preventing other, more costly health problems. In addition, several commenters noted that although family planning clinics that receive funding under Title X of the PHS Act and are funding covered entities under the PHS Drug Pricing Program, their 340B status is not permanent and could be lost due to funding deficits. Other commenters remarked that 340B clinics that rely on subsidies from non-340B clinics within the same organization to finance their operation may not be able to continue to keep their doors open because the non-340B clinics will no longer have access to excess funds when they can no longer purchase contraceptives at nominal prices. Numerous commenters wrote indicating that non-Title X family planning clinics are often the sole source of primary health care for uninsured or underinsured women and provide vital reproductive health care services including birth control drugs and supplies at deeply discounted prices, well-woman exams, screenings for breast and cervical cancer, and treatment for sexually transmitted diseases, diabetes, hypertension, and anemia. Many of these commenters also

noted that the ability of these providers to continue to provide quality health care at low or no cost rests on their ability to purchase contraceptives at nominal price. Other commenters noted that because Title X funding has not increased since 1977, newer clinics have not received Title X funding. Another commenter stated that where two non-profit entities perform the same function for similar populations and one is a 340B covered entity and the other is not, it is reasonable to believe that the Congress intended both to have access to the same discounted pricing structure.

Response: CMS recognizes the important role that family planning clinics play in providing for the basic health care needs of a vulnerable patient population. However, we do not agree that the broad categories of populations served by the clinics suggested by the commenters, which include student health centers, constitute a vulnerable population. It would also be difficult for us to distinguish between agencies; for example, agencies with non-profit status under the Internal Revenue Code that are truly serving a public interest from others that may not be doing so. Such an expansion would be far in excess of the current definition in the 340B Program. Therefore, we do not believe that there is sufficient reason to include these entities in the nominal price exclusion.

Comment: A few commenters noted that Congress established the nominal price exclusion to protect discounts offered to charitable organizations and clinics. One commenter noted that surveys conducted by the Senate Committee on Finance in 2004 and 2005 found that not-for-profit, acute care, teaching and other hospitals appeared to be the primary recipients of nominal prices. This commenter, along with others, urged CMS to define safety net provider as non-profit organizations, comprised of an outpatient clinic or several clinics, which offer health care to patients regardless of their ability to pay, and for whom the majority of their patients have income at less than 200 percent of the FPL.

Response: In its 2004 and 2005 surveys, the Senate Committee on Finance found that while hospitals appeared to be the primary recipients of nominal pricing, most manufacturers' policies did not reflect the use of the nominal price exception for charitable purposes. (This discussion can be found at *http://www.cms.hhs.gov/eRulemaking/ECCMSR/list.asp;* docket ID CMS–2238–P; paper comment number 33.)

Manufacturers did not differentiate between for-profit and non-profit entities when offering nominal pricing, and manufacturers' agreements frequently included market share requirements. Additionally, the surveys found that the use of the nominal price exception has declined since 2003.

Comment: A few commenters noted that their purchase price for a month's supply of oral contraceptives has increased more than tenfold. Other commenters reported that manufacturers are discontinuing nominal prices for oral contraceptives. Numerous commenters expressed concern that prices will increase for these patients, many of whom are on fixed incomes and unable to absorb additional expense to purchase these medications. Another commenter asked if a mechanism will be provided for non-Medicaid patients to continue to receive deeply discounted drugs if existing philanthropic programs no longer qualify for the best price nominal price exclusion.

Response: As previously stated, we believe that there are already programs in place by which manufacturers can continue to make available drugs to the indigent and underinsured without raising best price concerns for drug manufacturers.

Comment: One commenter expressed disappointment that we did not list community health providers that receive funding under Title V of the PHS Act as 340B covered entities because they serve the same populations as family planning clinics. They stated that by this oversight, the government would incur increased costs for maternity care and providing welfare. Additionally, the commenter noted that local health departments were considering no longer providing family planning services, which would have a tremendous impact on underserved populations and that this may pave the way for civil rights action.

Response: CMS does not determine what entities qualify for the 340B Program. In this final rule, as discussed above, we have decided not to expand the entities which can have nominal price sales excluded from best price for purposes of the Medicaid Drug Rebate Program.

Comment: One commenter requested that CMS clarify the scope of the best price exemption specifically to allow the best price exemption for nominally priced drugs to a 340B hospital to extend to drugs purchased for inpatient use and by other components of a large health system of which a 340B participating hospital is a part. Other commenters said that the loss of nominal pricing contracts in the non-340B parts of their hospitals would be devastating to the amount of service they could continue to provide.

Response: Section 1927(c)(1)(C)(i)(I) of the Act exempts inpatient prices charged to 340B hospitals from best price, so we believe that there is no need to address these prices in the context of the nominal price exemption. Section 1927(c)(1)(D)(i)(I) of the Act provides that nominal prices to 340B covered entities are exempt from best price; the statute does not extend the exemption to any part of a broader organization of which the 340B covered entity is a part. The Secretary has not chosen to expand the list of which entities qualify for the nominal price exclusion to include facilities not identified in the statute.

Comment: One commenter noted that a study of manufacturers' policies and practices with respect to nominal price practices indicated that the nominal price exclusion was used primarily as a competitive marketing tool and not used for charitable purposes as intended by Congress.

Response: We appreciate this comment and believe that this was a key factor in the legislation to restrict the types of entities eligible for the nominal price exclusion from best price.

Comment: One commenter requested that CMS provide a list of qualified safety net providers eligible for the best price exemption. Another commenter suggested that CMS maintain a current list of entities that qualify as ICFs/MR or State-owned or operated nursing facilities, similar to the CMS list of qualified SPAPs under Medicare Part D. Yet another commenter requested CMS to develop and publish procedures to be used to identify additional safety net providers. Yet another commenter recommended that safety net providers be required to complete a self-certification process. Another commenter stated that they appreciated the clear guidance given by CMS in delineating the covered entities eligible for the nominal pricing exemption.

Response: The Secretary has chosen not to designate a fourth category of safety net providers; therefore, the argument for a certification process is unnecessary, as is the need to establish and publish procedures for the identification of additional safety net providers. The Health Resources and Services Administration (HRSA) administers the 340B Program and we rely on that agency to identify providers in the 340B Program. Furthermore, ICFs/MR and State-owned or operated nursing facilities fall under State jurisdiction and we expect the State

Medicaid Agencies to identify these for manufacturers.

Comment: A few commenters requested that we add language in the preamble or in the regulation text of the final rule to state that the Secretary intends to retain his discretionary authority to add to the list of safety net provider entities for which sales at nominal prices are excluded from best price should CMS choose not to exercise the authority at this time. Several comments urged CMS not to relinquish the authority to establish nominal price exemptions for additional classes of providers.

Response: In accordance with the reasons stated above, the Secretary has chosen not to exercise his authority at this time. The Secretary retains the authority to propose expansion of this list for any appropriate safety net providers at a future time through the notice and comment process.

Comment: One commenter agreed with the proposed rule directing manufacturers to exclude nominal sales from the AMP calculation stating it would be unfair to allow deeply discounted prices offered only to safety net providers and not available in commercial transactions to put downward pressure on AMPs and depress Medicaid reimbursement to retail pharmacies.

Response: We agree that nominal price sales that are excluded from best price should not be included in AMP and we have retained that provision in the final rule.

Comment: One commenter asked whether the AMP used in determining a nominal price for purposes of the best price exclusion should be the combined AMP for the brand manufacturer who also has sold or licensed an authorized generic.

Response: Brand manufacturers who also have sold or licensed rights to an authorized generic should compute the AMP for the brand drugs according to the requirement in § 447.506.

Comment: A few commenters believed that nominally priced products should be excluded from best price calculations because those prices are not representative of the acquisition costs available to retail pharmacies. Several commenters stated that nominal prices are not available to the retail pharmacy class of trade and should therefore be excluded from any calculations.

Response: CMS concurs with the commenter that nominal priced sales to certain specified entities such as 340B entities, ICFs/MR and State-owned or operated nursing facilities are to be excluded from best price calculations. For purposes of this exclusion, nominal price is defined as less than ten percent of AMP in the same quarter for which the AMP is computed.

Requirements for Manufacturers (§ 447.510)

Electronic Data Submission

Comment: A few commenters expressed support for CMS' proposal to require manufacturers to submit all product and pricing data in an electronic format.

Response: We appreciate the support for this provision and have retained this requirement in the final rule.

Data Reported to CMS

Comment: One commenter asked CMS to revise the regulation text at § 447.510(a) to clarify that manufacturers are responsible to ensure that they report to CMS only those products/NDCs that are truly covered outpatient drugs. The commenter also asked CMS to coordinate with the FDA or other Federal agencies to ensure that the products manufacturers report to CMS actually are covered outpatient drugs. Finally, if any products are subsequently determined to not be covered outpatient drugs, the commenter asked that CMS clarify that States are not to be held accountable for any expenditures or rebates collected for the products in the interim.

Response: CMS already coordinates with the FDA to ensure that drugs covered by the Medicaid Program meet the statutory definition of covered outpatient drugs.

Comment: A few commenters expressed support for our position that AMP should be reported on a monthly basis and AMP, best price, and customary prompt pay discounts should be reported on a quarterly basis. Another commenter urged us to eliminate the monthly AMP reporting requirement.

Response: We continue to believe that in accordance with the DRA, AMP should be reported monthly, while AMP, best price, and customary prompt pay discounts should be reported quarterly.

Comment: Several commenters suggested that AMP must be reported weekly in order to accurately realize market costs and reimburse retail pharmacy accordingly. One commenter noted that the monthly reporting system would be inadequate and unfair, if not illegal. Some commenters noted that pricing changes daily; therefore, monthly reporting will cause too long of a delay in updated AMP prices. Another commenter noted that with manufacturers supplying CMS the pricing data 30 days after the month closes, the published pricing data will be at least 60 days behind the marketplace pricing. One commenter asked CMS to revise the AMP reporting period to a timeframe that is available in the private sector.

Response: The DRA requires manufacturers to report AMP monthly to CMS. While we acknowledge that prices change in the marketplace more frequently than monthly, we are implementing the monthly AMP reporting requirement in this final rule. We note that States are not required to base their Medicaid pharmacy reimbursement on AMP. AMP will be one of many prices that States can look at when setting their pharmacy reimbursement rates. Furthermore, we note that the FULs will be calculated based on 250 percent of the AMP, in accordance with the statute, which should allow for some market fluctuations.

Comment: A few commenters noted that the lag time between the timeframe covered by monthly AMP and when the AMPs are available may result in inaccurate AMPs due to the reporting delay. The commenters urged CMS to address this timing issue directly and in detail before we encourage States and others to use it as a reimbursement benchmark. One way to do this would be to compare AMPs to WACs, and only publish those AMPs that approximate the WAC for a brand name drug. Another commenter suggested that CMS issue new FULs within seven to ten days of receiving monthly AMP data.

Response: We share the commenters' interest in making sure that AMPs reported to CMS and released to the public are as accurate as possible. Also, we note that States have been notified of the limitations of the AMP data. We appreciate such concerns and have decided to establish a timeframe sufficient for initial implementation of the new FUL prices. CMS has posted a timeline for implementation of the FUL on its Web site (*http://www.cms.hhs.gov/DeficitReductionAct/Downloads/AMPFULTentativeTimeline.pdf*).

Comment: A few commenters noted that the record layout for the quarterly pricing report that CMS issued in December 2006 did not include a field for customary prompt pay discounts. The commenters asked for clarification as to how customary prompt pay discounts should be reported.

Response: We will issue a revised record layout to manufacturers to include customary prompt pay discounts in accordance with this final rule.

Comment: A few commenters asked for operational guidance on reporting customary prompt pay discounts to CMS. Specifically, should manufacturers recognize discounts given at the time of sale of the product to the customer? Also, should manufacturers report customary prompt pay discounts at the 9-digit NDC, 11-digit NDC, or at the labeler code level? Should the information be provided in whole dollars, units, or by percentage? Would reporting an accrued amount by NDC suffice? One commenter noted that the statement in the proposed rule, that these discounts should be reported at an aggregate level, including discounts paid to all purchasers in the rebate period is too vague to know what level of detail is required. The commenter asked CMS to include additional specification in this final rule.

Other commenters noted that it is difficult for a manufacturer to quantify the discounts taken by a purchaser, or deducted from payments made during the rebate period, as doing so requires the manufacturer to reconcile the deductions relating to customary prompt pay discounts and deductions taken for other reasons, such as shortages in the amount of product shipped. Even if the manufacturer could quantify such deductions, that amount would relate to the invoices paid rather than the sales made in the rebate period. In contrast, the commenters believed that manufacturers can readily quantify the customary prompt pay discounts offered during a rebate period, and ask that CMS clarify the reporting requirement accordingly.

Response: We want this reporting requirement to be as simple as possible. Therefore, manufacturers may report customary prompt pay discounts offered during a rebate period aggregated with respect to all purchasers. All of the pricing information reported to CMS, including customary prompt pay discounts, should be reported at the nine-digit NDC level. We also clarified in § 447.510(a)(3) that manufacturers should report customary prompt pay discounts provided to all wholesalers in the rebate period. We will clarify this requirement further when we issue a revised record layout after publication of this final rule.

Comment: One commenter asked for guidance on whether manufacturers should combine customary prompt pay discounts for authorized generics with customary prompt pay discounts for the brand name drug. Similarly, should nominal prices for authorized generics be combined with nominal prices for brand name drugs? The commenter believed there is no purpose to report a combined figure for these values.

Response: We agree with the commenter. A primary manufacturer should not include customary prompt pay discounts or nominal prices for authorized generic drugs marketed by another manufacturer when reporting these data to CMS.

Comment: One commenter asked for clarification about what format will be used to report nominal sales. Another commenter asked for clarification as to whether nominal price reporting should be at the gross or net level, with a preference for reporting at the net level. The commenter also asked CMS to provide an example of how nominal price data should be reported.

Response: In the proposed rule, we stated that nominal prices shall be reported as an aggregate dollar amount and shall include all sales to the entities listed in § 447.508(a) of this subpart. The dollar value of all sales should be aggregated for each drug at the 9-digit NDC level. We will issue further instructions and a revised record layout to clarify the format manufacturers should use to report nominal prices after the publication of this final rule.

Comment: One commenter asked CMS to clarify that quarterly AMP submissions should be based on quarterly sales, not the aggregate or average of the three monthly AMPs submitted during the same quarterly period. Other commenters urged CMS to allow manufacturers to calculate their quarterly AMPs based on the weighted average of monthly AMPs in the quarter and to clarify that manufacturers that select this option would not be required to restate their quarterly AMP, other than to correct an error. The commenters believed this approach would minimize discrepancies between monthly and quarterly AMP and would be administratively simple for manufacturers and CMS to administer.

Response: We concur with the commenters who suggested we define quarterly AMP as the weighted average of monthly AMPs. Accordingly, we have revised the regulation text at § 447.504(i)(2) to require manufacturers to calculate quarterly AMP as the weighted average of monthly AMPs in the quarter. We agree that this approach will minimize discrepancies between monthly and quarterly AMPs. However, because we do not agree that this will eliminate the need for manufacturers to correct their quarterly AMPs, we have retained in the final rule the requirement that manufacturers report revisions to quarterly AMPs for up to 12 quarters from the quarter in which the data were due. Furthermore, manufacturers should restate their quarterly AMPs if there are subsequent restatements of the monthly AMPs on which the quarterly AMPs are based.

In addition, we are revising the regulation text at § 447.510(d)(2) to clarify that monthly AMP should be calculated as the weighted average of prices for all the manufacturer's package sizes for each covered outpatient drug sold by the manufacturer during a month. It is calculated as net sales divided by number of units sold, excluding goods or any other items given away unless contingent on any purchase requirements.

Comment: One commenter expressed concern with the provision in the regulation that allows manufacturers to revise their quarterly AMPs for up to twelve quarters from the quarter in which the data were due. The commenter recommended that CMS address the ability of a payer to recoup erroneous payments or the ability of a provider to claim shortages based on incorrect AMPs in this final rule.

Response: We intend to use monthly AMPs in the calculation of the FULs. Although manufacturers will be allowed to restate their monthly AMPs, we do not anticipate that there will be any retroactive adjustments to the FULs because we will calculate the FULs based on the current monthly AMPs and we do not intend to recalculate the FULs if the monthly AMPs are subsequently revised by manufacturers.

However, we note that States may need to revise payments to the extent they base their reimbursement methodologies on AMPs that are subsequently revised by manufacturers.

Comment: One commenter asked for guidance on monthly reporting of AMP when a product is discontinued. Another commenter asked CMS to clarify that a manufacturer's reporting obligation for monthly AMP ceases with the product's termination date, beginning with the first monthly report after the expiration date of the last lot sold. Also, States should not be able to set reimbursement rates based on expired AMPs as they do not reflect the acquisition price of a product that is currently available for purchase by the retail pharmacy class of trade.

Response: Manufacturers should continue to report monthly AMP for twelve months past the product's termination date. The purpose of reporting a terminated product is that a product may be billed by the pharmacy for up to a year past the date the drug was dispensed. We have clarified this requirement in the final rule at § 447.510(d)(5).

In regard to the issue of State payment rates, we will continue to review SPAs to ensure that payment complies with section 1902(a)(30) of the Act.

Comment: A few commenters suggested that CMS implement a process that would trigger an alert if there is a severe shift in AMP from one reporting period to another. The commenters suggested that the OIG be alerted of all AMP price shifts and the OIG would research and then recommend an updated AMP figure to CMS. Such a trigger mechanism would limit the effects of price posting lag, mitigate potential market manipulation, mitigate a possible disincentive to fill generics by the retail pharmacies, limit incorrect public data, and provide CMS with the most up-to-date calculation of AMP. One commenter noted that there is even greater concern regarding the heightened risks of error and inconsistency among manufacturers because AMP is potentially a reimbursement metric that will be calculated and reported on a monthly basis. Other commenters urged CMS to implement systems checks and measures to hold manufacturers accountable for the quality of the data they provide, including reporting or not reporting accurate data. The commenters requested that CMS include representation from State Medicaid Agencies in developing this system of checks and accountability measures.

One commenter suggested that CMS compare the NDCs reported by manufacturers with the NDCs listed on databases maintained by First DataBank and Medispan in order to help assure that all NDCs and their AMPs are reported to CMS.

Response: We are not implementing a trigger mechanism at this time; we will use the monthly AMPs that are submitted by manufacturers to calculate the FULs, and we will post the monthly and quarterly AMPs on our Web site. In regard to the NDCs reported by manufacturers, we will address these ongoing operational issues at a later time.

Comment: One commenter suggested that CMS allow First DataBank, the pricing source used by most States, to have access to the AMP data electronically. This would centralize administrative tasks and allow efficient and cost-effective integration of AMPs into State data warehouses. The commenter also suggested that the AMP files include specific data elements to streamline importing AMPs into State databases. Those data elements are the 11-digit NDC, brand name, strength, dose form, metric billing unit (for example, each, milliliter, or gram), termination date, metric unit AMP, AMP begin date, AMP end date, and file reporting date.

Response: The monthly and quarterly AMPs will be on our Web site, so we do not see a need to provide them separately to First DataBank. In regard to the specific data elements, we expect to address these concerns in operational guidance after this final rule is published.

Comment: A few commenters noted that CMS' Drug Data Reporting System (DDR) requires that the employee posting submissions to provide his or her Social Security number (SSN). The commenters recommended that access to the DDR be revised to include the corporation's tax ID number (TIN) or SSN associated with the corporation instead of the individual's SSN. One of the commenters urged CMS to destroy records of employee SSNs once a company has been enrolled under its TIN and notify the technical contacts of the destruction.

Response: This issue is not addressed in the proposed rule; therefore, we cannot consider this comment as we consider revisions to be included in the final rule. We intend to address this issue in the future in guidance or regulations, as appropriate.

Comment: One commenter suggested that CMS revise the DDR system to allow manufacturers to submit a text document along with their AMP and best price reports.

Response: We are not revising the DDR system to permit manufacturers to submit a text document at this time. The DDR system was specifically designed to streamline the collection of product and pricing data from manufacturers. We believe that any alterations to the system at this time may hamper its functionality. Manufacturers that wish to submit documentation regarding their AMP and best price reports may do so outside the DDR system.

Comment: One commenter asked for guidance on how manufacturers may report pricing corrections on the record layout.

Response: We will clarify how manufacturers should report pricing corrections in future operational instructions.

Comment: A few commenters asked for guidance on how to handle zero or negative monthly AMPs. The commenters noted that for quarterly reports, CMS has instructed manufacturers to use the last quarter's positive value when the current quarter is a zero or negative value.

Response: Manufacturers should report the most recent positive AMP value. This is consistent with our past policy and we believe it best represents the AMP for each drug. This will assure that manufacturers pay a rebate and will prevent offsets due to a negative AMP.

Comment: A few commenters asked whether product reports must be filed monthly.

Response: As set forth in the national rebate agreement, initial product information must be submitted within 30 days after the first month in which the drug is marketed in order for the program to identify the relevant drug products covered by the program. Initial product data must be submitted once before any prices can be reported.

Comment: One commenter suggested that we require manufacturers to report AMP and best price information using NCPDP standard units, and that CMS report the FUL using the same.

Response: NCPDP standard units are based on package pricing. The AMP and best price information that manufacturers report is based on unit pricing, without regard to package size; therefore, we do not see a basis for using the NCPDP units given the Medicaid statute reporting requirements.

Monthly AMP

Comment: Several commenters focused on the issue of revising monthly AMPs. A few commenters agreed with the position we stated in the proposed rule, that manufacturers should not be permitted to revise their monthly AMPs. Otherwise, the commenters noted that the revised monthly AMPs could be used as a basis for reducing reimbursements already paid for the drugs. Another commenter urged CMS to allow manufacturers to revise their monthly AMPs for up to twelve quarters after initially submitted, as is currently allowed for quarterly AMP data. One commenter noted that a prohibition on restatements of monthly AMPs could have financial consequences for manufacturers, pharmacies, physicians and outpatient hospital departments.

Other commenters expressed concern with allowing manufacturers to revise their monthly AMPs for up to 30 days after each month. The commenters urged CMS to enforce the prohibition against adjusting monthly AMP beyond the 30-day period.

Response: After consideration of these comments, we have decided to allow manufacturers to revise their monthly AMPs for a period not to exceed 36 months from the month in which the data were due and have revised the regulation at § 447.510(d)(3). We reached this decision in part because we want to minimize the disparities between monthly and quarterly AMPs. If a manufacturer discovers an error one

year after the AMP is reported, we want the correction to be reflected in the monthly and quarterly AMPs.

We also recognize that because we are using monthly AMP in the calculation of the FULs, it would be impractical and burdensome for States and pharmacies if we revised the FULs based on revised monthly AMPs for up to three years. Furthermore, we note in § 447.510(d)(2) that manufacturers are required to submit monthly AMPs based on the best data available and to certify the accuracy of those submissions. As a result, we do not expect that we will need to revise the FULs. We will consider revisiting this issue if monthly AMP submissions become problematic.

Comment: One commenter noted that in our December 15, 2006 guidance to manufacturers, CMS stated that ''adjustments, such as those resulting from sales data, received after the reporting period ends, should be reflected in the next monthly AMP submission.'' The commenter noted that the addition of data attributable to a previous month's transactions into a later month's AMP could artificially inflate or deflate the later month's AMP.

Response: Our intent in the December 2006 release was to advise manufacturers that they should submit a revised monthly AMP in the next monthly AMP submission if they receive sales data after the reporting period ends. In this final rule, as noted above, we are permitting manufacturers to make revisions to monthly AMP for up to 36 months after the month in which the data were due. Therefore, data attributable to a previous month's transactions should not result in the artificial inflation or deflation of a later month's AMP. We further believe this concern will be addressed by requiring manufacturers to estimate their lagged price concessions, as discussed in detail below.

Comment: One commenter asked whether it is acceptable for manufacturers to run monthly reports of sales and discounts to be included in the AMP calculations based on the ''post'' date of chargebacks, which indicates when a chargeback has been ''paid.''

Response: We will continue to allow manufacturers the flexibility to count chargebacks based on their GAAPs, provided they use one methodology uniformly.

Comment: One commenter asked what procedure CMS will put in place if a manufacturer believes the monthly AMP on CMS' Web site is incorrect.

Response: We will establish a procedure to address this and will issue operational guidance after publication of this final rule.

Comment: One commenter suggested that CMS address the requirements for monthly AMPs under Determination of AMP, § 447.504, rather than addressing monthly AMP under Requirements for Manufacturers, § 447.510.

Response: We appreciate this comment but have decided to address the requirements for monthly AMP under § 447.510.

Comment: One commenter recommended that we include the 11-digit NDC on the monthly AMP file that we distribute to States.

Response: The 11-digit NDC will be included on the monthly file distributed to States.

Comment: One commenter asked CMS to consider defining monthly and quarterly AMPs differently. Another commenter agreed with CMS' proposal that monthly AMP be defined the same as quarterly AMP, except the monthly AMP would represent data for one calendar month.

Response: For reasons noted in the preamble to the proposed rule, we continue to believe that monthly and quarterly AMPs should be defined the same.

Lagged Price Concessions

In the proposed rule, we proposed allowing manufacturers to rely on estimates regarding the impact of their end-of-quarter rebates or other price concessions for purposes of calculating monthly AMP. We suggested a 12-month rolling average of all lagged price concessions for purposes of calculating monthly and quarterly AMPs and requested comments on the appropriate methodology for calculating monthly AMP.

Comment: Many commenters favored allowing manufacturers the flexibility to estimate lagged price concessions for monthly and quarterly AMPs. Many of these commenters expressed a preference for using a 12-month rolling average. Several commenters pointed out that a 12-month smoothing methodology for AMP would mirror the smoothing methodology CMS established for ASP; therefore, it would be easier for manufacturers to implement, would reduce the risk of errors, and would minimize the volatility in the data. One commenter noted that a 12-month rolling average is an auditable approach, but there are other, more credible approaches that would result in potentially more accurate AMPs (but the commenter did not elaborate on what those approaches are). Another commenter urged CMS to mandate that all manufacturers use a rolling 12-month average for reporting monthly AMP, but require actual discounts to be used in reporting the quarterly best price. Some commenters suggested manufacturers should be allowed to employ a variety of smoothing methodologies to calculate accurate quarterly and monthly AMPs, while one suggested that manufacturers be allowed to choose a preferred method, provided that the method is used consistently. One commenter asked that manufacturers be given the option to estimate lagged price concessions for quarterly AMP through a smoothing methodology or an estimation method based on accruals and sales experience. One commenter asked us to clarify that manufacturers can estimate all lagged rebates or concessions regardless of whether they are quarterly or on a different period. Other commenters asked us to specify whether manufacturers should calculate the 12-month rolling average using the date the rebate is earned versus the date the rebate is paid.

Commenters suggested a modification of the 12-month rolling percentage methodology. They suggested requiring manufacturers to look to the four full calendar quarters before the reporting period to calculate the rolling 12-month percentage, which could then be applied to all three monthly AMPs and the quarterly AMP. As an alternative, chargebacks and rebates could be singled out for lagged treatment on a routine basis. In addition, the commenters urged CMS to provide examples showing how the methodology should be applied in both the monthly and the quarterly context, taking into account the proper treatment of the various types of bundled sales.

Other commenters recommended that manufacturers be permitted to use a four-quarter rolling average of rebates to sales, and apply that percentage to monthly sales. The commenters believe that using a four-quarter rolling average for smoothing is more operationally feasible than a 12-month rolling average because rebates and other price concessions are typically invoiced by customers and paid by the manufacturer on a quarterly basis. The commenters also asked that CMS allow manufacturers to estimate excluded sales for the month using a four-quarter rolling average based on gross sales units divided by excludable AMP units.

One commenter noted that end-of-year rebates or chargebacks should be excluded from the AMP calculation in order to avoid significant 12 to 18-month revisions to AMP data. Such revisions would render AMP data unusable for reimbursement purposes.

An alternative would be to require manufacturers to estimate their end-of-year settlements at minimum discount levels.

Response: We have decided to require manufacturers to use a 12-month rolling average to estimate the value of lagged price concessions in their calculation of monthly and quarterly AMPs and have added this requirement to the regulation at § 447.510(d)(2). We believe this methodology will ensure the greatest stability and accuracy for AMP data.

Comment: One commenter noted that if CMS changes its position with regard to the treatment of Medicaid units and rebates to Federal programs such as Medicare Part D, that CMS should consider allowing discretionary smoothing of those units and removal of a corresponding value from gross sales dollars.

Response: We are not changing our position with regard to the treatment of Medicaid units and rebates to Federal programs such as Medicare Part D.

Comment: One commenter asked CMS to clarify what we consider to be ''lagged price concessions.'' Another commenter urged us to only allow manufacturers to estimate the value of price concessions between manufacturers and true wholesalers.

Response: We consider lagged price concessions to be any discounts or rebates that are realized after the sale of the drug, except for customary prompt pay discounts. Lagged price concessions are not limited to discounts or rebates offered to wholesalers. Accordingly, we have added a definition of lagged price concessions to the regulation text at § 447.502.

Comment: A few commenters asked CMS to clarify whether the current month should be included in the 12-month rolling average.

Response: Manufacturers should include the current month in calculating the 12-month rolling average they use to determine the value of lagged price concessions.

Comment: One commenter asked that manufacturers who estimate lagged price concessions be exempt from the requirement to report revised quarterly AMPs in § 447.510(b).

Response: The purpose of requiring manufacturers to report revised quarterly AMPs in § 447.510(b) is to ensure the Medicaid rebate amounts are as accurate as possible. In this final rule, we are requiring manufacturers to estimate the value of lagged price concessions using a 12-month rolling average; however, we do not expect this requirement will eliminate the need for manufacturers to correct their quarterly AMP calculations for other reasons, such as errors in the initial AMP calculation. Therefore, we are not creating a broad exemption from this requirement. Instead, we have clarified in this final rule at § 447.510(b)(2) that manufacturers should report revised AMPs except when the revision would be solely as a result of data pertaining to lagged price concessions.

Comment: One commenter asked that smoothing not be required for the first partial year of sales for new products because the base date AMP can be skewed by non-recurring post-launch start-up payments.

Response: We disagree with the commenter's suggestion about estimating lagged price concessions during the first partial year of sales for new products. We believe such an exception would run counter to the intent of the DRA, which is to provide for increased transparency in AMP pricing.

Comment: One commenter expressed concern that in light of the increasing vertical integration of the pharmacy market, manufacturers could use the monthly and quarterly ''dual reporting'' timeframes to manipulate AMP, thereby manipulating the market. This concern stems from the ability of manufacturers to restate their quarterly AMPs for twelve quarters from the quarter in which the data were due, as well as the ability of manufacturers to estimate their end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period. The commenter was also concerned that this situation could lead to a loss of price transparency.

Response: We disagree with the commenter that the possibility exists for a lack of price transparency. Beginning with the data for January 2007, we interpret the law to provide for posting of monthly and quarterly AMPs on our Web site, which allows full transparency for monthly and quarterly AMPs. The intent behind the decision to require manufacturers to estimate their end-of-quarter discounts was to minimize volatility in the monthly AMP data, which is used to set the FUL and which States may consider in setting their pharmacy reimbursement rates. Without this requirement, we anticipate there would be significant volatility in the data from month to month, thereby eroding its usefulness.

The provision requiring manufacturers to restate their quarterly AMPs for a period not to exceed twelve quarters from when the data were due became effective on October 1, 2003. Prior to that time, the national rebate agreement did not provide a specific period for recalculations. As noted in the final rule with comment period published on August 29, 2003 (68 FR 51912) we believe this provision helps streamline the administration of the Medicaid Drug Rebate Program.

Pricing Lag

Comment: A few commenters expressed concern with the lag time between when manufacturers calculate and report their monthly AMPs to CMS and when those AMPs are made public. They noted that the process could result in data being up to 90 days old and asked CMS to provide guidance to States and other users of AMP on the proper method to address any issues resulting from this lag time. One commenter noted that this problem highlights the challenges CMS faces in implementing AMP's new dual purpose of serving as a measure for quarterly Medicaid rebates and potentially as a reimbursement benchmark. Another commenter speculated that the lag time would likely result in brand name drug prices being higher than AMP, with the result that pharmacies will be underpaid if they are reimbursed based on AMP.

Response: While we will make every reasonable effort to publish this data as soon as possible after we receive it, we are aware that the monthly AMP data we make available to the public will likely be 45–60 days old, given the timeframes in the reporting requirements. While we will make these limitations known to the States and other parties, it will generally be up to them to determine how to best use this data.

Base Date AMP

Comment: Many commenters expressed support for allowing, but not requiring manufacturers to recalculate their base date AMPs. Noting the difficulty in performing a calculation using data that may be more than ten years old, several of these commenters further suggested that CMS permit manufacturers to estimate their recalculated base date AMPs by relying on reasonable assumptions, extrapolation or other accepted methods of estimation where partial data are available. One commenter suggested that CMS allow manufacturers to use a ratio derived from a comparison to the current AMP and the AMP calculated in accordance with this final rule. Another commenter asked CMS to allow manufacturers to use an alternate methodology to restate base date AMP when the original source data or systems are not available, such as a decrease of two percent. Several commenters urged CMS to clarify that

manufacturers have discretion to recalculate their base date AMPs on a product-by-product basis.

Response: Our intent in permitting manufacturers to report a revised base date AMP is to allow all manufacturers the opportunity to recalculate their base date AMPs in accordance with the definition of AMP in this final rule. We want this requirement to be minimally burdensome to manufacturers. Therefore, we have added a provision to the regulation at § 447.510(c)(2)(ii) to allow manufacturers to choose to recalculate their base date AMPs on a product-by-product basis. As with other pricing calculations, in the absence of specific guidance, manufacturers may make reasonable assumptions consistent with the statute, Federal regulations, and customary business practices. However, because the base date AMPs will be used to determine all future rebate calculations, we are not permitting manufacturers to rely solely on estimates or reasonable assumptions for calculating a revised base data AMP. Manufacturers must use actual data to calculate revised base date AMPs. We have clarified this requirement in the regulation text at § 447.510(c)(iii).

Comment: A few commenters noted that the preamble and regulation text appear to permit recalculation of base date AMP only in accordance with § 447.504(e), the provision defining retail pharmacy class of trade. The commenters asked CMS to clarify that manufacturers are permitted to recalculate base date AMP in light of all of the revisions and clarifications to the definition of AMP.

Response: We have clarified the regulatory text at § 447.510(c)(2)(i) such that a manufacturer's recalculation of the base date AMP should only reflect the revisions to AMP as provided for in § 447.504 of this subpart, rather than the provisions of § 447.504(e) of this subpart.

Comment: A few commenters requested that CMS consider a longer implementation timeframe for resetting base date AMP than two quarters following release of the final rule. One commenter suggested that CMS establish a date certain within which manufacturers must submit revised base date AMPs, but require that all manufacturers who choose to recalculate must refile their AMPs as of the effective date of the final rule. The commenter noted that given the importance of the base date AMP in determining a manufacturer's rebate liability, any recalculation should be undertaken in a manner that allows adequate time for thorough review and analysis. Another commenter specifically recommended that CMS allow manufacturers to restate their base date AMPs during the first four quarters after the publication of this final rule. One commenter suggested that revised base date AMPs can be reported during the third full calendar quarter following the publication of the final rule.

Response: We concur with the commenters about importance of an accurate base date AMP in the calculation of the Medicaid rebate amount. Therefore, in light of the comments we received, we will permit manufacturers to submit a revised base date AMP within the first four calendar quarters following publication of this final rule at § 447.510(c)(1). We expect that this extended timeframe will allow manufacturers to perform the necessary research and analysis regarding the decision to revise their base date AMPs in accordance with the definition of AMP in § 447.504.

Comment: One commenter asked CMS to explain how the revised base date AMP would be used for purposes of calculation of the Medicaid rebate amount.

Response: The revised base date AMP will be incorporated in the formula that CMS uses to calculate the Medicaid rebate on a prospective basis, beginning with the quarter in which the revised base date AMP is submitted. It will not be used to revise the rebate for prior periods.

Comment: Commenters asked CMS to allow manufacturers to restate base date AMPs back to January 1, 2007 to account for the impact caused by the implementation of the customary prompt pay discount and authorized generic provisions of the DRA that became effective on that date.

Response: In this final rule, we are permitting manufacturers to restate their base date AMPs in accordance with all of the clarifications to the determination of AMP. We believe it would be impractical to allow base date AMPs to be restated twice because, in accordance with the effective date of this rule, the restated base date AMPs will be used on a prospective basis. We don't see the administrative practicality of delaying restatements of base date AMP longer than four quarters after this final rule is published.

Comment: A few commenters asked CMS to clarify which quarter's AMP should be submitted for the base date AMP requirement.

Response: Manufacturers should submit the AMP for the same calendar quarter that is currently used as the base date AMP for each of its active NDCs.

Comment: One commenter asked for clarification as to how base date AMP is to be reported. The commenter noted that the record layout CMS issued in December 2006 for the quarterly report does not include a field for base date AMP.

Response: We will issue a revised record layout to manufacturers and will clarify how base date AMP is to be submitted after publication of this final rule.

Certification Requirement

Comment: Commenters noted several difficulties with complying with the requirement that the CEO or the CFO certify the pricing reports submitted to CMS. First, it may be difficult to obtain signatures from senior executives on a routine basis, and they may not be the best individuals to attest to the accuracy of the reporting to CMS. Further, these titles do not fit into the organizational structure of every manufacturer. One commenter suggested that CMS clarify that certification can be done by an individual with authority and accountability equivalent to an individual holding such a title. Another commenter suggested that the certification could be done by an individual who reports indirectly to the CEO or CFO. One commenter suggested that the individual designated as being responsible for reporting of pricing information be the one accountable for certification purposes. Commenters suggested that a quarterly certification could be applied to the quarterly and monthly data submissions; otherwise, the timeliness of the monthly data submissions would be compromised. Another commenter asked CMS to clarify whether an electronic signature or an e-mail will suffice in complying with this requirement.

Response: We recognize that manufacturers anticipate that it will be challenging to obtain signatures from a CEO or CFO on a monthly basis for purposes of complying with the certification requirements. We also recognize that those titles may not apply to the management structure of every company. Therefore, we are revising the regulation at § 447.510(e) to specify that the certification may be made by the CEO, the CFO, or an individual with another title who has authority equivalent to one of those positions. In addition, the certification may be made by an individual with the authority directly delegated to perform the certification on behalf of that individual.

In light of the fact that we are requiring manufacturers to submit data to CMS in an electronic format, we will provide that the certification be made electronically. In addition, the

certification must be made with every data submission to CMS, regardless of whether submission is for monthly data or quarterly data. We will issue further operational guidance on the mechanism manufacturers must use to certify their data after publication of this final rule.

Comment: A few commenters noted that the certification language for AMP should not be identical to the certification language for ASP. The commenters specifically recommended that the certification language for AMP include a knowledge qualifier until the AMP calculation standards are no longer in a state of flux. One commenter suggested that the certification language should be expressly qualified and should read as follows, ''To the best of my knowledge and belief, the reported average manufacturer prices and best prices were calculated accurately and all information and statements made in this submission are true, complete, and current.'' Another commenter asked CMS to clarify the certification requirements.

Response: We appreciate the commenters' suggestions regarding the certification language. As noted above, we will issue further guidance or regulation, as may be necessary, on the certification requirements after publication of this final rule.

Comment: One commenter noted serious reservations regarding the certification of data from other manufacturers or data submitted based on the company's best estimates regarding price concessions that may be redeemed in any given month. The commenter also asked for further elaboration as to how the certification requirements would be enforced.

Response: As of the effective date of this rule, we will not accept data from a manufacturer unless the certification requirement has been met. As discussed above, we are not requiring brand manufacturers to report sales by generic manufacturers for authorized generic drugs. We believe this decision will alleviate concerns regarding certification of data from other manufacturers.

Recordkeeping

Comment: One commenter asked CMS to clarify what customary prompt pay information is needed for retention under the recordkeeping requirements.

Response: These recordkeeping requirements are the same as for the rest of the manufacturer's data for computing the amount of the Medicaid drug rebate. As we noted in the proposed regulations text at § 447.510(f)(1), a manufacturer must retain the customary prompt pay data and any other materials from which the customary prompt pay information is derived, including a record of any assumptions made in the calculations.

Comment: One commenter suggested that CMS reduce the recordkeeping timeframe from ten years to seven years.

Response: CMS finalized the ten-year recordkeeping requirement for manufacturers in a final rule published on November 26, 2004 (69 FR 68815). In that rule, we provided a thorough rationale for requiring manufacturers to retain their pricing data for a period of ten years. We have not received information to support a lesser period; therefore, we are retaining the ten-year recordkeeping requirement at § 447.510(f).

Recalculations

Comment: One commenter asked CMS to specify whether manufacturers need to obtain CMS' approval of methodology changes where those changes are being made to comply with provisions of this final rule. Other commenters asked CMS to describe in this final rule the circumstances in which we would either expect or permit manufacturers to recalculate their AMPs. In particular, one commenter asked for guidance regarding whether, in light of the need to maximize stability in reimbursement metrics, restatements remain an appropriate means for correcting subsequently discovered AMP calculation errors. Another commenter suggested that the timeframe for restatements be shortened from twelve quarters to four quarters. One commenter asked CMS to permit, but not require manufacturers to restate their quarterly AMPs when actual data become available.

Response: Manufacturers do not need to obtain CMS' approval of methodology changes where those changes are being made to comply with provisions of this final rule. In regard to all other AMP restatements, manufacturers should submit their written requests to CMS and wait for CMS' response before submitting revised AMPs for retrospective restatements. For prospective restatements, manufacturers should submit their written requests to CMS, but they are not required to wait for CMS' approval to submit revised AMPs. We note that requirements regarding timeframes for recalculations at §§ 447.510(b) and (d)(3) apply to all restatements. Manufacturers should restate their quarterly AMPs if there are subsequent restatements of the monthly AMPs on which the quarterly AMPs are based.

We disagree with the suggestion that the timeframe for restatements be shortened from twelve quarters to four quarters. Quarterly data can be revised for up to twelve quarters after the quarter in which the data were due. Similarly, monthly AMP can be revised for up to 36 months after the month in which the data were due.

Drugs: Aggregate Upper Limits of Payment (§ 447.512)

Comment: One commenter asked that CMS clarify proposed § 447.512 to allow a physician to certify through electronic means that a brand is medically necessary. Another commenter stated that CMS should reconsider the requirement that a physician must certify in his or her own handwriting that a drug is medically necessary in order to indicate that a specific brand drug is to be dispensed to a patient, as this is inconsistent with State and Federal efforts to transition to e-prescribing and other health information technology innovations.

Response: We appreciate these comments and have revised the final regulation at § 447.512(c)(1) to permit certification by an electronic alternative approved by the Secretary. CMS intends to address electronic certification in future program guidance or regulations, as appropriate.

Upper Limits for Multiple Source Drugs (§ 447.514)

Comment: Several commenters support the agency's goal of paying appropriately for generic drugs. One commenter raised concerns regarding the pre-DRA FUL system including infrequent adjustments to the FULs, which did not necessarily reflect market trends.

Response: We agree. Numerous OIG reports found that the published prices used to set FUL amounts often greatly exceeded prices available in the marketplace. As noted in those reports, the pre-DRA FUL amounts often greatly exceeded pharmacy acquisition costs, and thus, could have unnecessarily increased costs to the State and Federal Governments.

Implementation of FULs

Comment: Another commenter stated that CMS should suspend implementation of the FULs until States are able to adopt the changes necessary to ensure that pharmacies are properly compensated for providing generic drugs; that is, until States have evaluated their dispensing fees.

Response: We disagree. The DRA changed the formula used to establish the FUL. Effective January 1, 2007, the DRA required CMS to calculate the FUL at 250 percent of the AMP (computed

without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent drug. The States have been advised that they should evaluate the reasonableness of their dispensing fees in light of the changes in payment methodology for multiple source drugs under the DRA.

Comment: One commenter proposed that the effective date of the new FUL should be 90 days after release of the new source file to provide time for CMS to issue guidance to States regarding the source of the revised FULs, including the file parameters, in order to allow advance programming to take place. Another commenter said that at least a 60-day timeframe should be allowed for the implementation of FULs.

Response: We appreciate such concerns and have decided to establish a timeframe sufficient for initial implementation of the new FUL prices. CMS has posted a timeline for implementation of the FUL on its Web site (*http://www.cms.hhs.gov/DeficitReductionAct/Downloads/AMPFULTentativeTimeline.pdf*).

Comment: One commenter requested CMS to release its best estimate of FULs based on AMPs in order to analyze their impact. One commenter also requested an extension of the formal comment period to the proposed rule to analyze the data.

Response: We appreciate the comment. CMS has stated that the new FULs would not be issued until the AMPs for 2007, which reflect the exclusion of customary prompt pay discounts and authorized generic drugs, are available and processed. CMS is required by the DRA to publish a regulation by July 1, 2007. Given this deadline, we do not feel that an extension or complete reopening of the formal comment period is appropriate.

Comment: One commenter stated that the FULs published data should be in a format that allows importing data into Excel. One commenter also stated that all unique and identifiable data elements should be included on the file; that is, name, strength, dosage, billing unit, FUL implementation date, NDC, and AMP file reporting date used to establish the FUL.

Response: CMS will publicly post the FUL data in a format similar to the current Web site posting of FUL reimbursement prices. We expect that further specifications will be provided in future program instructions.

Comment: One commenter stated that the final rule should state our schedule of FULs updates.

Response: CMS expects to publish the updated FULs reimbursement prices on a monthly basis consistent with our understanding of congressional intent to keep FUL reimbursement in line with market pricing trends.

Comment: One commenter stated that the FUL data on the CMS website should indicate the effective date. Another commenter stated that the identity of the manufacturer whose product is used to set the FUL should be made public to provide a checks-and-balance system whereby the pharmacy community could supply feedback on the availability of the drug product.

Response: CMS expects to publish the AMP data when it finds them sufficiently complete and accurate. The AMP data will have corresponding NDCs; thus, specific drug product prices, as well as the manufacturer, will be available to the public and transparent. CMS expects that the FULs will be established monthly for all groups and will be in effect until the next monthly update.

Comment: A commenter questioned whether CMS will calculate and disseminate the FUL list, or if the individual States will be responsible for calculating the FUL based on the published AMP data. The commenter proposes that CMS post the FUL.

Response: We agree. We will calculate the FUL based on the criteria established in the final rule, and post the FULs on our website.

Comment: One commenter expressed concern that it will be difficult for CMS to establish an accurate FUL if all AMPs are not submitted monthly on a timely basis by manufacturers.

Response: Manufacturers are required to submit monthly AMP data to CMS not later than 30 days after the last day of the month. Manufacturers must comply with this reporting requirement to continue participation in the Medicaid Drug Rebate Program and avoid potential penalties, as set forth in section 1927(b)(3)(C) of the Act. CMS will monitor compliance rates from manufacturers and initiate action or make referrals to the OIG, as may be necessary, for non-compliance of data submission.

Comment: One commenter expressed concern that updating the FUL on a monthly basis could increase administrative burden on States and make planning of inventory levels for pharmacies difficult.

Response: Timely updating of FULs is necessary in order that States and the Federal Government receive the cost savings benefits of market changes. This regulation encourages pharmacy providers to buy the lowest priced generic available in the market, as may be appropriate, to ensure to bill for drugs at or below the FUL price.

Comment: Another commenter supported the provision in law that CMS determine whether a drug product should have a FUL within seven days after receiving notification from the RPS contractor to assure the FULs are updated in a timely manner.

Response: We agree. CMS is required to determine if a drug is eligible for a FUL within seven days of notification by the RPS contractor. CMS intends to make additions to the FUL list in a timely manner to achieve cost savings for States and the Federal Government.

Comment: Several commenters stated that additions or changes to the FUL should be disseminated to the larger pharmacy community for their input on availability and pricing before releasing as final.

Response: We disagree. The 250 percent markup of the lowest priced drug with respect to the FUL calculation, and our outlier policy which assures that two drugs are available at or below the FUL price should assure the availability of those drugs at or below the FUL price for the pharmacists.

Comment: Several commenters stated that CMS should provide a timely appeals mechanism, to allow providers and States an opportunity to seek removal or modification of a FUL which is not consistent with changing market conditions. One commenter said that severe price shifts and significant issues associated with pricing lags could be effectively addressed by a redetermination process similar to the exceptions and appeals process under Medicare Part D, including a toll-free number which would be monitored by CMS. The commenter further suggested that the OIG or other Federal agency could review appeals and recommend an updated AMP figure to CMS. Another commenter stated that changes to the FUL list should be allowed on a State-by-State basis to reflect availability. One commenter stated that CMS should be vigilant in monitoring the marketplace for signs of negative effects of using AMP as a basis for FULs, and be prepared to alert Congress of the negative effects and recommend any changes to ameliorate them.

Response: We believe that basing reimbursement on actual sales data such as AMP will help capture transparent pricing data to assure that the Federal Government and State Medicaid programs are paying appropriately for generic drugs. We do not agree that an appeal or redetermination process is necessary or would be useful because AMPs will be updated on a monthly basis to reflect changes in prices. We also note that the 250 percent markup

of the lowest priced NDC used to compute the FUL, and the outlier policy established in this regulation, will help to ensure that two or more drugs can be purchased at or below the FUL. To address the need for a State variation in the FUL, we note that States may pay above the FUL for an individual drug, given that the FUL is designed as an ''aggregate'' limit.

Comment: Many commenters urged that the implementation of the new FULs based on the DRA provisions be permanently suspended because the new generic reimbursement methodology of 250 percent of AMP will be below acquisition cost. One commenter who analyzed AMP and drug acquisition cost data said that the proposed FULs poorly estimate pharmacy acquisition costs.

Response: We disagree. The DRA requires that, effective January 1, 2007, CMS calculate the FUL at 250 percent of the AMP (computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent drug. The 250 percent markup of the lowest priced drug, along with our outlier policy will assure the availability of drugs at or below the FUL price for pharmacies.

Comment: One commenter stated that a pharmacy's acquisition cost may exceed the FUL reimbursement for a particular drug because wholesalers sell to independents under contractual agreements which are not readily transferable, and independent retail pharmacies are not able to ''cherry pick'' between wholesalers on a product-by-product basis.

Response: We believe that the FULs will be sufficient to allow all pharmacies to purchase drugs at or below the FUL price. If a State finds it necessary to pay a higher price than the FUL price, it can do so as long as it remains within the aggregate limit.

Comment: Several commenters stated that AMP was never meant to be a reimbursement metric.

Response: The law requires the FULs to be based on AMP and permits States to use AMP in their reimbursement methodologies. We believe that basing reimbursement, in part, on AMPs will help capture transparent pricing data to assure that the Federal Government and State Medicaid programs are paying appropriately for generic drugs.

Comment: Many commenters stated that AMP and the resulting FUL will not only impact Medicaid Programs, but will substantially impact the entire private market. Therefore, it is imperative that the FUL represent actual acquisition costs. Another commenter stated that the impact of using AMP for reimbursement cannot be gauged at this time.

Response: The law provides that AMPs be publicly available. Therefore, they may have an impact on reimbursement from other payers. AMP will be based, in part, on the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. The 250 percent markup of the lowest priced drug should assure the availability of those drugs at or below the FUL price for the pharmacies.

Comment: One commenter stated that pharmacies will seek further price reductions from manufacturers to maintain their margins and that this will further reduce AMPs and FULs, creating a downward cycle that will continue to lower profits for pharmacies.

Response: CMS appreciates the comment but has no reason or evidence to believe the use of AMP data would lead to price reductions or a downward cycle of prices.

Comment: One commenter stated that the FUL amount should be the minimum reimbursement amount that the States can reimburse pharmacies for a multiple source drug. The State maximum allowable cost (MAC) programs should be discouraged with the implementation of the AMP-based FULs, which will better reflect acquisition cost to pharmacies.

Response: We disagree. The DRA clearly mandates that the FUL amount be the upper limit for payment. States retain the authority to implement a MAC program to limit reimbursement amounts for certain drugs. Individual States retain the authority to determine the types of drugs that are included in their MAC programs and the method by which the MAC for a drug is calculated.

Methodology of FUL

Comment: Many comments were submitted pertaining to the new calculation/methodology for establishing a FUL for multiple source drugs. Some commenters recommended using an AMP ''average'' instead of the lowest AMP to establish a FUL.

Response: The DRA provides, effective January 1, 2007, that the upper limit for multiple source drugs be established at 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent. Therefore, we do not believe that the statute allows for an AMP average to be used to set the FUL amount.

Comment: One commenter requested that CMS clarify how an aggregate payment system can be implemented prospectively given the uncertainty of utilization for multiple source drugs subject to a FUL.

Response: States have flexibility with respect to implementation. For example, they can look at the previous years' claims data to estimate their aggregate caps.

Comment: Many commenters expressed concern that the new FULs methodology will create a disincentive to dispense generic drugs. One commenter stated that the proposed rule does not affect brand name drugs that have the greatest budgetary impact on State Medicaid programs.

Response: The commenter is correct that the FULs apply to multiple source drugs. However, we do not believe that this will lead to a decrease in the dispensing of generic drugs. States will continue to require the use of generic drugs when appropriate. We also believe that drug pricing transparency will lead to more equitable and appropriate reimbursement for prescription drugs as States gain greater knowledge about the actual market price of prescription drugs. Because AMPs for all covered outpatient drugs will be available to States, they will have more information to use in setting appropriate prices for brand name drugs as well as generic drugs.

Disincentive To Market or Dispense Generic Medications

Comment: Other commenters stated that manufacturers may choose to not introduce new generics to the market and wholesalers may not buy generic products because pharmacies will prefer to dispense brand name drugs.

Response: We do not agree that these changes with respect to the calculation of the FUL will so dramatically change market dynamics.

Net Payments to States

Comment: A few commenters said that FULs should be compared to net payments after rebates, since that will allow the State to take advantage of higher rebates on brand name drugs.

Response: We disagree. In accordance with provisions of the DRA which amend section 1927(e) of the Act, the FUL is based on 250 percent of the AMP. Thus, we have based the FULs on AMP, as opposed to any payments by States net of rebates.

Comment: Several commenters stated that it is not uncommon for a State to designate a multiple source brand name drug as preferred when the supplemental rebate offered by a manufacturer results in the brand name drug being less expensive than the A-rated generic equivalent. The new FULs

will require States to reanalyze these arrangements, and possibly require States to cancel or amend supplemental rebate contracts with manufacturers.

Response: In accordance with the DRA amendments, States' payments for multiple source drugs must not exceed, in the aggregate, the FULs. States may need to consider how this may affect their preferred drug lists.

Nine-Digit Versus Eleven-Digit NDC

Comment: Some commenters supported using the 9-digit NDC weighted AMP to calculate the FUL and noted that this method is sufficient because per-unit pricing differences between package sizes are not generally significant. Other commenters expressed concern that significant system changes would be required to move to the 11-digit NDC method.

Response: We agree that the AMP should continue to be weighted at the 9-digit NDC level, and retain this requirement in the final rule. CMS has used the weighted 9-digit AMP since the start of the rebate program and there is nothing in the statute or legislative history to indicate that the Congress meant for this to change when AMP is used for FULs.

Comment: With the changes in the DRA to compute the FUL based on AMP, some commenters questioned if the weighted AMP, calculated at the 9-digit NDC level (as currently reported for the Medicaid Drug Rebate calculation) will result in adequate reimbursement levels that will be in line with market-based acquisition costs and preferred that we set FULs using the 11-digit NDC.

Response: We believe that using a weighted AMP will result in adequate reimbursement and have retained this in the final rule.

Comment: One commenter stated that the use of the 9-digit weighted AMP to calculate the FUL will be problematic when the weighted average is controlled by high volume sales of larger-sized packages with a lower unit cost.

Response: We disagree. We believe a weighted average will adequately reflect all package sizes.

Comment: Some commenters stated that using the 11-digit AMP to set the FUL would allow the FUL to be based on individual package sizes, or would allow a FUL to be established on the most commonly used package size. Other commenters stated that using the 11-digit AMP would reflect the difference in the popularity of a drug in different areas of the country, or the package size that is most economical for a pharmacy provider to purchase. Several commenters said that AMP prices should be based on the most commonly prescribed package sizes as the current FULs are calculated.

Response: We disagree. Using an 11-digit level NDC specific to a package size to calculate the AMP may allow manufacturers to avoid best price implications for certain products by manipulating sales. The use of the 11-digit level NDC to calculate AMP would also have an effect on rebates paid by manufacturers which we believe is inconsistent with the statute.

Comment: Commenters expressed concern that AMPs calculated and reported at the 9-digit NDC level, would adversely affect 340B covered entities, whose ceiling prices are based on AMP, because of a lack of transparency and efficiency in setting prices.

Response: We continue to believe that in accordance with the statute, AMPs should be uniform across package sizes.

Comment: Several commenters stated that the 11-digit NDC should be used to calculate the AMP, as this aligns with State Medicaid Agencies' drug payments that are based on package size.

Response: We continue to believe that in accordance with the statute, AMPs should be uniform across package sizes.

Manufacturer-Submitted Utilization

Comment: One commenter stated that manufacturers should submit drug utilization numbers so that FULs can be based on the most commonly prescribed package size. Also, the commenter suggested that CMS could calculate the 9-digit weighted AMP from this information for rebate purposes, and this information could also be used to identify outliers by noting supply numbers. One commenter suggested that CMS require manufacturers to submit information on their net units shipped for each product so CMS can determine if a product is widely available, bearing in mind that such information is confidential. The commenter noted that this requirement would mirror the requirement for ASP reporting. The commenter also suggested that CMS consider additional factors when setting FULs, such as whether the product is available from several wholesalers. The net unit information could also be used for weighting, as required for the rebate calculation process.

Response: We disagree. While CMS appreciates the comment, it does not believe that such information is necessary in light of the DRA amendments.

Therapeutic Equivalency

Comment: One commenter stated that the inclusion of B-rated multiple source drugs in the FUL reimbursement means that CMS is sanctioning the practice of dispensing generic drugs which are not therapeutically equivalent. This commenter further stated that if CMS chooses to include B-rated drugs, then it must indemnify retail pharmacies from all adverse patient reactions and/or negative outcomes. One commenter states that some Medicaid Programs will only reimburse A-rated equivalent drugs.

Response: We disagree. We believe that in light of the provisions of section 1927(e) of the Act, as amended, it is appropriate to continue to apply the FUL to B-rated drugs. To do otherwise may encourage pharmacies to substitute B-rated drugs to avoid the FUL. Based on section 1927(e)(4) of the Act, while the FUL would apply to a B-rated drug, the FUL will only be set based on the AMP of formulations that are therapeutically and pharmaceutically equivalent.

Number of Suppliers

Comment: Several commenters expressed concern that the FUL criteria should be revised to require an adequate number of suppliers, or that drug supplies should be nationally available. One commenter stated that CMS should develop a method to survey manufacturers to determine if the products included in the calculation of the AMP are actually widely available in the marketplace. A reasonable threshold for marketplace penetration should be defined and applied to ensure that products are available nationally and in consistent supply. One commenter pointed out that smaller generic manufacturers seek to capture market share when entering the market by discounting their prices by 20–30 percent, but do not have product inventories sufficient to serve the entire Medicaid population. One commenter stated that repackagers of drugs may often have limited availability, yet the prices of such drugs could be used to set a FUL. One commenter suggested that three suppliers of ''A'' rated products should be necessary to establish a FUL. One commenter stated that the FUL should not be applied until there are two or three different suppliers in the market, because establishing a FUL with just an innovator multiple source drug and an authorized generic by a subsidiary of the company may not show much price difference between the two. One commenter stated that a drug should not be considered to be available unless it is available from the top five wholesalers in each CMS region. Another commenter said that CMS should include a provision for a

product-specific exemption or adjustment by State or region when products are unavailable in those markets at the FUL price. Another commenter agreed that revision of criteria to establish a FUL for ingredient groups with two therapeutically equivalent drugs was a positive step.

Response: We proposed to revise the methodology we use to establish FULs for multiple source drugs based on the provisions of the DRA. Specifically, sections 6001(a)(3) and (4) of the DRA changed the definition of multiple source drug established in 1927(k)(7)(A)(i) of the Act to mean, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which is rated as therapeutically equivalent (under the FDA's most recent publication of *Approved Drug Products with Therapeutic Equivalence Evaluations*). Also, section 6001(a)(1) of the DRA amended section 1927(e)(4) of the Act to require that a FUL be established for each multiple source drug for which the FDA has rated two or more products therapeutically and pharmaceutically equivalent. We do not agree, in light of these DRA revisions, with the comment that CMS should survey manufacturers regarding availability or make product-specific exemptions when products are not available at the FUL price. We believe that our policy of applying the FUL in the aggregate, not using terminated products when setting FULs, and adopting an outlier policy on the use of AMPs to set FULs addresses the commenters' concerns.

Listing in National Compendia

Comment: One commenter raised concerns with the upper limit methodology set forth in § 447.514(a)(1)(ii) and specifically questioned if CMS would consider a drug to be available for sale nationally, and thus consider it eligible to set the FUL, if the drug otherwise meeting the criteria in § 447.514(a)(1)(i) is not listed in a current edition or update of published compendia of cost information.

Response: In this final rule, CMS is revising the text language in § 447.514(a)(1)(ii) by deleting ''based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally,'' because in light of the DRA amendments CMS will not be using the published compendia of cost information, (for example, *Red Book, First DataBank,* or *Medi-Span*) to establish and set the FUL. CMS will be using AMPs submitted by manufacturers to establish the FUL.

National Availability

Comment: One commenter stated that CMS should consider revising § 447.514(b) to read, ''for the least costly therapeutic equivalent available for sale nationally'' to ensure that AMPs used to set the FUL are available nationally and will yield sufficient FUL prices.

Response: We disagree. We believe that the FUL will be calculated to ensure that a drug is available nationally at or below the FUL price. The FUL will be calculated based on a 250 percent markup of AMP, will be applied in the aggregate, will not be set using terminated products, and will incorporate an outlier policy on the use of AMPs. We believe these considerations address the commenter's concern.

Outlier AMPs

Comment: Many commenters submitted recommendations pertaining to the FUL outlier policy, under which one or more of the lowest AMPs for an ingredient group would be passed over when setting the FUL in order to avoid a FUL reimbursement below the cost at which the drug is nationally available. Commenters agreed with CMS that an outlier policy should be implemented, but differed on the metrics that should be used. Several commenters proposed that we set the FUL on the lowest AMP that is not less than 80 percent of the next highest AMP. Another commenter stated that we should set the FUL on the lowest AMP that is not less than 60 percent of the next highest AMP. Another commenter stated that, to reduce the potential for volatility in the AMP-based reimbursement system, we should exclude outliers that are more than 10 percent below the next highest AMP, looking at each AMP available in the ingredient group. Another commenter stated that AMPs no more than 20 percent less than the next highest AMP should be excluded. Another commenter proposed that CMS should establish a different outlier policy for immunosuppressive multiple source drugs due to the critical access need for these drugs by transplant recipients, under which the FUL would be based on the lowest AMP that is not less than 70 percent of the next-highest AMP in the multiple source drug group. Another commenter stated that the rationale behind the 30 percent outlier rule proposed by CMS is not readily apparent, because verifiable data was not supplied in the proposed rule. One commenter suggested that the 30 percent outlier rule was appropriate, but wanted CMS to remove all outlier AMPs that are less than 30 percent of the next highest AMP, and use the industry-wide weighted average AMP to establish the FUL.

Several commenters agreed with CMS' proposal to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP. One commenter stated that CMS should use a statistical calculation of a standard deviation for each group of therapeutically equivalent drugs. Any manufacturer's AMP falling below one standard deviation would be removed as an outlier. The AMP would then be based upon the lowest value within one standard deviation. Another commenter suggested that AMPs falling at or below the 25th percentile of drug prices within the ingredient group should be excluded from establishing the FUL. Several commenters stated that the FUL should be calculated using the AMP of the lowest priced drug that is not less than 50 percent of the next highest AMP. In other words, look at the lowest AMP, and then the next lowest AMP, and so on, rejecting AMPs until an AMP is at least 50 percent of the next highest AMP.

Other commenters suggested that manufacturers should report AMPs at the 11-digit NDC level with their respective unit volume. These commenters state that the final rule should include a FUL outlier methodology that examines AMPs on a cumulative market share basis, starting with the lowest AMP, then the next lowest and so on, rejecting AMPs until a cumulative market share of 50 percent has been reached.

Response: We appreciate the many suggestions for how we could determine outlier AMPs. We have expanded our outlier policy in the final rule by excluding the lowest AMP if it is less than 40 percent of the next highest AMP in § 447.514(c)(2). That is to say, that the AMP of the lowest priced therapeutically equivalent drug will be used to establish the FUL, except in cases where this AMP is more than 60 percent below the second lowest AMP. In those cases, the second lowest AMP will be used in the FUL calculation. By setting this as our outlier exclusion policy, we ensure that at least two drugs are available at or below the FUL price. Also, further analysis of the manufacturer-submitted AMP data revealed that we could exclude more outlier prices by using the 40 percent standard. We have also decided to publish § 447.514(c)(2) as a final rule with comment period. This will allow for further public comment after the clarified definition of AMP becomes

effective and States would then have an opportunity to analyze AMPs, as revised by the DRA, and FULs. It will also give CMS an opportunity to receive further comments based on a broader analysis of the data. CMS will accept comments on the outlier (and as discussed previously on the AMP) policy for a period of 180 days from the date of publication of this final rule in the **Federal Register**.

Comment: Several commenters strongly recommended that, in lieu of an outlier, CMS should set FULs based on the weighted average AMP of the therapeutically equivalent products available in the market. One commenter stated that this would avoid regional pricing that may not be widely available for a specific product, ''fire sale'' pricing on short-dated products, and prices that are not sustainable over a consistent period of time.

Response: We disagree. The DRA provides, effective January 1, 2007, that the upper limit for multiple source drugs be established at 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent.

Comment: One commenter stated that if the calculated FUL exceeds the AWP of the innovator multiple source drug, or exceeds the innovator multiple source drug's AMP by 25 percent or more, CMS should not publish a FUL for that ingredient group.

Response: We do not agree that a FUL should not be set if it exceeds the AWP for the innovator multiple source drug. There is no basis, given the statutory amendments, to calculate a FUL using an AWP standard. We agree that States may not find a FUL useful if it exceeds the AMP of the innovator multiple source drug by 25 percent; however, we do not believe we should make an exception in this instance. The FUL is designed to be an aggregate upper limit, not necessarily a payment rate for drugs.

Terminated Drugs

Comment: Some commenters submitted comments regarding the use of a terminated drug to set the FUL. One commenter expressed concern that the proposed rule does not take into account that an AMP may be from a terminated product. One commenter stated that CMS should provide notification of terminated NDCs associated with the establishment of FULs, so that State Medicaid agencies do not continue to reimburse for a terminated drug. One commenter stated that CMS should clarify the meaning of ''terminated.''

Response: The proposed rule would exclude terminated NDCs from consideration when setting a FUL beginning with the first day of the month after the actual termination date reported by the manufacturer to CMS. We are retaining this provision in the final rule. A FUL reimbursement applies to all drugs within an ingredient group, including drugs that are being terminated by the manufacturer, but still being produced by a manufacturer. However, a terminated NDC would not be used to set the FUL. We continue to define a terminated drug according to the reason the product is being discontinued. If it is being pulled from the shelf immediately due to a health or safety reason, whether it is by FDA or labeler directive, the termination date is the date removed. If, however, it is being replaced by an improved version, or discontinued, the termination date is the shelf life of the last batch sold.

Upper Limits for Drugs Furnished as Part of Services (§ 447.516)

Comment: One commenter pointed out that while the FUL will be revised monthly, managed care capitation arrangements are negotiated for longer periods of time, making it difficult for State Medicaid Agencies to comply with frequent FUL changes when setting capitation rates. Another commenter stated that the final rule should be amended to exclude FULs from capitation arrangements to address this concern.

Response: States will need to consider possible fluctuations in FULs when negotiating future MCO contracts and modify current contracts, if necessary, to address any revisions needed to capitation rates as a result of monthly FUL changes. Also, to note the FULs are designed to be aggregate upper limits, and do not represent individual payments for drugs. In accordance with § 447.516, the upper limits for payment for prescribed drugs also apply to payment for drugs provided under prepaid capitation arrangements. CMS has not changed this requirement.

State Plan Requirements, Findings and Assurances (§ 447.518)

Comment: One commenter requested that CMS insert language in the final rule that would require States to consult with Tribes in the development of any SPA which would modify existing payment methodologies for prescription drug reimbursement. This would allow each Tribe the opportunity to work with its State to assess local impacts prior to submission of SPAs.

Response: A State Medicaid Director letter dated November 9, 2006 was sent encouraging States to consult with Tribes in open, good faith dialogue, on the DRA provisions that have the potential to impact Tribes and American Indian and Alaska Native Medicaid beneficiaries. The letter stated that it is important to maintain ongoing communication between States and Tribes in the redesign of Medicaid Programs and services.

Comment: One commenter requested that CMS insert language in the final rule to encourage States to maintain their current level/type of reimbursement and filling fees to Tribal and IHS pharmacies. Tribal and IHS providers should be explicitly recognized as essential safety net pharmacies.

Response: We appreciate the comment and will take this suggestion into consideration as we consider revisions to State payment rates. In accordance with longstanding policy, we believe that States should have the flexibility to establish payment rates and reasonable dispensing fees, consistent with the upper limits and standards set forth in our regulations.

Comment: One commenter believed that the SPA process must be more deliberative and transparent than the process that has been used to date by States to make changes in their payment methodologies. States need to be more diligent and transparent in providing public notice about reimbursement methodologies and substantiating the impact that the changes could have on Medicaid beneficiaries' access to community retail pharmacies.

Response: We disagree with the commenter. States must follow Federal regulations at 42 CFR 430 subpart B for all State plans.

Comment: One commenter suggested to amend § 447.518(b)(1) by adding another § 447.518(b)(1)(iii), which would say, ''in the aggregate, the dispensing fees paid to pharmacies cover the costs described in § 447.502 and are designed to encourage the utilization of multiple source drugs where appropriate.''

Response: We disagree with the commenter. In accordance with longstanding policy, we believe that States should have the flexibility to establish payment rates and reasonable dispensing fees, consistent with the upper limits and standards set forth in our regulations.

FFP: Conditions Relating to Physician-Administered Drugs (§ 447.520)

We received many comments regarding the requirement that State Medicaid Agencies provide for the submission of NDCs on claims for

physician-administered drugs, as discussed below:

Comment: Several commenters stated that CMS has failed to define outpatient drugs that are physician-administered as required by the statute. The commenter further stated that CMS is incorrectly interpreting the law by including drugs administered in the outpatient hospital setting.

Response: In light of the definition of covered outpatient drug provided in section 1927 of the Act, we have chosen not to define what is meant by a covered outpatient drug that is administered by a physician. We believe that the DRA amendments to section 1927 of the Act were intended to emphasize that where covered outpatient drugs are administered by a physician and separately billed to Medicaid, States are required to collect rebates from manufacturers for these drugs. The law requires that States obtain information on the claims forms that will allow them to bill manufacturers for rebates for specific covered outpatient drugs in accordance with section 1927 of the Act.

Comment: A few commenters stated that the statute permits the use of J-codes as well as NDCs.

Response: The statute allows the Secretary to specify the required codes. We proposed to allow J-codes, also known as HCPCS codes, to be used beginning January 1, 2006 for single source physician-administered drugs. We also specified that the NDC be required for single source drugs and the 20 multiple source drugs identified by the Secretary beginning January 1, 2007. We are finalizing these requirements in this final rule.

Comment: Several commenters asked that CMS provide a list of NDCs within the J series of HCPCS codes that are subject to rebates under the Medicaid Drug Rebate Program.

Response: At this time, CMS does not intend to publish a list of NDCs for each physician-administered drug that is subject to Medicaid rebates, as such a list would be quite expansive. However, CMS provides monthly files of drugs of manufacturers that have a national rebate agreement under the Medicaid Program. CMS also maintains a list of NDCs within HCPCS that can be found on our Web site at *http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a_2007aspfiles.asp#TopOfPage.*

Comment: One commenter asked that CMS revise the HCPCS J-code crosswalk to NDCs on our Web site to identify: (1) physician-administered drugs not routinely covered by Medicare but covered by Medicaid, (2) the sole source and 20 multiple source drugs for which NDCs must be collected, and (3) NDCs for manufacturers that participate in the Medicaid Drug Rebate Program.

Response: At this time, we do not intend to revise the HCPCS crosswalk to identify drugs not routinely covered by Medicare but covered by the Medicaid Drug Rebate Program. However, the publicly available AMP pricing data will be listed with NDCs which will indicate manufacturers participating in the Medicaid Drug Rebate Program as well as the products covered by the program. The list of the top 20 multiple source physician-administered drugs are posted on CMS' Web site at *http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Top20PhysicianAdministered.pdf.*

Comment: Several commenters asked that CMS clarify the prospective nature of the proposed definition of physician-administered drug.

Response: The DRA requirement that States collect information sufficient to bill for rebates on single source drugs was effective January 1, 2006 and States must bill for rebates to collect a Federal match on these drugs. For single source physician-administered drugs and the 20 specified multiple source physician-administered drugs, States must collect NDCs beginning January 1, 2007. However, Federal match remains available until January 1, 2008, at which time we expect that States will be in compliance with this requirement. We would note that the requirement for States to submit utilization data to collect rebates on covered outpatient drugs in section 1927(b) of the Act predates the DRA requirements and inasmuch as physician-administered drugs are covered outpatient drugs, we believe that the January 1, 2006 effective date was reasonable. The DRA emphasized physician-administered drugs because these drugs historically have been billed by providers in such a way that prevented States from collecting rebates for these drugs.

Comment: Many commenters expressed the opinion that manufacturer rebate liability should be proportional to State Medicaid expenditures when Medicaid is the secondary payer. They contended that this is more consistent with the overall intent of the rebate program to reduce the cost of drugs to Medicaid and to ensure Medicaid the best price provided to other purchasers. Other commenters believed that CMS' position concerning the intent of the Medicaid statute that full rebates are due when Medicaid pays any amount of the claim is incorrect and is procedurally invalid because this policy was not established through formal notice-and-comment rulemaking. Another commenter wished CMS to continue with the historical practice of having Medicaid claim rebates on the total amount paid for the drug by all parties.

Response: We disagree that the rebate should be proportional to the amount of the claim paid by Medicaid. Neither the law nor the national rebate agreement makes provision to reduce the rebate liability based on the amount of payment made by the Medicaid Program. Rather, the law provides formulas for rebate payments for single source, innovator multiple source, and noninnovator multiple source drugs that are used when Medicaid makes payment for a drug. This has been the consistent policy position of the Agency since the start of the Medicaid Drug Rebate Program.

Comment: One commenter said that CMS should not deny Federal matching funds for physician-administered drugs not covered by the national rebate agreement.

Response: The statute requires drug manufacturers to participate in the Medicaid Drug Rebate Program in order for their drugs to be covered by Medicaid. We recognize that States may not always be aware of what drug was administered when a bill is submitted using a HCPCS code. However, when the law requires billing with an NDC, a State Medicaid Agency cannot knowingly pay that claim and collect the Federal match.

Comment: Some commenters said that the requirement that outpatient hospitals record NDCs would have a negative impact on patient safety because it would disrupt the workflow for dispensing drugs and divert limited staff from accurate dispensing.

Response: We have no reason to believe that patient safety will be affected by this requirement.

Comment: One commenter stated the belief that contrast agents, typically used during hospital-based radiological procedures, are excluded from Medicaid rebates.

Response: Only physician-administered drugs that are separately billed to Medicaid as covered outpatient drugs will be considered physician-administered drugs for the purposes of this rule. If the contrast agents are not billed to Medicaid as outpatient drugs, they would not be considered physician-administered drugs for purposes of this provision.

Comment: One commenter stated that the regulation should exempt drugs administered in an emergency room from this provision because physicians should not need to concern themselves with whether the patient is a Medicaid

beneficiary and because the physician does not know at the time drugs are administered if the patient will be admitted or sent home.

Response: Drugs administered incident to an emergency room service that are billed separately as covered outpatient drugs, as defined by section 1927(k)(2) of the Act, are covered under the Medicaid Drug Rebate Program and must be billed using the NDC in order for States to collect the Federal match. Drugs that are billed as part of an emergency room service as described in section 1927(k)(3) of the Act, where the cost of the drug is bundled within the cost of the service, are not covered by the Medicaid Drug Rebate Program.

Comment: One commenter asked if HCPCS will be assigned to drugs that do not currently have them.

Response: We do not plan to assign HCPCS to drugs as the provisions addressed in this rule require the submission of NDCs on claims when billing Medicaid for physician-administered drugs.

Comment: One commenter asked CMS to clarify in the final rule that claims for physician-administered drugs must meet all covered outpatient drug requirements, specifically, that the drug must be subject to a Medicaid rebate, not have a termination date prior to the date or service, and not be a drug with a DESI value of five or six.

Response: The commenter is correct that all requirements for Medicaid drug coverage apply to physician-administered drugs.

Comment: Several commenters believe that CMS went beyond congressional intent by including outpatient hospitals and clinics in the requirement for States to collect NDC-level information on pharmacy claims. Commenters stated that the OIG report on this topic addressed only drugs administered in physicians' offices and that this report was the impetus for the legislation.

Response: We base our interpretation on the language in the statute which does not differentiate between providers in requiring that States collect information sufficient to bill for rebates for covered outpatient drugs under section 1927(k)(3) of the Act. To the extent that providers bill for covered outpatient physician-administered drugs separately; that is, the cost of the drug administered is a separate line item from the service provided, we believe that, in accordance with the statute, States should be seeking rebates with respect to such drugs.

Comment: Several commenters wrote that the DRA does not change the existing statute at section 1927(j)(2) of the Act that exempts from Medicaid drug rebates drugs administered to patients in hospital outpatient clinics and departments.

Response: We agree that the DRA did not change the exclusion of drugs from Medicaid rebates when dispensed in an outpatient hospital setting as long as Medicaid is billed at the hospital's purchasing costs. However, hospitals commonly bill Medicaid without regard to their costs and accept the full reimbursement provided under the Medicaid State plan. When this is the case, drug manufacturers are responsible for paying rebates with respect to those drugs that qualify as covered outpatient drugs under section 1927(k)(3) of the Act.

Comment: One commenter said that rebates should not be collected on hospital outpatient drugs because they are not part of the retail pharmacy class of trade for AMP.

Response: The commenter is not correct in that sales to hospital outpatient departments are considered in the retail pharmacy class of trade and are included in the calculation of AMP at the option of the drug manufacturer, as specified in this final rule. Physician-administered drugs will be excluded from the Medicaid Drug Rebate Program requirements only when hospital outpatient departments have dispensed these drugs using drug formulary systems, and have billed Medicaid at acquisition costs, consistent with section 1927(j)(2) of the Act.

Comment: Several commenters stated that 340B hospitals should not need to forgo receiving discounts on drugs as a result of Medicaid collecting rebates on them and have asked to be exempted from the requirement.

Response: This provision of the DRA does not apply to 340B hospitals that receive discounted drugs and bill Medicaid at the acquisition cost of the drug as determined under the State plan.

Comment: One commenter noted that certain safety-net hospitals receive discounts under the 340B Program and that the law provides that such drugs not be also subject to Medicaid rebates.

Response: We agree with the commenter that drug manufacturer sales to safety-net hospitals under the 340B Program are not subject to Medicaid rebates as long as they are billed to Medicaid at acquisition cost as determined under the State plan.

Comment: One commenter asked that HRSA post the National Provider Identifiers (NPI) of providers who will be billing for physician-administered drugs from 340B covered entities on its Web site in addition to the NPIs of 340B covered entities.

Response: We are not addressing the concerns of other agencies within the Department of Health and Human Services in this rule. Instead, we suggest that the commenter should address HRSA regarding the posting of NPIs on its Web site.

Comment: One commenter noted that physicians will not know which drugs are included in the Medicaid Drug Rebate Program to be able to administer only those drugs to Medicaid patients. Several commenters noted that physicians need to know which manufacturers participate in the Medicaid Drug Rebate Program because drugs of non-participating manufacturers will not be covered by Medicaid.

Response: We understand the commenter's concern and believe that compliance with this provision will depend upon the level of education/coordination provided by States to the provider community regarding the resources available to them. As previously discussed in this rule, AMPs for drugs covered by the Medicaid Drug Rebate Program will be publicly available and listed by NDC on our Web site. We believe that this resource, along with State information, will assist physicians to make informed decisions regarding the list of covered outpatient drugs available under Medicaid.

Comment: Several commenters asked that CMS develop standard literature for physicians to assist in education and outreach about the requirement for including NDCs on bills for Medicaid.

Response: States traditionally are responsible for provider outreach and education. Materials will vary by State based on processes and procedures determined by each State. We believe that States can avoid duplication of effort by working through the National Association of State Medicaid Directors to share materials and best practices concerning this new requirement.

Comment: One commenter asked CMS to develop a form for hospitals to use to bill States with NDCs because the UB04 billing form does not allow for the inclusion of NDCs. The commenter believed this would be more efficient than each State developing its own form.

Response: CMS would be happy to work with States if they wish to develop a model form.

Comment: A few commenters asked that CMS develop a standard UB04 form that allows for the reporting of the NDC quantity and unit of measure.

Response: CMS cannot specify what is included on the UB04 form. The

National Uniform Billing Committee determines the content of the form. Both CMS and State Medicaid Agencies are represented on this committee and need to work together to establish the need for any changes to the form and to obtain approval for the changes.

Comment: A few commenters noted that not all Durable Medical Equipment Regional Carriers (DMERC) pass through the NDC to the Medicaid agency. The commenters believed that the provision that States allow for the submission of NDCs on claims for physician-administered drugs should also apply to claims for supplies/durable medical equipment for which Medicaid is the secondary payer so that States are able to collect rebates on these claims.

Response: We are aware that not all DMERCs provide the NDC to the Medicaid agency when Medicaid is the secondary payer. We also agree with the commenter that States should be collecting NDCs with respect to separately reimbursed drugs in order to secure rebates under section 1927 of the Act to the extent that they are not included within a bundled rate.

Comment: Several commenters asked that the Secretary use the waiver authority provided by statute to delay the requirement for States to collect NDC-level information from hospitals to provide additional time for them to reconfigure their systems to capture this information.

Response: The statute provides for a hardship waiver for States that require additional time to implement necessary changes to their reporting systems. We will consider States' requests on a case-by-case basis.

Comment: One commenter noted that CMS stated in the proposed rule that we do not expect States to need hardship waivers to postpone the requirement that States collect NDCs on claims for physician-administered drugs by January 2008. The commenter believed that States may find it difficult to meet this date because of other priorities for systems such as the NPI.

Response: We anticipate that many States will have had ample time to meet the January 1, 2008 deadline to comply with the DRA requirements since the DRA was enacted nearly two years prior to that deadline and CMS guidance was given to State Medicaid Directors (SMDL 06–016, *http://www.cms.hhs.gov/smdl/downloads/SMD071106.pdf*) nearly 18 months prior to the deadline.

Comment: One commenter suggested that CMS should re-examine this requirement as it will result in reduced access to care for Medicaid beneficiaries because of the non-standard billing requirements it imposes.

Response: While we appreciate the comment, we have no reason to believe that the DRA requirement will result in reduced access to care.

Comment: One commenter noted that not all package labels carry the 11-digit NDC which is needed for billing. Some carry a 10-digit number and knowledge of conversion conventions is needed to translate the number to the 11-digit NDC. Another commenter stated an inability of some billing systems to capture the 11-digit NDC. Another commenter noted that the billing units of certain drugs are different from the units used for Medicaid rebates. This will cause confusion and require translation.

Response: As we have previously stated, the education of the provider community by the States will be paramount in ensuring proper billing procedures and the successful implementation of this requirement.

Comment: Several commenters stated that it will be nearly impossible for hospitals to accurately record the NDCs for some drugs. This will occur when drugs are bought in bulk or for cases in which a portion of the drug unit is used. The commenter noted that the difficulty will likely be encountered in instances when multiple drugs are mixed into a treatment ''cocktail'' and injected or infused into the patient.

Response: We recognize the operational difficulties that may exist for some hospitals but note that the law, as amended by the DRA, makes no exceptions for physician-administered drug claims billed by hospital outpatient departments. This process should be easier when hospitals use the Uniform Product Codes for drugs dispensed.

Comment: One commenter asked that CMS bill manufacturers for rebates directly as opposed to implementing this requirement.

Response: This request is not feasible because States, not CMS, receive claims data necessary to bill manufacturers for rebates. Drug manufacturers do not know which or how much of their drugs are supplied to Medicaid beneficiaries until States submit utilization data as required in section 1927(b)(2) of the Act.

Comment: One commenter suggested that it would be more appropriate for States to obtain detailed NDC information from the drug manufacturers rather than from the community hospitals. The commenter noted that drug manufacturers have access to detailed NDC information and other detailed purchasing information because the drug company representatives often call the community hospital pharmacy directors to inform them of the number of items hospitals have purchased and how many items are returned for credit.

Response: While we appreciate the commenter's suggestion, this approach would not be operationally feasible because manufacturers would not have utilization data to determine the unit amounts of drugs dispensed to patients.

Comment: One commenter stated that his hospital uses drug dispensing machines located throughout the hospital that have unit dosages of drugs that are not differentiated by NDC. Compliance with this provision would require the hospital to limit each slot on the machine to one NDC, ordering only one NDC for each drug, or billing by unit dose, all of which would be costly and inefficient.

Response: We understand that some hospitals and providers' offices will require systems modifications and changes in dispensing and billing procedures in order to comply with the billing requirements of this provision.

Comment: One commenter asked CMS to specify how compounded drugs should be billed. The commenter suggested that only the NDC and quantity for the NDC that most closely ties to the HCPCS narrative description be required.

Response: We require that NDCs and corresponding quantities for those NDCs for each drug be included on the claims for Medicaid reimbursement.

Comment: One commenter expressed concern that the requirement that providers submit NDCs for physician-administered drugs will create an administrative burden for both the providers and the State Medicaid Agencies. The requirement is impractical with respect to the CMS–1500 because the claims are usually submitted after the drugs are administered making it difficult for the provider to capture the NDC administered to the patient on the claim. Providers will need access to a list of rebatable NDCs and have them in stock, which could result in a delay in administering the necessary medication. The requirement may in fact impair patients' access to necessary medication.

Response: The law requires States to collect rebates on physician-administered covered outpatient drugs in order to receive a Federal match for the cost of the drugs. Because NDCs are required by the manufacturer in order for States to collect rebates on these drugs, providers are required to submit NDCs for physician-administered covered outpatient drugs. We encourage

States to educate the provider community regarding the resources available to them that may assist them in their transition to the requirements. We have no reason to believe that this requirement will have a negative impact on providers or patients' access to medication therapies in an outpatient hospital setting.

Comment: One commenter asked CMS to include a provision in the final rule to encourage States to provide a furnishing fee for blood clotting factors modeled after that provided by Medicare.

Response: State Medicaid programs have sufficient latitude under other provisions of the statute to determine in their State plans how they will reimburse adequately for blood clotting factors. This final rule does not revise options that States have under other provisions of the statute and the State plan to ensure access.

Comment: One commenter noted that the HCPCS crosswalk is only effective for single source drugs where there is a one-to-one relationship between HCPCS code and NDC. There are, in fact, several single source drugs for which there is one J-code but numerous NDCs.

Response: We agree with the commenter that the HCPCS crosswalk is only effective for certain single source drugs and believe that this fact fully supports the need for NDCs to be submitted on claims for physician-administered drugs as set forth in statute and required by this rule.

Comment: Several commenters noted that Part B carriers will need to provide the NDC on the crossover claim for the Medicaid agency to have the information needed to invoice drug manufacturers for rebates. One commenter asked that CMS ensure that Medicare carriers provide NDCs on crossover claims sent to Medicaid. Another commenter noted that the quantity administered for each NDC must also be recorded.

Response: If the NDC is on the electronic claim submitted (CMS–837), the Part B carrier will include it on the crossover claim sent to the Medicaid agency. Although the new CMS–1500 claim form does allow entry of the NDC, the UB04 claim form does not contain a section to capture the NDC. As previously stated, States will need to make it clear that providers must submit claims, complete with the NDC information, to the Medicaid agency. We encourage States to provide educational outreach to providers to inform them of the manner in which the NDCs and corresponding quantities should be recorded on the claims forms as they deem necessary for the accurate billing of drug manufacturers for rebates.

Comment: One commenter asked us to develop a better remedy for States than rejecting the claim and asking the provider to rebill when an NDC is not provided on a crossover claim. The commenter believes this method is costly, results in delay, is counter to the intent and spirit of HIPAA, and may result in a loss of access for Medicaid beneficiaries to needed drugs.

Response: It is crucial for States to communicate to the provider community the importance of including NDCs on the claims when billing Medicaid for physician-administered drugs. In cases where providers have not included NDCs on claims for physician-administered drugs, we recommend that States coordinate with provider billing offices in any manner that they deem appropriate in order to obtain the NDCs necessary for States to bill manufacturers for rebates as required by the statute.

Comment: One commenter stated that the burden of recording the NDC will fall on clinicians, not support staff. Because Medicaid is the secondary payer for most of these claims, the clinicians may note that the patient has Medicare, which does not require NDCs for billing, and may overlook the Medicaid requirement.

Response: We encourage States through provider education to convey the importance of including the NDCs on the claim in order for States to process claims and payment for the service.

Comment: One commenter believed that the top 20 list of multiple source drugs published on the CMS Web site incorrectly included Factor VII Recombinant and Factor VIII plasma-derived because the commenter did not believe these products meet the statutory definition of multiple source drug.

Response: We agree with the commenter and will remove these products from the top 20 list of multiple source drugs published on our Web site.

Comment: One commenter questioned the inclusiveness of the list of the 20 multiple source physician-administered drugs for which billing with the NDC will be required. The commenter stated that the list should include all NDCs with a particular HCPCS code.

Response: At this time, we do not intend to include all NDCs for a given HCPCS code.

Comment: One commenter asked when the list of 20 drugs will be updated.

Response: We intend to annually review the list of top 20 multiple source physician-administered drugs on our Web site and update it as necessary.

Comment: One commenter asked that we specify the file format for the submission of claims for physician-administered drugs using NDCs for the top 20 drug list.

Response: States are responsible for determining the file format to be used for the submission of claims. We encourage the States through provider education to inform providers of the correct file format to use when billing for physician-administered drugs using NDCs.

Comment: Several commenters said that State Medicaid Agencies should be required to bear the cost for hospitals to change their systems in order to meet the NDC reporting requirement, as some outpatient hospital departments' systems do not currently capture NDC level utilization data for patient billing.

Response: We do not believe that the law requires Medicaid agencies to pay hospitals for systems modifications that may be necessary to document claims for payment in a manner that would comply with DRA requirements to identify the NDC. States have the option to pay for overhead costs, such a provider billing systems, through dispensing fees to pharmacies or other providers.

Comment: One commenter stated that many State Medicaid processing systems are not designed to capture NDCs on outpatient hospital bills and that implementation of this provision should be delayed until alternate systems can be designed. Another commenter stated that the manual coding of NDCs would come at the expense of staff resources and would disrupt administrative operations.

Response: The timeframe for implementing this provision is set by statute. The DRA was signed into law on February 8, 2006. While States were required to start billing manufacturers for rebates for single source drugs on claims beginning January 1, 2006, States could crosswalk HCPCS to NDCs for these drugs. States continue to have until January 1, 2008 to collect NDCs on the 20 multiple source physician-administered drugs identified by the Secretary before losing Federal match for these drugs. States that cannot meet this deadline can request a waiver from the Secretary to implement this requirement at a later date.

Issues Not Addressed in the Proposed Rule

We received several comments on issues that were not addressed in the proposed rule. A summary of those comments and our responses follow.

Posting AMP

Comment: Many commenters requested that CMS should delay any public posting of the AMP data on a public Web site until after the final regulation has been issued and AMPs are determined to be reliable and accurately reflect the prices paid to manufacturers by wholesalers for sales to the retail pharmacy class of trade. Commenters contended that AMP data may be flawed and to post the flawed AMP data may cause confusion to the general public and adversely affect community retail pharmacies if Medicaid Programs and commercial markets use these data for reimbursement purposes. They pointed out that CMS already delayed release of these data once, and urged CMS to consider delaying the release of the data again. Delaying the posting of AMP data could permit manufacturers time to adjust the submission of their data consistent with the requirements of the final regulation and allow community retail pharmacies time to validate that the AMPs are consistent with congressional intent.

One commenter concurred with the OIG's findings in its May 2006 report that future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors.

One commenter raised concerns that the public disclosure of manufacturer-specific AMPs negates the confidentiality provisions of section 1927 of the Act. The commenter expressed the opinion that such disclosure must be implemented through notice-and-comment rulemaking, and that failure to do so would violate the Administrative Procedures Act. Another commenter asked that we not make AMPs publicly available. The commenter noted concern that public release of AMP would stifle competition among manufacturers, ultimately driving up the price of generic drugs.

Response: We disagree with the commenters about the need to further delay the public release of AMP. By statute, CMS is required to update AMP data posted on a Web site accessible to the public. Furthermore, effective January 1, 2007, the confidentiality provisions of the statute were amended to permit public disclosure of AMP data. CMS has interpreted these provisions to mean that we must publicly disclose data that the manufacturers report following January 1, 2007. We understand the importance of the accuracy of the AMP data; however, it is also important that we carry out the DRA amendments to make the AMP data publicly available. We also disagree that the public disclosure of AMP negates the confidentiality provisions of section 1927(b)(3)(D) of the Act. The DRA amended section 1927(b)(3)(D)(v) to provide for the release of AMP data to the public.

Comment: A few commenters expressed concern that CMS' failure to provide AMP data to the retail industry has hampered its ability to provide definitive and accurate commentary related to this matter. The commenter further said the final rule should be delayed until adequate information is provided to the retail industry to allow for statistically significant evaluation of the AMP data. Another commenter urged CMS to provide AMPs to community retail pharmacies on a confidential basis for the 77 multiple source drugs provided to the GAO because this would allow community retail pharmacies to speak with specificity as to the costs that they will bear under the proposed regulation.

Response: We disagree with the commenters. The DRA amended section 1927(e) of the Act to require that the FULs be calculated based on AMP data. The DRA also required that we publish the regulation clarifying requirements concerning AMP by July 1, 2007. In accordance with the effective date of the amendments to section 1927(b)(3)(D) of the Act, we consider AMP data prior to January 1, 2007 to be confidential; therefore, we did not publicly disclose the AMP data in the proposed rule. However, in accordance with the amendments to the confidentiality provisions and section 1927(b)(3) of the Act, we will post this information on the Web site and update that information on at least a quarterly basis.

Comment: A few commenters urged CMS to preface any Web postings of the AMP data with an introductory discussion explaining the current shortcomings of AMP as a measure of retail prices and pharmacy acquisition costs and highlighting the potential for changes in the calculation methodology underlying AMP over the next year.

One commenter also expressed that CMS should post a disclaimer stating that limited instructions were provided to guide manufacturers' January AMP calculations. Posted data should be viewed as preliminary and may not accurately reflect prices available in the market to community retail pharmacies. The commenter stated that similar disclaimers should be sent to the States with their download tapes or new electronically transmitted price report files. These disclaimers should also be reiterated in a State Medicaid Director letter.

Response: We will consider this comment when we issue further clarification regarding the provisions of this final rule.

Comment: A few commenters recommended that CMS develop clear guidelines for the electronic format and standardized unit reporting. Although the proposed rule requires submission of data by manufacturers in an electronic format, data specifications and unit reporting are not provided in adequate detail.

Response: CMS will post the AMP data file including labeler code, product code, package size code, the calendar month and year of the most recently reported AMP, and the AMP per unit per product code for the month and year covered, based on the sales. If a drug is distributed in multiple package sizes, there is one weighted AMP for the product, which is the same for all package sizes. We will address most of the procedural issues, such as data specifications and unit reporting, in guidance documents and on our Web site.

Comment: A few commenters recommended that AMP data should be posted on a secured password-protected internet Web site that can only be accessed by authorized practitioners, providers, and government agencies. The commenter argued that open access to this information could allow competitor manufacturers to access AMP information that can lead to information intelligence on specific products and affect both commercial and Medicaid supplemental rebate offers.

Response: We disagree with the commenter. By statute, CMS is required to post AMP data on a Web site accessible to the public. To post the AMP data on a secured Web site would limit access to the AMP data.

Comment: One commenter wanted to know how often the posted AMP data will be updated and which AMP data will be posted so that AMPs reflect the most accurate AMPs filed by the manufacturers. The commenter contended that failure to keep publicly available AMPs accurate and in agreement with revised AMPs reported by manufacturers is going to invite controversy from others interested in AMPs.

Response: We expect that AMP data will be updated on a monthly basis once posted on a Web site accessible to the public. We will post the most recently reported monthly and quarterly AMP data received from manufacturers, as well as any revised monthly and

quarterly AMPs for a period not to exceed twelve quarters from the quarter in which the data were due.

Comment: A few commenters recommended that AMP data should be made available in an easily downloadable format.

Response: The AMP data will be posted in a flat text file format for easy conversion to other file formats.

Comment: One commenter requested that CMS permit manufacturers to review monthly and quarterly AMP data prior to its publication by CMS to ensure its accuracy and give manufacturers opportunity to bring any concerns about the accuracy of the data to CMS' attention before it is used by States for reimbursement purposes.

Response: We disagree with the commenter. Monthly and quarterly AMP data that will be posted are those originally submitted by manufacturers; thus, manufacturers should be reviewing their data for accuracy prior to submitting them to us.

Comment: A few commenters requested that CMS provide the U.S. territories with access to the new AMP data so they may leverage the information in their calculations for reimbursement on brand name and generic drugs, as well as on rebate negotiations with the drug companies. Access to the proposed new AMP data would provide a benchmark in the rebate negotiation process, maximizing the utilization of available Medicaid funds.

Response: By statute, CMS is required to post the AMP data on a Web site accessible to the public. This requirement allows everyone to have access and to view the AMP data.

Comment: One commenter requested that the AMP data accurately reflect the reimbursement methodologies for hemophilia factor therapies. The commenter stated that if the AMPs reported to the States under the DRA do not reference the additional furnishing fee for blood clotting factors, they can potentially create inadequate reimbursement. The commenter argued that if States rely solely on the AMPs in setting their reimbursement levels and do not take into account the furnishing fee payment that Congress recognized as critical, then payment amounts may be too low. The commenter recommended we include this information in the AMP data.

Response: We disagree with the commenter. The AMPs to be posted are defined in the laws and these regulations. In accordance with these definitions, AMPs do not include wholesaler or retailer mark-up, dispensing fees, or furnishing fees. Elsewhere in this final rule, we have encouraged States to examine dispensing fees to assess whether they are reasonable. Some of the fees for furnishing hemophilia factors could also be paid in other Medicaid service categories.

Comment: Several commenters offered alternatives to publishing the monthly and quarterly AMPs for each manufacturer's drugs. A few commenters recommended that we publish an aggregated, industry-wide weighted average that combines individual manufacturer AMPs into one AMP for each drug. One commenter suggested that we publish an AMP that represents the weighted average of all of the 11-digit AMPs for the manufacturers' most commonly dispensed retail package size that is widely and nationally available for purchase by community retail pharmacies. This commenter also suggested that CMS release a limited number of AMPs initially to allow the marketplace to assess the validity of the data. This would be similar to the approach CMS used in adopting the use of ASP for Part B drug reimbursement.

Response: We considered these comments, but we want to reiterate our belief, which is supported by the legislative history of the DRA, that the intent in making AMPs available to the public is to bring about increased transparency in prescription drug pricing for the Medicaid Program. The OIG and the GAO have consistently found over the years that Medicaid reimbursement for prescription drugs is well in excess of the cost of the drugs. Limiting access to the data or masking individual manufacturer's data by publishing aggregate AMPs across different manufacturers would counteract the overarching purpose of the Medicaid drug provisions of the DRA.

Comment: One commenter raised concerns over the lack of controls and accountability measures for manufacturers submitting AMP data. The commenter suggested that CMS' processes have been insufficient in monitoring and managing the prescription drug files submitted by manufacturers. The commenter stated that this lack of updated data will undoubtedly result in inappropriate calculations. The commenter also argued that these erroneous calculations will impose an unforeseen burden on States to identify and subsequently report any inaccuracies to CMS. The commenter urged CMS to implement system checks and measures to hold manufacturers accountable for the quality of data they provide, including the reporting or not reporting of accurate data.

Response: We disagree with the commenter. Manufacturers are fully accountable for the accuracy of their data and subject to civil monetary penalties under section 1927(b)(3)(C) of the Act in situations where they report untimely or false information. While we encourage further scrutiny of these AMPs, there is no further burden on the States imposed by this regulation to review those numbers.

Comment: A few commenters raised concerns that the monthly AMP data file that CMS sends to States contains only the drug name. States have to translate the drug descriptions in the file to analyze the impacts of the FUL with their processed claims. In addition, having only the drug name may lead to misinterpretations and lack of identification of applicable products with their NDCs that are necessary to process claims. The commenter recommended that CMS provide on at least a monthly basis descriptive drug information, unique identifiers, and pricing data, and include updated NDC codes to the nationally recognized pricing compendia.

Response: CMS is not considering providing any data to the pricing compendia. CMS has been sending States AMP data files on a monthly basis since July 1, 2006. The AMP data file includes the labeler code, product code, package size code, the calendar month and year of the most recently reported AMP, and the AMP per unit per product code only for the month and year covered, based on the sales. If a drug is distributed in multiple package sizes, there is one weighted AMP for the product. The posted AMPs will also have this level of detail.

Comment: One commenter asked that CMS refrain from making quarterly AMP data publicly available. The commenter contended that only monthly AMP data should be made available. Unlike monthly AMP, which may be used to set reimbursement rates, there is no need for the public to have access to quarterly data, which can lead to confusion.

Another commenter also expressed concern with publishing both monthly and quarterly AMPs on the CMS Web site. The commenter noted that having two different AMP values could lead to confusion. The commenter urged CMS to only publish the last month's AMP data for the quarter. Another commenter urged CMS to publish AMP quarterly, not monthly.

Response: AMPs reported by manufacturers beginning January 1, 2007 are no longer confidential. By

statute, CMS is required to post AMP data on a Web site accessible to the public. CMS has interpreted this provision to mean that we must publicly disclose AMP data, monthly or quarterly, that the manufacturers report.

Comment: One commenter requested that CMS provide the AMP data for numerous drugs covered in the GAO study for review. The commenter was troubled by reports that CMS demanded data to support suggested changes to the AMP definition but refused to make the same data available for public review. In addition, the commenter contended that CMS rejected the findings of the GAO study on the issue and that if CMS was going to dismiss the GAO report it should make a sampling of the AMP data available for the public to review and use in their comments on the proposed rule.

Response: In accordance with section 1927(b)(3)(D) of the Act, AMP data prior to January 1, 2007 are considered confidential and cannot be released to outside parties. CMS rejected GAO's findings because we found GAO's conclusion to be premature, contrary to the DRA AMP revision, and unsupported by the report. The study could not be thoroughly analyzed or replicated because GAO was not willing to release the data on which the study was based.

340B Drug Pricing Program

Comment: Many commenters noted that HRSA has adopted a different definition of AMP from the definition of AMP described in this final rule. In effect, HRSA is asking manufacturers to report two different AMPs; one for Medicaid, and one for the 340B Program. Most of these commenters objected to HRSA's interpretation and urged the Department to encourage consistency between the two agencies. One commenter provided a detailed analysis of alternatives available to CMS and HRSA to resolve the issue, while another noted that requiring different AMP calculations will further strain manufacturer resources. One commenter forwarded us a copy of the letter HRSA issued on January 30, 2007.

Other commenters expressed support for HRSA's position and asked CMS to clarify that the AMP described in this final rule is not applicable in calculating 340B ceiling prices. One commenter urged CMS to support HRSA's interpretation and for CMS to provide the data required for the calculation of two AMPs. The commenter also suggested that this final rule should specify that HRSA will receive the specific data needed to calculate the 340B ceiling prices from drug manufacturers and/or from CMS.

Response: The question of whether HRSA should use the same definition of AMP for the 340B Program that CMS uses for the Medicaid Program is beyond the scope of this regulation. This final rule implements the revisions to AMP and best price as described in the DRA, as well as regulatory provisions related to the Medicaid Drug Rebate Program.

Comment: A few commenters expressed concern with the impact of the provisions in §§ 447.504 and 447.505 on the calculation of prices available to covered entities that participate in the 340B Program under the PHS Act. Commenters also noted that the economic impact estimates do not include the potential costs to the 340B Program and the costs manufacturers incur to meet the 340B Program requirements. Commenters asked CMS to analyze the fiscal effect of these changes and revise the rule in order to retain the most favorable pricing for covered entities.

Response: This final rule is designed to implement the DRA amendments and other provisions concerning the Medicaid Drug Rebate Program, not provisions concerning section 340B of the PHSA. In addition, we note that because the 340B Program is administered by HRSA, that agency, not CMS, is the appropriate source for clarification on the rules for the 340B Program.

Comment: A few commenters urged CMS to exempt hospital outpatient clinics from the requirement to bill Medicaid using the NDC code; otherwise, the facilities represented by the commenters will forego the benefits of 340B Program discounts.

Response: The requirement to bill Medicaid using the NDC code for physician-administered drugs is established by statute; therefore, we are not creating an exemption for such facilities in the final rule.

Comment: Section 6004 of the DRA amends section 1927(a)(5)(B) of the Act to provide a basis for the participation of certain children's hospitals in the 340B Program. A few commenters noted that CMS did not address section 6004 in the proposed rule. One commenter asked HHS to address this provision through a **Federal Register** notice. Other commenters noted that the Medicaid drug rebate statute was amended to include children's hospitals in the definition of ''covered entity'' for purposes of the best price exclusion; however, the definition of ''covered entity'' under the PHS Act was not amended. Commenters asked us to clarify whether prices to such children's hospitals will be eligible for the nominal price exclusion for AMP.

Response: CMS believes that HRSA is the appropriate agency to address the issue of which entities may participate in the 340B Program. As to the question of whether prices to children's hospitals will be eligible for the nominal price exclusion for AMP, section 6004 of the DRA amended section 1927(a)(5)(B) of the Act by adding certain children's hospitals to the definition of covered entity. Section 6004 did not amend the PHS Act, which governs the 340B Program, nor did it amend section 1927(c)(1)(D) of the Act, which addresses the nominal price exemption from best price. Therefore, we do not believe that prices to children's hospitals can be considered within the list of entities addressed in the nominal price exemption.

RPS

Comment: Several commenters raised concern that 6001(e) of the DRA, which provides for a survey of retail prices and State performance rankings, is not addressed in the proposed regulation which does not allow for comment.

Response: The DRA requires the Department to enter into a contract with a vendor to perform the survey. While this provision of the DRA did not necessitate public comment on the method of the survey, when the RPS is published, the methodology will be made available.

Policy Inquiries

Comment: One commenter noted that the drug rebate operations area at CMS has an e-mail address for manufacturers to send operational questions. The commenter asked whether the Division of Pharmacy in CMS' Center for Medicaid and State Operations (CMSO) has a similar resource. If not, the commenter asked to whom manufacturers should send policy inquiries.

Response: Formal policy inquiries should be addressed to the Director of CMSO within CMS.

Cost of Healthcare

Comment: Some commenters noted that a good way to control the cost of healthcare in America is to educate people about prevention, disease management, and the proper use of medications through medication therapy management programs. Other commenters pointed out that it should not be the entire responsibility of pharmacies to mitigate the cost of decreasing expenditures on prescription medication. All parties involved in the

production to dispensing of a prescription medication should share proportionately in the cost sharing involved in reducing medical expenditures.

Response: We appreciate the ideas shared by the commenters about ways to control the cost of healthcare, but at this time, we are not planning to add new provisions to this regulation to control drug costs.

Medicare Part B

Comment: Commenters noted that revisions to the calculation of AMP could cause AMP to decrease for certain drugs and biologicals. A decrease in AMP would increase the likelihood that the applicable threshold percentage will be triggered, forcing the substitution of AMP for ASP under Medicare Part B. In such circumstances, the commenters asked CMS to refrain from substituting AMP for ASP when the threshold is triggered due to the revised definition of AMP.

Response: This issue is not addressed in the proposed rule; therefore, we cannot consider these comments as we consider revisions to be included in the final rule. Issues regarding ASP substitution and the applicable threshold were discussed in recent Medicare notice-and-comment rulemaking concerning the payment for Part B drugs and biologicals (see 71 FR 48981, 49004 (Aug. 22, 2006) and 71 FR 69624, 69680 (Dec. 1, 2006)).

Comment: One commenter noted that CMS advised manufacturers during an Open Door Forum to look to their customary business practices and their AMP procedures for guidance whenever the Act and the ASP regulations left doubts about the proper handling of a particular issue with regard to ASP reporting. Given the similarities between the calculation methodologies for AMP and ASP, the commenter urged CMS to consider including a discussion in the preamble to this final rule explaining when, or whether, manufacturers should apply new instruction from the AMP regulation to their ASP policies. Another commenter asked CMS to clarify that the treatment of bona fide service fee should be the same in ASP as it is for AMP.

Response: These issues are not addressed in the proposed rule; therefore, we cannot consider these comments as we consider revisions to be included in the final rule. Inquiries regarding the definition of ASP should be addressed to the director of the Center for Medicare Management in CMS.

Medicare Part D

Comment: One commenter urged CMS to require electronic data transfer to support community pharmacy's efforts to obtain electronic funds transfer (EFT) reimbursement payment from PBMs for Part D claims submitted via EFT by pharmacies. Other commenters expressed concern that Medicare Part D had already cut pharmacy profits by 30 percent. One commenter noted that independent pharmacies made Medicare Part D work by loaning medicine and taking out loans to make ends meet. Another commenter noted that his pharmacy has stopped charging copayments for Medicare Part D enrollees because they can't afford the copayments.

Response: These issues are not addressed in the proposed rule; therefore, we cannot consider these comments as we consider revisions to be included in the final rule. Questions regarding Medicare Part D should be addressed to the Director of the Center for Beneficiary Choices in CMS.

Comment: One commenter noted that inconsistent policies in Medicaid and Medicare Part D will lead to confusion and burdensome administrative recordkeeping requirements for drug manufacturers, health plans, wholesalers, and pharmacies.

Response: To the extent practicable, we have made every effort to ensure the provisions of this final rule are clear and concise, with the minimum administrative burden for all affected parties. The authorizing statutory provisions for the Medicaid Drug Rebate Program and Medicare Part D are fundamentally different, making it difficult to streamline the regulatory requirements for these two programs.

Industry Price Controls

Comment: One commenter suggested that CMS regulate the pharmaceutical industry so prices would only increase every six months, and there would be a 60-day advance notice of pricing changes. Another commenter suggested that all drug companies should be required to sell their products to all pharmacies at the same price. Other commenters expressed concern that the government is promoting unfair competition because certain purchasers (for example, mail order pharmacies, hospital outpatient department, and outpatient clinics) can receive better prices than independent pharmacies. One commenter suggested that manufacturers be required to report to CMS any anticipated pricing increases with a 90-day advance notice.

Response: This rule is not designed to promote unfair competition or negotiate drug prices. These issues are not addressed in the proposed rule; therefore, we cannot consider these comments as we consider revisions to be included in the final rule.

Comment: One commenter urged CMS to address severe price fluctuations, which currently can take months to address and correct. Another commenter urged CMS to identify atypical manufacturer pricing practices and recommend remedies to Congress to address such practices.

Response: These issues are not addressed in the proposed rule; therefore, we cannot consider these comments as we consider revisions to be included in the final rule.

Comment: One commenter requested that CMS develop a specific methodology for timely verification of the integrity and accuracy of calculations and price information reported by manufacturers.

Response: We appreciate the comment and will work with the OIG in HHS to ensure the integrity of drug rebate data.

State Supplemental Rebate Agreements

Comment: One commenter noted that some States are promoting the use of brand name versions of generically-available drugs because they are receiving supplemental rebates from branded manufacturers that lower the net cost of the brand to that of the generic. This practice has potential negative implications for generic drug use in Medicaid because it can discourage the overall availability of generic drugs in the marketplace. The commenter urged CMS to prohibit States from entering into such agreements with manufacturers.

Response: We believe any adverse impact on generic drug use by the implementation of State supplemental rebates is mitigated by the fact that the overall FULs cap is applied to multiple source brand name drugs as well as generics.

State Rebate Claims

Comment: A few commenters expressed concern with the lack of Federal regulation regarding the time limit for States to submit rebate claims to drug manufacturers under the Medicaid Drug Rebate Program. The commenters noted that CMS (then the Health Care Financing Administration) proposed a 60-day time limit in the 1995 NPRM, but that provision was never promulgated in a final rule. The commenters requested that CMS enact a time frame not to exceed one year to prevent continued State submission of

untimely rebate claims to manufacturers.

Response: We encourage States to submit timely rebate claims to manufacturers, but we are not establishing a regulatory timeframe in this final rule.

Comment: One commenter urged CMS to require States to use an electronic claims system to invoice manufacturers for rebates.

Response: States currently have the option to submit electronic invoices; we are not establishing this as a requirement in this final rule.

Medicaid Eligibility

Comment: One commenter expressed concern with individuals potentially abusing the public health system and costing taxpayers money. Rather than cut reimbursement to pharmacies, CMS should enforce who is covered under the Medicaid and Medicare Programs.

Response: We appreciate the commenter's concerns; however, this issue is not addressed in the proposed rule. We will keep this suggestion in mind for future revisions of the regulations.

Consistency in CMS Policies

Comment: One commenter noted that this final rule should be consistent with established Medicaid rebate policies, definitions and terms set forth in current CMS guidance, such as Medicaid Program Releases and the national rebate agreement created under the OBRA 90. The commenter also believed the final rule should be consistent in treating similarly-situated entities, while recognizing entities that are not similarly situated.

Response: We believe the provisions in this final rule are, in large part, consistent with the policies we have previously adopted. To the extent that we have clarified or revised our policies, we have so noted in the final rule.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

In § 447.300, we updated a statutory reference.

In § 447.502, we added definitions of three terms: lagged price concession, noninnovator multiple source drug, and States. We also moved the definition of bona fide service fee to § 447.504 and clarified that bona fide service fees mean payment for an expense that would have been paid by the manufacturer at the same rate had these services been performed by the manufacturer or other entity. We also clarified that bona fide service fees are paid by a manufacturer to an entity.

In § 447.502, in the definition of dispensing fee, we inserted ''or service'' after, ''is incurred at the point of sale.''

In § 447.502, we clarified that an innovator multiple source drug includes an authorized generic drug. We also clarified that term to include any labelers operating under the NDA.

In § 447.502, we clarified that a single source drug includes a covered outpatient drug approved under a BLA.

In § 447.504(c), we revised the definition of customary prompt pay discount by inserting ''frame and consistent with industry standards and normal business practices for payment'' after ''a specified time.''

In § 447.504(d), we revised the definition of net sales by inserting ''except customary prompt pay discounts extended to wholesalers,'' after ''cash discounts allowed.''

In § 447.504(e), we removed PBMs from the definition of retail pharmacy class of trade. We also removed entities that arrange for the purchase of drugs from this definition.

In § 447.504(f), we removed ''a pharmacy, chain of pharmacies, or PBM'' and ''arranges for the sale of'' from the definition of wholesaler. We also inserted ''those entities in the retail pharmacy class of trade'' after ''including.''

In § 447.504(g)(3) and (h)(4), we clarified that direct and indirect sales to hospitals that cannot be identified with adequate documentation as being used in the outpatient pharmacy for outpatient use are not included in AMP.

In §§ 447.504(g)(6), 447.504(h)(22), and 447.504(i)(1), we clarified that discounts, rebates, or other price concessions to PBMs are excluded from the determination of AMP, except for purchases through the PBMs' mail order pharmacies.

In § 447.504(g)(8), we clarified that sales to outpatient facilities (for example, clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers) are included in AMP.

In §§ 447.504(g)(9) through (13), we added sales to home infusion providers, specialty pharmacies, home health care providers, and physicians to the list of sales included in AMP.

In § 447.504(g)(15), we removed manufacturer coupons redeemed by any entity other than the consumer from the list of entities included in AMP. In § 447.504(h)(15), we clarified that manufacturer coupons redeemed by an agent, pharmacy, or other entity acting on behalf of the manufacturer are excluded from AMP. We further clarified that such coupons are excluded as long as the full value of the coupon is passed on to the consumer, pharmacy, agent, or other entity does not receive any price concession.

In § 447.504(g)(15), we clarified that sales of drugs reimbursed by third party payers are included in AMP, provided such drugs are provided to the retail pharmacy class of trade. We further clarified that third party payers include a qualified retiree prescription drug plan under section 1860D–22(a)(2) of the Act, HMOs and MCOs that do not purchase or take possession of drugs, and TRRx. In § 447.504(h)(23) we added associated rebates, discounts, or other price concessions to third party payers including the Medicare Part D Program, an MA–PD, a qualified retiree prescription drug plan under section 1860D–22(a)(2) of the Act, SCHIP, SPAPs, TRRx, and Medicaid programs to the list of prices excluded from AMP.

In § 447.504(h)(5), we clarified that sales to HMO or MCO-operated pharmacies that purchase or take possession of drugs are excluded from AMP.

In § 447.504(h)(6), we clarified that sales to nursing facility pharmacies, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities, are excluded from AMP.

In §§ 447.504(h)(7) through (12), we added sales to hospices (inpatient and outpatient), veterinarians and prisons, sales outside the 50 States and the District of Columbia, sales to State, county, and municipal entities, and sales to patient assistance programs to the list of sales excluded from AMP.

In § 447.504(h)(16) and (17), we added that manufacturer vouchers and manufacturer-sponsored drug discount card programs are excluded from AMP.

In § 447.504(h)(19), we clarified that bona fide service fees to any entities included in the retail pharmacy class of trade are excluded from the determination of AMP.

In § 447.504(h)(21), we clarified that returned or replaced goods, when accepted or replaced in good faith, are excluded from AMP.

In § 447.504(h)(24), we added Medicaid rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement are excluded from AMP.

In § 447.504(i)(1), we clarified that AMP includes cash discounts except

customary prompt pay discounts extended to wholesalers. We also clarified that other fees are included in AMP.

In § 447.504(i)(2), we revised the methodology for calculating quarterly AMP to be the weighted average of monthly AMPs in the quarter.

In § 447.505(c)(2), we deleted PBMs from the list of entities included in best price. We also added ''PBM rebates, discounts, or other price concessions except mail order purchases'' to the list of prices excluded from best price in § 447.505(d)(13).

In § 447.505(c)(12), we removed ''manufacturer coupons redeemed by any entity other than the consumer'' from the prices included in best price. We also added manufacturer coupons redeemed by an agent, pharmacy or other entity acting on behalf of a manufacturer, as long as the full value of the coupon is passed on to the consumer and the pharmacy, agent or other entity does not receive any price concession, to the list of prices excluded from best price in § 447.505(d)(8).

In § 447.505(d)(3), we limited the SPAP best price exemption to any prices or price concessions provided to designated SPAPs.

In § 447.505(d)(4), we deleted TRICARE from the list of prices excluded from best price.

In § 447.505(e)(2), we clarified the reference to the nominal price provisions in § 447.508.

In § 447.506(a), we removed the phrase ''directly or indirectly'' from the definition of authorized generic drug.

In § 447.506(b), we revised the initial provision requiring the manufacturer holding title to the original NDA to include the authorized generic sales of the secondary manufacturer in the AMP of the brand drug by specifying that the manufacturer holding title to the original NDA of an authorized generic must include the sales of authorized generics in the AMP of the manufacturer holding title to the original NDA only when the products are sold directly to a wholesaler.

In § 447.506(c), we removed the initial provision that requires the manufacturer holding title to the original NDA to include the sales of the secondary manufacturer in the best price of the brand drug. We added language that would require sales from the manufacturer holding title to the original NDA to the secondary manufacturer to be included in the best price of the manufacturer holding title to the original NDA. We also added language to state that the best price is the lowest price at which the authorized generic drug is sold.

In § 447.510(a)(3), we clarified that customary prompt pay discounts shall be reported for each covered outpatient drug at the 9-digit NDC level. We also clarified that this term includes discounts provided to all wholesalers in the rebate period.

In § 447.510(a)(4), we clarified that nominal prices include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) of this subpart.

We added § 447.510(b)(2) to specify that manufacturers should not revise AMP when the revision would solely be as a result of data pertaining to lagged price concessions.

In § 447.510(c)(1), we changed the timeframe in which a manufacturer must report base date AMP to CMS from the first full calendar quarter following publication of this final rule to the first four full calendar quarters following publication of this final rule.

In § 447.510(c)(2)(i), we clarified that a manufacturer's recalculation of base date AMP must only reflect the revisions to AMP as provided for in § 447.504 of this subpart, as opposed to § 447.504(e) of the same.

In § 447.510(c)(2)(ii), we added a provision to allow a manufacturer to choose to recalculate base date AMP on a product-by-product basis.

In § 447.510(c)(2)(iii), we added a provision to require manufacturers to use actual and verifiable pricing records in the calculation of base date AMP.

In § 447.510(d)(2), we revised the reg text by removing the reference to § 447.504 and replacing it with the requirement that monthly AMP should be calculated as the weighted average for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month. We also added a requirement that a manufacturer must estimate the impacts of its lagged price concessions using a 12-month rolling average to estimate the value of those discounts.

In § 447.510(d)(3), we removed the prohibition against reporting revised monthly AMP and replaced it with a requirement that a manufacturer report revisions to monthly AMP to CMS for a period not to exceed 36 months from the month in which the data were due.

We added § 447.510(d)(4) to prohibit manufacturers from reporting revisions to monthly AMP if the revisions would be solely as a result of data pertaining to lagged price concessions.

We added § 447.510(d)(5) to address monthly AMP reporting requirements for terminated products.

In § 447.510(e)(3), we added a provision to allow pricing reports to be certified by an individual other than a CEO or CFO who has authority equivalent to a CEO or a CFO.

In § 447.510(e)(4), we allowed pricing reports to be certified by an individual who has the directly delegated authority to perform the certification on behalf of a CEO, a CFO, or an individual with authority equivalent to a CEO or a CFO.

In § 447.512(c)(1), we added language that would allow a physician to indicate that a specific brand is necessary when prescribing by an electronic means.

In § 447.514(a)(1)(ii) we deleted ''list the drug which has met'' and ''based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

In § 447.514(c)(2), we changed ''30 percent'' to ''40 percent'' per the outlier policy which will be implemented during the period of the final rule with comment period.

In § 447.514(c)(3), we clarified the regulation text by replacing ''innovator single source'' with ''brand name.''

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

Section 447.510 Requirements for Manufacturers

Section 447.510 states that a manufacturer must report, electronically, product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. In addition, customary prompt pay discounts and nominal prices must be reported quarterly. Detailed information

pertaining to the manufacturer's reporting requirements is located under §§ 447.510(a), (b), (c), (d), and (e).

The burden associated with these new requirements is the time and effort it would take for a drug manufacturer to gather product and pricing information and submit it to CMS in an electronic format. We estimate that these requirements would affect the approximately 550 drug manufacturers that currently participate in the Medicaid Drug Rebate Program. Our current reporting and recordkeeping hour burden for each manufacturer in the Medicaid Drug Rebate Program is 71 hours per quarter or 284 hours annually. We believe the new reporting requirements will require less than half of this time. Specifically, we believe it would take each manufacturer 31 hours per quarter or 124 hours annually to report additional new information to CMS. The total estimated burden on all drug manufacturers associated with the new requirements under § 447.510 is 68,200 annual hours. These new reporting requirements for drug manufacturers participating in the Medicaid Drug Rebate Program associated with the Medicaid Drug Program Monthly and Quarterly Reporting Form (CMS–367) are approved under OMB# 0938–0578. CMS will revise this collection to include changes in burden based upon this regulation.

Section 447.510(f) requires a manufacturer to retain records (written or electronic) for ten years from the date the manufacturer reports data to CMS for that rebate period. The ten-year time frame applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised quarterly pricing data subsequently submitted to CMS. As stated under § 447.510(f)(2), there are certain instances when records must be maintained beyond the ten-year period.

While this requirement is subject to the PRA, the retention of quarterly data is not a new requirement and is currently approved under OMB# 0938–0578. While this requirement will now also apply to monthly AMP data, we believe a similar set of data is now retained to support the quarterly retention requirement. It may require some additional record-keeping to retain the monthly, as well as the quarterly data, in the AMP system for manufacturers that do not retain this information there now. However, we believe that most manufacturers already have such monthly sales data (for example, data of sale information) in their system and transferring this to the system for calculating monthly AMP would not be a significant burden.

Section 447.520 FFP: Conditions Relating to Physician-Administered Drugs

Section 447.520 requires providers, effective January 1, 2007, to submit claims to the State for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

Assuming all States impose this requirement, the burden associated with this requirement is the time and effort it would take for a physician's office, hospital outpatient department or other entity (for example, non-profit facilities) to include the NDC on claims submitted to the State. We estimate this requirement would affect an excess of 20,000 physicians, hospitals with outpatient departments and other entities that would submit approximately 3,910,000 claims annually. We believe this would take approximately 15 seconds per claim. We estimated the cost based on the average annual wage and benefits paid for office and administrative support services in 2006 of $21.14 per hour (*www.bls.gov/news.release/pdf/ecec.pdf*). The per claim cost would be under nine cents.

Many hospital outpatient departments will also need to modify their billing systems to capture the NDC on Medicaid claims (hospitals that receive discounted drugs and bill Medicaid at the actual acquisition cost of the drug and hospitals that use a drug formulary system and bill at the hospital's purchasing cost are exempted). The American Hospital Association (AHA) in 2002 estimated that it would cost $200,000 per hospital for changes needed to use NDC codes for billing. Inflating this figure by the Consumer Price Index (CPI) would make the current cost approximately $230,000 for each of the 5,655 hospitals that participate in Medicaid for the total cost to be $1.3 billion.

We are not adopting this estimate as we believe it to be high. This estimate was developed in 2002 to implement a stand alone NDC system from scratch. Since its development, FDA in 2004 issued a final rule requiring drug manufacturers to include Uniform Product Codes (bar codes) with NDC numbers on drug packages. In their final rule, FDA estimated a significant percent of hospitals would voluntarily start to implement bar-coding systems, in order to lower the number of medication errors and to realize other efficiency gains. Consistent with FDA's findings, some commenters noted that hospitals are planning to use bar codes on drugs in the future. When use of these codes is adopted, hospitals will be able to take the NDC from the bar code when billing Medicaid, minimizing the cost of implementing this provision.

Section 447.520(c) allows States requiring additional time to comply with the requirements of this section to apply for an extension. The burden associated with this requirement is the time and effort it would take for each State to apply for a one-time extension. We estimate that it would take five hours for each State to apply for the extension; however, we believe that only a few States will apply. Therefore, we believe this requirement to be exempt as specified at 5 CFR 1320.3(c)(4). We believe the total estimated annual burden for this rule is 84,492 hours.

OMB No.	Requirements	Number of respondents	Number of burden hours	Total annual burden
0938–0578	447.510	550 Drug Manufacturers	31 hours per quarter	68,200 hours.
None	447.520	20,000 Physicians	15 seconds per claim	16,292 hours.
None/Exempt	447.520(c)	Less than 10 States	NA	NA.
Total Annual Burden				84,492 hours.

We have submitted a copy of this final rule to the OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by the OMB.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attn: Melissa Musotto, [CMS–2238–FC] Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office

Building, Washington, DC 20503, Attn: Katherine Astrich, CMS Desk Officer, CMS–2238–FC, *katherine_astrich@omb.eop.gov*. Fax (202) 395–6974.

Comments and Responses on Collection of Information Requirements

A. Section 447.510 Requirements for Manufacturers

Comment: Some commenters stated that CMS greatly underestimated the burden on pharmaceutical manufacturers, including manufacturers that are small businesses, to implement the additional reporting requirement. Commenters asserted that the burden would be significant to implement a new methodology for AMP calculations while quickly implementing monthly reporting of AMP and quarterly reporting of both customary prompt pay discounts and nominal prices. Commenters did not provide revised estimates of the increased hourly annual burden on manufacturers. They believed that CMS' estimated 31 hours per quarter is low by several hundred hours. Some commenters noted that pharmaceutical companies must pay to modify their drug price reporting systems, hire and train additional personnel to meet the reporting requirements, change operating procedures and government pricing systems, and dedicate additional employees to Medicaid price reporting.

Response: Because the comments contained general estimates, but did not provide adequate documentation of the estimates of burden on manufacturers, we have no basis to revise the estimates; therefore, we have retained the same estimates in the final rule.

Comment: One commenter asserted that the estimated start-up cost per manufacturer to implement the rule significantly exceeds the $50,000 estimate stated in the proposed rule. The commenter suggested that CMS should conduct industry surveys on implementation costs before making such proposals.

Response: The public comment process, of which this comment is a part, is intended to provide an opportunity for interested parties to submit additional information for us to consider before we finalize the estimates. We are not required to conduct a survey and, given the timeframe for issuance of this rule mandated by the DRA, do not have the time and resources to do so.

Comment: One commenter stated that completing monthly AMP data will be very demanding, especially for smaller manufacturers. The commenter further explained that this burden is increased because the monthly AMP data will be collected using an internet-based system that requires manual data entry by the manufacturer rather than capturing data from an existing system. The commenter further asserted that this will have a major impact to manufacturers.

Response: The commenter did not document the additional burden on manufacturers. We continue to believe that the estimates from the proposed rule best represent the costs that will be incurred by manufacturers. The new data collection system offers two types of data transmission, on-line data entry and file transfer to accommodate the manufacturers that use a file transfer. The new Web-based data collection method should not place any additional burden on manufacturer's existing systems.

Comment: Another commenter asserted that the approximate $50,000 start-up cost per drug manufacturer appears quite low and that most of their larger pharmaceutical manufacturing clients have already spent more than this amount. The commenter further stated that the $50,000 start-up estimate does not include the ongoing impact of additional resources required to oversee the twelve additional annual submissions required by monthly AMP reporting and inclusion of authorized generics in AMP and best price.

Response: Our estimate includes the costs to hire one full-time employee (FTE) to undertake the new reporting requirements for larger manufacturers and one half FTE costs for small manufacturers; therefore, we have retained the same estimated ongoing burden in the final rule.

Comment: The commenter believed that the start-up burden for complying with the requirements of the proposed rule of $50,000 and 208 hours greatly underestimate the costs of developing a system for allocating bundled sales. The commenter further suggested redefining a bundled sale and how such a sale should be treated for purposes of determining AMP and best price.

Response: The requirement for allocating discounts for bundled sales is not new with this regulation. Further discussion of the requirements for bundled sales is discussed earlier in this preamble.

Comment: Commenters asked about how customary prompt pay discounts and nominal pricing data is to be reported and noted that they believe that these new data reporting requirements will have a major impact on manufacturers.

Response: We are adopting in the final rule a quarterly reporting policy and will collect a single dollar value for nominal and customary prompt pay discounts for each drug. This is the minimal collection possible under the statute.

B. Section 447.520 FFP: Conditions Relating to Physician-Administered Drugs

Comment: Many commenters stated that the RIA concerning the collection of NDCs on outpatient hospital claims was seriously understated. These commenters said that most, if not all, hospital patient accounting systems are not designed to capture NDC data. One commenter estimated that a short-term workaround would require 500 to 1,500 hours per hospital to design, build, and test. Other commenters estimated the cost to be from $.25 to $10 per dose. One commenter estimated the systems changes necessary to automate the process to cost $1.7 million over five years per hospital. Several commenters cited the cost estimate of $200,000 per hospital, or $1.3 billion for all hospitals, that was presented by the AHA when the final regulation for electronic health data standards for hospitals was under development in 2002. Other commenters estimated annual costs to update systems with ever-changing NDCs to be up to $200,000 per hospital per year. Many commenters noted that these costs far exceed the projected saving of $179 million over five years to Medicaid for this provision.

Response: Based on the comments received, we believe that we may have underestimated the costs to outpatient departments of hospitals. The estimates provided by commenters varied widely and commenters offered little documentation to support their estimates. We have revised the Impact Analysis to acknowledge an estimate, cited by some commenters, provided by the AHA on the proposed rule to adopt modifications to standards for electronic transactions published by the Office of the Secretary on May 31, 2002 (67 FR 38047–38048). The AHA estimated that it would cost a minimum of $200,000 per hospital for hospital outpatient departments to switch from using HCPCS to NDCs. Costs would vary based on the size of the facility. If this estimate is accurate, the present cost, updating this amount by the CPI from 2002 to 2007 the cost would be $230,000 for the 5,655 hospitals that participate in the Medicaid Program, or a total of $1.3 billion.

We do not accept that the cost would be this high. We note, as did some commenters, that the Food and Drug Administration is planning on requiring drug manufacturers to place Uniform

Product Codes (bar codes) on drug products which will include the NDC of the drug. Commenters stated that hospitals are transitioning to use the bar codes on the drugs they dispense. Bar coding will allow hospitals to bill Medicaid with NDCs.

Comment: Many commenters reported that outpatient hospital billing systems capture the NDC only for the primary drug. Hospitals often restock with the same drug of a different manufacturer, without recording the NDC for the restocked drug. Similarly, hospitals are increasingly using automated drug dispensing machines, which do not accommodate multiple NDCs. Drug products of multiple manufacturers are used in a single slot in the machines. The machines do not have the capacity to separate drugs by NDC.

Response: We acknowledge that many hospitals will need to change their procedures to comply with this billing requirement. However, the statute requires States to collect utilization data with respect to covered outpatient drugs in order to identify the manufacturer of the drug to secure rebates.

Comment: Several commenters raised other technical difficulties with recording an accurate NDC on the claim. These include the complexity of translating from units purchased to the amount of the drug dispensed and how to track and record multiple NDCs when a drug administered is comprised of multiple drugs or the same drug from multiple manufacturers; for example, with compounded drugs or injectible drugs.

Response: We recognize that many hospitals will need to institute new procedures to obtain the information with respect to covered outpatient drugs that is required by the statute for billing Medicaid agencies.

Comment: Several commenters noted that the requirement for billing using NDC codes would apply only to Medicaid patients, but that the clinicians delivering the medications do not know the source of payment for patients.

Response: We understand from the comments received that hospitals may need to change procedures to meet this new requirement.

Comment: One commenter said that physician billing systems currently allow for one HCPCS code and cannot accommodate multiple NDCs. The commenter also said that discussions with vendors of billing systems have not offered a solution to accommodate NDCs.

Response: The statute, as revised by the DRA, requires States to collect NDCs with respect to covered outpatient drugs so that they can collect rebates from drug manufacturers. Physician offices and their vendors may need to revise systems as necessary to comply with this new requirement.

Comment: One commenter stated that the claims processing system in the Medicaid agency in his State is incapable of processing outpatient pharmacy claims billed with the NDC, so that his hospital would incur additional costs, but it would not yield additional revenue to Medicaid.

Response: The statute requires States to implement this provision or lose FFP for the drugs administered. The statute requires States to collect NDCs with respect to covered outpatient drugs in order to identify manufacturers and secure rebates. If a State cannot implement the provision, it may request a waiver from the Secretary until the State can come into compliance.

Comment: Several commenters believed that the Regulatory Impact Statement should reflect costs to State Medicaid Agencies for outreach and education of providers concerning this requirement.

Response: We agree that States will incur some costs for outreach and education of physicians and outpatient hospital staff. We have not included State administrative costs. We note again, as we did in the proposed rule, that States will save considerably more from this regulation than the costs they will incur to implement it.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132, and the Congressional Review Act (CRA, 5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258, which reassigns responsibility of duties) directs 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). An RIA must be prepared for major rules with ''economically significant'' effects ($100 million or more in any 1 year). We believe this rule will have an economically significant effect. We believe the rule will save $8.4 billion over the next 5 years ($4.93 billion Federal savings and $3.52 billion State savings as shown in the table below). This figure represents a 5.6 percent reduction in total Medicaid drug expenditures in Federal fiscal years 2007–2011. We consider this final rule with comment to be a major rule for purposes of the CRA.

STATE AND FEDERAL SAVINGS OVER 5 YEARS

[In millions]

DRA section and provision	FFY Federal State	2007	2008	2009	2010	2011	2007–11 total savings
Section 6001—Federal Upper Payment Limits and Other Provisions	Federal	$465	$750	$1,075	$1,155	$1,250	$4,695
	State	330	535	765	825	890	3,345
	Total	795	1,285	1,840	1,980	2,140	8,040
Section 6002—Rebates on Physician-Administered Drugs.	Federal	18	19	20	22	24	103
	State	13	14	15	16	18	76
	Total	31	33	35	38	42	179

STATE AND FEDERAL SAVINGS OVER 5 YEARS—Continued

[In millions]

DRA section and provision	FFY Federal State	2007	2008	2009	2010	2011	2007–11 total savings
Section 6003—Reporting of Authorized Generics for Medicaid Rebates	Federal	10	25	28	32	36	131
	State	7	19	21	24	27	98
	Total	17	44	49	56	63	229
Total Savings for FFY	Federal	493	794	1,123	1,209	1,310	4,929
	State	350	568	801	865	935	3,519
	Total	843	1,362	1,924	2,074	2,245	8,448

All savings estimates were developed by the Office of the Actuary (OACT) in CMS. We note that the CBO, in its estimates of the budgetary effects of these provisions of the DRA, reached an almost identical estimate for these years, about $4.8 billion in Federal outlay reduction compared to the CMS estimate of $4.9 billion.

Savings estimates for section 6001 of the DRA—FULs and other provisions—were derived from simulations of the new FULs performed using price and utilization data from the Medicaid Drug Rebate Program combined with generic group codes from First DataBank. Percent savings from these simulations developed by CMS' OACT were applied to project Medicaid prescription drug spending developed for the President's fiscal year 2007 budget. Savings were phased in over 3 years to allow for implementation lags. On the previous chart, the estimate for FFY 2007 through FFY 2010 includes $5 million for the RPS.

The savings estimates for section 6002 of the DRA—rebates on physician-administered drugs—are based on the 2004 OIG report, ''Medicaid Rebates for Physician-Administered Drugs.'' A key finding of the report is the amount of additional rebates that could have been collected in 2001 if all States had collected rebates on physician-administered drugs. This amount was then projected forward using historical data (2001–2005) and projections consistent with the 2007 President's Budget forecast for Medicaid spending to develop the total estimated impact.

The savings estimates for section 6003 of the DRA—Reporting of authorized generics for Medicaid rebates—were developed by CMS' OACT and are based on the consensus of Medicaid experts and the review of available and relevant data. After estimating the impact of the proposal in the first year of implementation, the total impact was projected using assumptions consistent with the 2007 President's Budget forecast for Medicaid spending as well as adjustments given that the proposal is limited to a subset of the prescription drug market.

None of the estimates include Federal or State administrative costs. We believe these costs will be small as they involve changes in work processes rather than new activities. The resulting program savings will be many times these costs.

The RFA requires agencies to prepare a regulatory flexibility analysis and to analyze options for regulatory relief of small businesses and other small entities if a proposed or final rule would have a ''significant impact on a substantial number of small entities.'' For purposes of the RFA, small entities include small businesses, non-profit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, three types of small business entities are potentially affected by this regulation. They are small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, small retail pharmacies, and physicians and other practitioners (including small hospitals or other entities such as non-profit providers) that bill Medicaid for physician-administered drugs. We will discuss each type of business in turn.

According to the SBA'S size standards, drug manufacturers are small businesses if they have fewer than 500 employees (*www.sba.gov/size/sizetable2002.html*). Approximately 550 drug manufacturers participate in the Medicaid Drug Rebate Program. We believe that most of these manufacturers are small businesses. We anticipate that this rule will have a small impact on small drug manufacturers. The rule will require all drug manufacturers participating in the Medicaid Drug Rebate Program to submit pricing information (AMP) on each of their drug products on a monthly basis. Currently drug manufacturers are required to submit similar information quarterly. In addition, drug manufacturers will be required to submit two additional pricing data elements—customary prompt pay discounts and nominal prices—on each of their drugs on a quarterly basis. Because drug manufacturers provide nominal prices and customary prompt pay discounts, we believe that these figures are available in the manufacturers' existing data systems and do not require new data collection. Rather, it simply requires that existing information be reported to CMS. For this reason, we believe the burden to be minimal.

In addition, the rule will affect the level of rebates due from manufacturers. The DRA provides that customary prompt pay discounts be excluded from AMP. This will result in higher AMPs and, consequently, higher rebate payments. We have been told informally by manufacturers that customary prompt pay discounts are generally about two percent. We have found no independent source to confirm this percentage. We also do not know what percent of sales qualify for customary prompt pay discounts. Based on this limited information, we believe that the removal of customary prompt pay discounts will cost manufacturers up to $160 million (two percent of $8 billion in rebate payments annually). In this rule, we also will remove sales to PBMs and nursing home pharmacies from AMP as well as provide manufacturers the option to exclude hospital outpatient sales if information is insufficient to accurately identify sales of drugs to hospitals used in the outpatient department. We have been told by industry representatives that nursing home pharmacies and hospitals receive larger discounts than other sectors, thus potentially resulting in an increase in AMP from these changes. Likewise, some commenters believe that the exclusion of PBM sales will increase AMP. However, because we have no independent data on the cost of drugs to these entities, we cannot quantify the

effect of these provisions other than to say that we have been told by the industry that it will increase rebates owed by drug manufacturers. Public comments and responses specifically regarding small businesses including drug manufacturers are discussed under ''Comments and Responses on the Regulatory Impact 6. Effects on Small Business Entities.''

According to the SBA's size standards, a retail pharmacy is a small business if it has revenues of $6.5 million or less in 1 year (*www.sba.gov/size/sizetable2002.html*). The SBA estimates that there are about 18,000 small pharmacies. These pharmacies will be affected by this regulation as the law will result in lower FULs for most drugs subject to the limits, thus reducing Medicaid payments to pharmacies for drugs. The revision to the FULs will generally reduce those limits and, thereby, reduce Medicaid payment for drugs subject to the limits. The savings for section 6001 of the DRA reflect this statutory change. The other provisions concerning payment for drugs will provide States two new data points to use to set payment rates. After their release in January 2007, States may use AMP and retail survey prices in their payment methodologies when they are released. The savings for section 6001 of the DRA do not reflect decreases to State payments for drugs not on the FUL list. As analyzed in detail below, we believe that these legislatively mandated section 6001 savings will potentially have a ''significant impact'' on some small, independent pharmacies. Public comments and responses specifically regarding small businesses including retail pharmacies are discussed under ''Comments and Responses on the Regulatory Impact 6. Effects on Small Business Entities.'' The analysis in this section, together with the remainder of the preamble and the regulatory impact analysis, constitutes a Final Regulatory Flexibility Analysis (FRFA) for purposes of compliance with the RFA, section 605.

According to the SBA's size standards, physician practices are small businesses if they have revenues of $9 million or less in 1 year (*www.sba.gov/size/sizetable2002.html*). Nearly all of the approximately 20,000 physician's practices that specialize in oncology, rheumatology and urology may experience some administrative burden due to new requirements that claims include the NDC for drugs administered by these physicians. These practices will be required to transfer the NDC code for drugs administered by a physician to the electronic or paper claim. We estimate that 3,910,000 claims will be submitted a year. We derived this number by multiplying the 23 million annual Part B claims by the percentage (17) of Medicare beneficiaries who are also Medicaid beneficiaries (Calendar Year 2004 Medicare Carrier Claims Data in the National Claims History extract). We believe most of the Medicaid beneficiaries who receive physician-administered drugs are also in Medicare because of the severity of the medical conditions of people who require these drugs. We then assume that it will take 15 seconds per claim. Multiplying 3,910,000 by 15 seconds equals 58,650,000 seconds or 16,292 hours (58,650,000/3,600 seconds per hour). We multiplied 16,292 hours by the hourly wage and benefit rate of $21.14 for office and administrative staff published by the Department of Labor, Bureau of Labor Statistics for March 2006 to estimate the annual cost to be $344,000. We divided the total cost of $344,000 by the 3,910,000 claims to estimate the cost per claim will be under 9 cents. Calculated another way, the annual cost per physician practice will be under $20 ($344,000 divided by 20,000 equals about $17). Accordingly, we believe that there is no ''significant impact'' on these physicians.

According to the SBA's size standards, hospitals are small businesses if they have yearly revenue of $31.5 million or less (*www.sba.gov/size/sizetable2002.html*). As with physician practices, outpatient units of hospitals will need to include NDCs on claims for physician-administered covered outpatient drugs. Outpatient hospital claims for physician-administered drugs are included in the 3,910,000 annual total claims discussed in the previous paragraph. In addition we believe that most hospitals will need to change their billing systems to capture NDC codes. In 2002 when CMS proposed to rescind the use of NDCs for drug claims submitted by institutional providers, the AHA estimated that these changes would cost hospitals a minimum of $200,000 each ($230,000 in 2007 adjusted by the CPI). Because this estimate is not documented, CMS is not adopting it for purposes of this impact analysis; however, we do accept that hospitals will incur some costs. We do not have an adequate basis to estimate this cost, however, several commenters noted that hospitals are in the process of instituting bar codes on drugs that contain the NDC. This will minimize the cost for hospitals to implement this provision. Other small entities such as non-profit providers may also be affected by this provision. We do not have data to quantify how many of the 3,910,000 annual total claims are submitted by these entities. In any case, the cost will be under nine cents per claim.

Section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. There are approximately 700 small rural hospitals that meet this definition. We do not know how many of these hospitals have outpatient departments. However, we believe that this rule will impact small rural hospitals to the extent that billing systems will need to be changed to capture NDCs on claims for drugs administered by physicians in the outpatient department. We acknowledge the AHA estimate of $200,000 per hospital for these changes ($230,000 in 2007 adjusted by the CPI), but we have no documentation to analyze or verify this estimate. We also believe that hospitals can minimize the cost to the extent that they use bar codes on the drugs they dispense, as this will identify the NDC of the drug needed to bill Medicaid.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates on States and private entities require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $125 million. This rule will mandate that drug manufacturers provide information on drug prices, and that these data be used in calculating FULs. However, our estimate of costs to manufacturers (see next section: Effects on Drug Manufacturers) falls far below the threshold and we anticipate this rule will save States $3.5 billion over the five-year period from October 1, 2006 through September 30, 2011.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this rule will impose only minimal new administrative burden on States and yield substantial savings to States, we believe that these costs can be

absorbed by States from the substantial savings they would accrue.

B. Anticipated Effects

1. Effects on Drug Manufacturers

As previously indicated, approximately 550 drug manufacturers participate in the Medicaid Drug Rebate Program. The rule will require all drug manufacturers participating in the Medicaid Drug Rebate Program to submit pricing information (AMP) on each of their drug products on a monthly basis. Currently drug manufacturers are required to submit similar information quarterly. In addition, drug manufacturers will be required to submit two additional pricing data elements—customary prompt pay discounts and nominal prices—on each of their drugs on a quarterly basis. We believe that drug manufacturers currently have these data; therefore, the new requirement will not require new data collection. Rather it simply requires that existing information be reported to CMS. For this reason, we believe the burden to be minimal. The estimated startup burden to the manufacturers is $27.5 million for a one-time systems upgrade, or $50,000 for each of the 550 manufacturers that participate in the Medicaid Drug Rebate Program. To estimate the ongoing burden, we expect that the manufacturers will each spend 208 hours annually (114,400 total hours annually) in complying with these requirements. The estimated annual operational expenses are $5.7 million, which is 114,400 total annual hours multiplied by $37.50 per labor hour in wages and benefits, or $4.3 million in labor burden, plus $1.4 million in technical support.

In addition, the proposed regulation would affect the level of rebates due from manufacturers. The DRA provides that customary prompt pay discounts be excluded from AMP. This will result in higher AMPs and, consequently, higher rebate payments. We have been told informally by manufacturers that customary prompt pay discounts are generally about two percent. We have found no independent source to confirm this percentage. We also do not know what percent of sales qualify for customary prompt pay discounts. Based on this limited information, we believe that the removal of customary prompt pay discounts will cost manufacturers up to $160 million (two percent of $8 billion in rebate payments annually). In this rule, we also will remove sales to PBMs and nursing home pharmacies from AMP and allow drug manufactures to exclude sales to outpatient departments of hospitals when data is not available to separate out drugs administered in the outpatient department from the hospital as a whole. We have been told by industry representatives that PBMs, nursing homes and hospital pharmacies receive larger discounts than other sectors. If this information is accurate, removing these prices will increase AMP. However, because we have no independent data on the cost of drugs to these entities, we cannot quantify the effect of this provision other than to say that we believe it will increase rebates owed by drug manufacturers.

2. Effects on State Medicaid Programs

States share in the savings from this rule. As noted in the table above, we estimate 5-year State savings of over $3.5 billion. State administrative costs associated with this regulation are minor as States currently pay at or below the FUL for drugs subject to that limit, determine their drug reimbursement rates, and collect claims information on physician-administered drugs.

3. Effects on Retail Pharmacies

Retail pharmacies would be affected by this regulation, as the law will result in lower FULs for most drugs subject to the limits, thus reducing Medicaid payments to pharmacies for drugs. The revision to the FULs would generally reduce those limits and, thereby, reduce Medicaid payment for drugs subject to the limits. The savings for section 6001 of the DRA reflect this statutory change. The other provisions concerning payment for drugs would provide States two new data points to use to set payment rates. Beginning in 2007, States may use AMP and retail survey prices in their payment methodologies. The savings for section 6001 of the DRA do not reflect decreases to State payments for drugs not on the FUL list that may result if States change their payment methodologies.

The savings to the Medicaid Program will largely be realized through lower payments to pharmacies. As shown earlier in this analysis, the annual effect of lower FULs and related changes will likely reduce pharmacy revenues by about $800 million in 2007, increasing to a $2 billion reduction annually by 2011. These reductions, while large in absolute terms, represent only a small fraction of overall pharmacy revenues. According to recent data summarized by the National Association of Chain Drug Stores, total retail prescription sales in the United States, including chain drug stores, independent drug stores, and supermarkets totaled about $200 billion in 2006 (*www.nacds.org/wmspage.cfm?parm1=507*). Based on comments, we decided to exclude mail order and reflect only community-based retail sales in the total sales because the savings will principally come from retail pharmacies. Assuming, conservatively, that sales will rise at only five percent a year, 2007 sales would be over $210 billion and 2011 sales over $255 billion, for a 5-year total of $1160 billion. Dividing the $8 billion projected Medicaid savings by the $1,160 billion results in a loss in revenue of less than one percent. Thus, the effect of this rule will be to reduce retail prescription drug revenues by less than one percent, on average. Actual revenue losses will be even smaller because pharmacies have the ability to mitigate the effects of the rule by changing purchasing practices. The 250 percent FUL will typically be lower than the prices available to pharmacies only when one or more very low cost generic drugs are included in the calculation. Pharmacies will often be able to switch their purchasing to the lowest cost drugs and mitigate the effect of the sales loss by lowering costs.

Although it is clear that the effects will be small on the great majority of pharmacies, whether chain or independent, we are unable to estimate quantitatively effects on ''small'' pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. We received general comments that these pharmacies will be greatly impacted by the provisions of this rule; however, we did not receive documented estimates of these effects. Because of the lack of evidence as to the true effect, we have retained our prior conclusion that this proposed rule is likely to have a ''significant impact'' on some pharmacies.

4. Effects on Physicians

This regulation will affect physician practices that provide and bill Medicaid for physician-administered drugs. This includes about 20,000 physicians as well as hospitals with outpatient departments. The effect on physicians is the same as discussed in section A—Overall Impact above for small businesses because all or nearly all physician offices are small businesses.

5. Effects on Hospitals

This regulation will affect hospitals with outpatient departments that provide and bill Medicaid for physician-administered covered outpatient drugs. As discussed above, hospitals with outpatient departments would need to include the NDC on claims for such

physician-administered drugs. We believe this will need to be done manually or will require a one-time systems change. We believe the cost of adding the NDC to each claim would be small. We are not able to estimate the cost to make needed systems changes but note that the AHA has estimated this to be at least $200,000 per hospital ($230,000 in 2007 adjusted by the CPI). We also note that CMS has encouraged States to collect information on physician-administered drug claims to enable them to collect rebates. Some States have required that NDCs be included on claims and others are in the process of doing so. We expect that, in the absence of the DRA requirement, the number of States requiring NDCs on these claims would have increased.

6. Effects on Small Business Entities

As previously discussed, for purposes of the RFA, three types of small business entities are potentially affected by this regulation. This regulation would affect small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, small retail pharmacies, and physicians and other practitioners (including small hospitals or other entities such as non-profit providers).

According to the SBA's size standards, we believe that most of the 550 pharmaceutical manufacturers in the Medicaid Drug Rebate Program are small businesses. We previously indicated that this rule impacts drug manufacturers by requiring them to submit pricing information (AMP) on each of their drug products on a monthly basis with an estimated impact that is minimal. The rule could also increase the amount of drug rebates that manufacturers will pay as a result of removing customary prompt pay discounts and nursing home sales from AMP, which is used in the rebate calculation. To the extent that PBMs are also excluded from best price, the amount of rebates could decrease. The exclusion of customary prompt pay discounts will cost manufacturers up to $160 million (two percent of $8 billion in rebate payments annually). Additional detail regarding the effects of this proposed rule for the determination of drug prices and calculation of drug rebate liability for drug manufacturers is described in the preamble under ''Definition of Retail Pharmacy Class of Trade and Determination of AMP.''

We estimate that 18,000 small retail pharmacies will be affected by this regulation. However, we are unable to specifically estimate quantitative effects on small retail pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. The preamble under ''Definition of Retail Pharmacy Class of Trade and Determination of AMP'' provides additional information regarding the entities included in the retail pharmacy class of trade and the discounts or other price concessions for drugs provided to the retail pharmacy class of trade. As shown earlier, the annual effect of lower FULs and related changes will likely reduce overall pharmacy revenues by about $800 million in 2007, increasing to a $2 billion reduction annually by 2011.

Nearly all of the approximately 20,000 physician practices that specialize in oncology, rheumatology and urology are considered small businesses. The rule could impose some administrative burden on these practices due to new requirements that claims include the NDC for physician-administered drugs. As shown earlier, we believe that the annual cost per claim would be under 9 cents and the annual cost per physician practice would be under $20. Accordingly, we believe that there is no significant impact on these physician practices.

We also previously indicated that this rule may have a significant impact on the operations of small rural hospitals. There are approximately 700 small rural hospitals that meet the small business standard. As previously discussed, small rural hospitals would need to include the NDC on claims for physician-administered covered outpatient drugs through outpatient departments. We do not have data to quantify how many of the overall claims for physician-administered drugs are submitted by these 700 small rural hospitals. In any case, the cost to manually include the NDC on the claim will be under nine cents per claim.

The following chart depicts the number of small entities and the estimated economic impact for each category of small entity affected by this rule.

Small entity	Number affected by rule	Estimated economic impact
Pharmaceutical Manufacturers in Medicaid Drug Rebate Program.	550	$160 million (2 percent of $8 billion) higher rebates result from removal of customary prompt pay discounts from rebate calculations. Other clarifications of AMP may also raise AMP and result in higher rebate payments. Independent cost data not available for excluded nursing home drug sales that are expected to increase rebate cost.
Small Retail Pharmacies	18,000	Reduces overall pharmacy revenues by about $800 million in 2007 increasing to $2 billion annually by 2011. Unable to quantitatively estimate effects on small retail pharmacies, particularly in low income areas.
Physicians in their Offices, Hospital Outpatient Settings or Other Entities (e.g., Non-profit Facilities) that Specialize in Oncology, Rheumatology and Urology.	20,000	Under 9 cents per claim to enter NDC number. About $17 annual cost per physician practice to enter NDC number on claims for physician-administered drugs. Changes in hospital billing systems will be needed for many hospital outpatient departments. Total estimated impact is $344,000.
Small Rural Hospitals	700	Minimal impact.

C. Alternatives Considered

We considered a number of different policies and approaches during the development of the final rule.

With regard to the definition of AMP, we considered one definition for quarterly AMP and a different definition for monthly AMP. However, we believe the better reading of statute is for AMP to be defined the same way for quarterly and monthly reporting.

We also considered redefining the entities included in ''retail pharmacy class of trade'' for purposes of the

definition of AMP. Options considered included whether to include or exclude sales to nursing home pharmacies, PBMs, mail order pharmacies, and hospital outpatient departments. We chose to exclude sales to PBMs and nursing home pharmacies and to allow drug manufacturers to include or exclude sales to hospital outpatient departments depending on the availability of information to document these sales.

We considered retaining the current base date AMP rather than allowing manufacturers to recalculate their base date AMP to reflect the revised definition of AMP. However, we decided that retaining the current base date AMP is not required and it would create a financial burden on manufacturers that was not intended by section 6001 of the DRA.

We considered whether and how to provide for manufacturers to ''smooth'' the AMP data to account for lagged discounts and other changes to monthly sales. We proposed to allow manufacturers to rely on estimates regarding the impact of their lagged price concessions when calculating monthly AMP. We also requested comments on the possible use of a 12-month rolling average. Many commenters asked for a 12-month rolling average as is used for Medicare Part B. Other commenters suggested that we allow manufacturers to use a four quarter rolling average. We have incorporated the 12-month rolling average in the final rule.

We considered adding other entities to those that may receive drugs at nominal prices and have those sales excluded from best price. However, we were concerned that expanding the list of entities eligible for nominal pricing would drive up best price, which would effectively lower the amount of rebates manufacturers pay for Medicaid drugs.

We considered using a non-weighted AMP, which is specific to a package size, to establish the FUL. However, we decided to continue to base AMP on all package sizes for each drug. We did not find any indication that the Congress intended to change how package size is used for AMP. Such a change would be burdensome on manufacturers and would not have a significant impact on how States pay for drugs.

We considered various methods for determining outlier prices in order to avoid the use of such prices in the FUL calculation and to ensure sufficient national supply. We proposed to set the FUL on the lowest AMP that is not less than 30 percent of the next highest AMP for the drug. Based on comments, we considered substituting a greater percentage difference, expanding outliers to include drugs with AMPs above the lowest but below the next highest AMP by a set percentage, and using market share in determining outliers. We decided to change the outlier policy to set the FUL on the AMP that is not lower than 40 percent of the next highest AMP.

D. Other Requirements in the Regulatory Flexibility Act

The RFA lists five general requirements for a FRFA and four categories of burden-reducing alternatives. We know of no relevant Federal rules that duplicate, overlap, or conflict with the final rule. The preceding analysis, together with the rest of this preamble, addresses all these general requirements.

We have not, however, adopted any of the various categories of burden reduction listed in the RFA as appropriate for IRFAs. These alternatives, such as an exemption from coverage for small entities, establishment of less onerous requirements for small entities, or use of performance rather than design standards, simply do not appear to apply in a situation where uniform payment standards are being established. However, we welcome comments with suggestions for improvements we can make, consistent with the statute, to minimize any unnecessary burdens on pharmacies or other affected entities.

E. Accounting Statement

As required by OMB's Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the table below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. This table provides our best estimate of the decreases in Medicaid payments under sections 6001–6003 of the DRA. All expenditures are classified as transfers to the Federal and State Medicaid programs from retail pharmacies and drug manufacturers.

ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FFY 2007 TO FFY 2011

[In millions]

Category	Transfers	Discount rate (percent)	From whom to whom?
Total Federal Savings	$3,927.3	7	Reduction of transfers from the Federal Government to State Governments.
	4,459.0	3	
	4,929.0	0	
Federal Annualized Monetized Transfers (Millions/Year).	957.8	7	
	973.6	3	
	985.8	0	
Total State Savings	2,803.6	7	Reduction of transfers from State Governments to Retail Pharmacies and increased transfers from Drug Manufacturers to the State Governments.
	3,183.3	3	
	3,519.0	0	
State Annualized Monetized Transfers (Millions/Year)	683.8	7	
	695.1	3	
	703.8	0	

F. Conclusion

We estimate savings from this regulation of $8.4 billion over 5 years, $4.9 billion to the Federal Government and $3.5 billion to the States. Most of these savings result from a change in how the FULs on multiple source drugs are calculated and from a change in how authorized generic drugs are treated for AMP and best price. The majority of the savings would come from lower reimbursement to retail pharmacies. The provision on physician-administered drugs does not change the legal liability of drug manufacturers for paying rebates but would make it easier for States to collect these rebates.

While the effects of this regulation are substantial, they are a result of changes to the law.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the OMB.

Comments and Responses on the Regulatory Impact

A. Overall Impact

We have retained most of the original estimates of burden; however, we have updated our impact analysis from what was presented in our December 22, 2006 proposed rule. Our update reflects responses to public comments and improvements to the analysis based on additional information.

B. Anticipated Effects

1. Effects on Drug Manufacturers

Comment: Commenters said that the proposed rule's treatment of PBM rebates will lead to lower AMPs which will reduce the amount of rebates paid by manufacturers for some single source drugs. Commenters further asserted that they do not have access to the data needed to estimate this revenue reduction, but they are confident the losses will be significant.

Response: In this final rule in § 447.504(i), we have excluded PBM rebates, discounts or other price concessions from the determination of AMP and best price, except for purchases through the PBMs' mail order pharmacies. Excluding PBM rebates and price concessions may affect AMP, and, thereby, rebates. However, we do not have information on how manufacturers currently calculate AMP. In its report, the OIG cited inconsistent treatment of PBM rebates by manufacturers in calculating AMP. Therefore, we have no data to estimate the impact of excluding PBM rebates and cannot conclude that the effect would be significant.

2. Effects on State Medicaid Programs

Comment: One commenter expressed concern that States will have insufficient time to prepare to implement the final regulations. States may need to make revisions in the Medicaid Management Information System and manual processes to implement the provisions. States may not have enough staff and funding to meet the deadline. The commenter further stated that the 2006 AMP data received by the States was inaccurate and insufficient to make firm policy decisions. Any changes that are needed to revise the State Medicaid plan or reimbursement structure will take considerable time.

Response: We emphasize that the FUL is the only reimbursement change that States are required to address. States may need to adjust payments to stay below the FUL in the aggregate. Unless otherwise indicated, these regulations are effective on October 1, 2007 and any adjustments will not be necessary until after CMS issues any revised FULs.

Comment: One commenter suggested that the State savings estimate in the proposed rule is overstated unless it took into account that reimbursement is lower than the FUL in those States that have State MAC programs. This would negate some or most of the savings projected in the proposed rule.

Response: The savings estimates for section 6001 of the DRA were derived from simulations of the new FULs compared to States' current reimbursement levels, including use of State MACs; therefore, we do not believe the savings estimates are overstated.

Comment: One commenter expected that the FUL will be below the average retail acquisition cost and that States will have to increase the dispensing fee to offset the reimbursement reduction expected for pharmacies to ensure accessibility to the drugs. State financial support for increased dispensing fees will subsequently decrease the State savings projected in the proposed rule.

Response: We believe that the new methodology for determining AMP will provide for adequate reimbursement and assure the availability of drugs at or below the FUL price for pharmacies.

3. Effects on Retail Pharmacies

Comment: One commenter stated that the FUL estimates should be published so that commenters can thoroughly and accurately analyze the impact of the proposed rule on the pharmaceutical supply chain and on retail pharmacies, especially those in low-income areas that serve a large percentage of Medicaid beneficiaries. The commenter requested that CMS provide the FUL and extend the comment period by a minimum of 60 days.

Response: We share these concerns and we are analyzing the data to ensure that the new FULs will allow States to reimburse generic drugs adequately and appropriately. We continue to believe that the new FUL will be sufficient to allow all pharmacies to purchase most drugs at or below the FUL price. Additionally, we believe that it is important for us to be sure the data is complete and accurate prior to its release. In response to the commenters' request to extend the comment period, we do not believe that we can reopen the comment period and meet the requirement in the DRA that we must promulgate a regulation by July 1, 2007.

Comment: Many commenters indicated that the drug reimbursement levels will be inadequate under the revised formula used to establish the FUL. With inadequate reimbursement anticipated, the independent pharmacies asserted that they would go out of business, leaving Medicaid beneficiaries and other patients with limited access to drugs and resulting in loss of jobs for employees. Other commenters stated that pharmacy profit margins will be reduced so patient drug therapy, medication counseling, prescription services in a single location, home drug delivery, transportation services to the pharmacy, prescription services on holidays and translation services will be eliminated. One commenter stated that it may be necessary to increase fees for some patients in order to cover losses from Medicaid.

Response: We are analyzing the FULs data to ensure that it will allow States to provide adequate reimbursement for generic drugs and avoid any serious consequences to the pharmacy community. Additionally, drugs subject to the FUL represent only 8.3 percent of the total drug expenditures under the Medicaid Drug Rebate Program. Medicaid policy allows States to pay above the FULs as long as total expenditures for FULs drugs do not exceed the aggregate FUL amount which is calculated at 250 percent of the relevant AMP. We are confident that FULs calculations for drug reimbursement will allow States to provide adequate reimbursement.

Comment: Many commenters stated that the lack of access to drugs and prescription use services will lead to increased doctor visits, emergency room care, hospital stays and long-term care expenses, resulting in increased costs for Medicaid.

Response: We are continuing to analyze the new FUL to assure that it is sufficient and adequately reimburses community pharmacies. As we have said elsewhere in this regulation, we believe the system for calculating the FUL will permit pharmacies to be reasonably compensated.

Comment: One commenter noted that this rule will be particularly hard on pharmacies that serve Medicaid beneficiaries who suffer from HIV/AIDS which are often pharmacies which receive almost 50 percent of total revenue from Medicaid and participate in the 340B Program. The commenter further stated that even a ten percent cut in Medicaid reimbursement will render these pharmacies non-viable.

Response: We believe that States will ensure that pharmacies serving HIV/AIDS patients on Medicaid will be

compensated adequately to ensure their continued viability.

Comment: One commenter stated that any changes in Medicaid reimbursement may have the unintended consequence of causing Indian health programs that operate in remote rural areas to close.

Response: We believe that the impact of this regulation will be far less than many commenters believe and that States will be able to set appropriate reimbursement rates under the aggregate FULs to allow pharmacies to continue to serve Medicaid and other vulnerable populations.

Comment: Other commenters noted that the impact on long-term care pharmacies and on rural independent pharmacies has not been addressed adequately in the proposed rule. These commenters believed that reimbursement to long-term care pharmacies should remain at the current levels in order for them to be able to afford to provide the needed services. The commenter would like the impact analysis to address long-term care pharmacies independently from retail pharmacies.

Response: We do not have sufficient data to analyze the impact of this regulation on segments such as long-term care of the pharmacy market. However, states will continue to have flexibility to set reimbursement rates. We believe that States are in the best position to set payment levels to appropriately reimburse different sectors of the pharmacy market.

Comment: One commenter stated that if the FUL decreased reimbursement by $3 to $4 per prescription, as some have asserted, this reduction will exceed the one percent decreased reimbursement estimated by CMS.

Response: CMS estimates that total reimbursement for drugs will, on average, decline by less than one percent. We derived the $8 billion five-year savings by dividing it by an estimated $1,160 billion in total prescription drug revenues for community pharmacies to obtain this figure.

Comment: One commenter noted that analysis in the proposed rule does not take into account decreases in State payments for drugs that are not on the FUL list, which may occur if States use AMP as a reimbursement metric. The commenter suggested that CMS should revise the impact analysis to reflect the projected impact of the use of AMP, rather than AWP, as a reimbursement benchmark for drugs other than those subject to the FUL.

Response: We do not know what changes States may make to reimbursement for drugs not subject to FULs; therefore, we have no basis to estimate possible savings due to the availability of AMP to States.

Comment: Some commenters believed that the estimate of a one percent loss to retail pharmacies should be revised to only reflect community-based retail pharmacy sales and not mail order sales since there is almost no mail order use in Medicaid.

Response: We have reduced the five-year total sales by $50 billion to exclude mail order and reflect only community-based retail pharmacy sales because the savings will principally come from retail pharmacies. Even with removing these sales, our original estimate stands; that is, the total loss in the retail prescription drug revenues will be less than one percent, on average.

Comment: Some commenters believed that the reduction to pharmacy reimbursement will exceed the one percent cited. The commenters indicated that retail pharmacy profit ranges from 2.8 percent to 3.6 percent per prescription. Decreasing reimbursement to pharmacies does not change the prices that pharmacies pay to wholesalers or manufacturers or for their costs to support staff and operate stores.

Response: As stated in our prior response, the one percent reduction is to total revenues for drugs to pharmacies, and does not reflect profit levels. We have no data to analyze the effect of these changes on profits.

Comment: One commenter believed that the one percent estimated Medicaid pharmacy revenue reduction for retail pharmacies should be revised to account for the availability of AMP on the Web site which could result in additional reductions to reimbursements to retail pharmacies such as encouraging other non-Medicaid third party payers that represent a majority of the average retail pharmacy business to use the published AMP as a basis for their reimbursement to pharmacies too. Subsequently, this could potentially result in additional reductions of reimbursement to pharmacies beyond Medicaid.

Response: We agree that there is potential for non-Medicaid third party payers to use the published reimbursement methodology established under this rule. However, we do not know if non-Medicaid third party payers will use AMP for reimbursement or what effect it would have on reimbursement levels.

Comment: Another commenter asserted that the published AMP based on a reliable methodology may provide States with a more accurate estimate of prices available to wholesalers, but that this AMP methodology would not prevent drug manufacturers from continually pricing drugs at a premium.

Response: Neither the DRA or this rule addresses prices set by drug manufacturers.

Comment: One commenter asserted that it is unlikely that pharmacies will have the ability to mitigate the effects of the proposed rule by changing purchasing practices.

Response: We believe that pharmacies will find it in their interest to seek the lower cost drugs.

Comment: One commenter stated that when manufacturer prices are public, the manufacturers will no longer offer better prices to move the market share. In addition, if the manufacturers are forced to lower the prices to certain purchasers, they may need to make up for the loss by raising prices to larger buyers. Public posting of prices would lead to comparable or identical prices and would reduce incentives to offer lower prices because price increases would increase revenues and result in higher reimbursements to retail pharmacies.

Response: We believe that transparency in pricing will introduce competition in the marketplace that will result in more appropriate drug pricing.

Comment: One commenter expressed concern that the private PBMs sector will decrease their reimbursement levels and this could lead to a loss of revenue to pharmacies and cause them to go out of business.

Response: As previously stated, we believe that Medicaid reimbursement will be sufficient to retain access to drugs for Medicaid beneficiaries and that transparency in pricing will introduce competition in the marketplace.

Comment: A few commenters asserted that it is unlikely that most retail pharmacies can make up the estimated loss of pharmacy revenue with increased front-end store sales and sales of non-prescription drug products as these sales are a minority of total sales in most retail pharmacies. In addition, pharmacies would need to invest in larger front-end areas, relocate stores to high visibility areas, add staffing, and make other changes that many pharmacy retailers may not be able to afford or want to do. The commenters said that non-prescription revenue in chain pharmacies is 28 percent of total sales, and only 2 percent of total sales in independent pharmacies.

Response: We agree that we cannot assess the ability of pharmacies to increase non-drug revenue and have removed this language from the impact analysis.

Comment: One commenter asserted that the $8 billion estimated savings in the RIA will be generated from the reduced reimbursement for multiple source drugs. Savings of $8 billion out of $27 billion in spending for generic drugs equates to a 30 percent reduction in reimbursement for generic drugs. Several commenters believed that this change to a lower reimbursement will not cover the pharmacy's acquisition costs of purchasing generic medications.

Response: The new FUL could reduce Medicaid payments to a more reasonable amount and eliminate the opportunity for profits through the reporting of artificially inflated prices. We agree that most of the savings result from lower prices paid for multiple source drugs, as this is what the DRA intended; however, we continue to believe that it is appropriate to compare the savings to overall revenues of drugs to show the impact on pharmacies. As we have said elsewhere in this regulation, we believe the system for calculating FUL will permit pharmacies to be reasonably compensated.

Comment: Many commenters asserted that a reduction of $8 million in generic drug reimbursement could have a considerable impact on incentives to dispense medications when pharmacies have a choice of dispensing brand versus generic drugs. The commenter believed that pharmacies will receive far less revenue from a generic drug rather than it will with a brand name drug. When brand products are dispensed to Medicaid beneficiaries, they are likely to be paid above the FUL due to a ''dispense as written'' designation.

Response: The commenters correctly note that a brand name drug in a FUL group is subject to the FUL unless the physician asserts that the brand name drug is medically necessary for the Medicaid beneficiary. States frequently require prior authorization for dispensing a brand name drug; therefore, we do not agree that pharmacists will be able to substitute brand name drugs over generic drugs. Many States also have been requiring the substitution of a generic drug for a brand name drug; therefore, pharmacies do not always have a choice to substitute a brand drug for a generic drug.

Comment: Commenters referred to findings in the GAO report that said the AMP-based FULs would be, on average, 36 percent lower than the average retail pharmacy acquisition cost.

Response: We do not concur with the GAO findings that the AMP-based FUL would be lower than average retail pharmacy acquisition cost. The GAO report looked at drugs subject to the FUL, which are 8.3 percent of Medicaid expenditures. The GAO also did not remove customary prompt pay discounts or outlier AMPs when calculating FULs as provided in this final rule, or account for the ability of States to set reimbursement levels below or above the FUL as long as expenditures for FUL drugs are less than the aggregate of all FUL prices. We also were not provided the price data used by the GAO. For these reasons, we do not concur with GAO's conclusion.

Comment: Several commenters estimated their losses based on the 36 percent reduction reported in the GAO report.

Response: As noted above, the GAO report only applies to drugs with a FUL which currently accounts for 8.3 percent of Medicaid drug expenditures. We believe that many commenters believed that reimbursement for all generic drugs would be reduced by 36 percent. We also believe that as discussed previously, reimbursement will be sufficient to meet acquisition costs.

Comment: Commenters asserted that States will need to fill the financial gap caused by this rule to avoid pharmacy closings and maintain beneficiary access to community pharmacy services.

Response: We do not believe that States will find that reimbursements under the FUL are insufficient for pharmacies and that they will need to cover a shortfall. We believe that the new FULs methodology sets pharmacy pricing at reasonable levels while allowing States to set reimbursement that is based on true prices, thus ensuring that taxpayers do not overpay for prescription drug benefits provided to Medicaid recipients.

Comment: Several commenters stated that independent pharmacies have assisted CMS in providing outreach and information to Medicare Part D beneficiaries in their communities and it is inappropriate to decrease their Medicaid reimbursement after the pharmacies provided support to CMS. These commenters further stated that their pharmacies are still recovering and experiencing losses from Medicare Part D implementation due to low reimbursement and delays in payment.

Response: We recognize that community pharmacy partners provided considerable assistance to Medicare beneficiaries and helped make the implementation of Medicare Part D a success. Nevertheless, the DRA requires CMS to calculate the FULs based on 250 percent of the AMP for Medicaid outpatient drugs.

Comment: One commenter said that this rule will have a far greater impact on pharmacies than implementation of the prescription drug sections of the Medicare Part D Program.

Response: We recognize that the DRA and this rule will result in lower reimbursement for some drugs. However, as discussed previously, we believe that pharmacy reimbursement will be adequate for pharmacies to continue to serve Medicaid beneficiaries.

4. Effects on Physicians

See discussion under ''V. Collection of Information Requirements for Effects on Physicians.''

5. Effects on Hospitals

See discussion under ''V. Collection of Information Requirements for Effects on Hospitals''.

6. Effects on Small Business Entities

Comment: One commenter believed that CMS grossly underestimated the administrative cost for small pharmaceutical manufacturing businesses participating in the Medicaid Drug Rebate Program to implement the additional reporting requirements. The commenter did not provide an estimate of the hourly annual burden but asserted that small pharmaceutical companies will be required to spend hundreds of thousands of dollars to modify their drug price reporting systems and hire additional personnel in order to meet the additional reporting requirements.

Response: The commenter did not document the estimates provided; therefore, we have no basis to revise the estimated burden in the rule. We do not believe that the burden will be greater for small drug manufacturers than for other drug manufacturers. The data required for monthly reporting of AMP and reporting for customary prompt pay discounts and nominal prices should already exist in the manufacturer's accounting systems.

Comment: Several commenters asked that CMS revise the overall one percent impact on retail pharmacy revenues and quantify an impact specifically on small, predominately independent pharmacies, especially rural independents since small business pharmacies serve a disproportionate number of Medicaid patients and have significantly lower revenues than the broader retail pharmacy community. This could account for the higher cost of doing business in rural areas than in other areas. One commenter noted that data from a recent nationwide survey found that Medicaid accounted for approximately 12 percent of all prescriptions filled by rural pharmacies. (See Grant Thornton LLP, ''National

Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies'' (January 2007)).

Response: We recognize that pharmacies with a higher Medicaid prescription volume relative to their overall prescription volume could experience a greater financial impact. However, the method for setting FULs was established by the DRA and we do not have data by subgroups of pharmacies, such as small independent or rural pharmacies, to separately analyze the impact for these segments.

Comment: Some commenters raised the concern that small rural pharmacies will be forced to go out of business as a result of inadequate reimbursements for all patients. The commenters believed a reduction in beneficiary access to prescriptions in rural areas could result in higher costs for other Medicaid services, such as hospitalizations, physician office visits and emergency room visits. The commenters further suggested that CMS provide a public opportunity for small businesses to comment on the revised analysis.

Response: In the proposed rule, we noted that we did not have data to allow us to quantify the effect of this rule on small rural pharmacies. We further requested information to help us better assess those effects before we make final decisions. The commenters did not provide data to allow us to assess separately the burden on pharmacies that are small businesses. Nevertheless, as previously stated, we believe that reduction to reimbursement to pharmacies will not force them to go out of business.

Comment: One commenter suggested that the one percent retail revenue reduction in the proposed rule be revised to comply with the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Response: We believe the estimate complies with the provisions under the SBREFA. It should also be noted that the commenter did not provide specific information as to how the estimated reduction does not comply with this law.

Comment: Several commenters stated that we should analyze the impact on traditional retail pharmacies and institutional pharmacies separately. The institutional pharmacy industry is composed of hundreds of small pharmacies in addition to national companies. These commenters suggested that the number of small business pharmacies should be expanded to include pharmacies in retail chains because these pharmacies operate as independent pharmacies and must generate enough revenue to cover costs of purchasing, maintaining, and dispensing their pharmaceutical inventory. The commenters estimated that the average total sales in traditional pharmacies are about $4.5 million per year.

Response: We used the SBA's size standards for a retail pharmacy of $6.5 million or less in revenue per year (*http://www.sba.gov/size/sizetable2002.html*). The SBA estimates that there are about 18,000 small pharmacies. We do not believe it is appropriate to expand the number of small business pharmacies to include pharmacies that are not consistent with this standard.

Comment: Several commenters suggested that the final rule should exempt small retail pharmacies from the new reimbursement formula, create a separate reimbursement formula for small retail pharmacies, or exempt pharmacies if their Medicaid business exceeds ten percent.

Response: The law specifies that the FUL is to be set at 250 percent of the lowest AMP and does not provide the Secretary the authority to exempt small pharmacies.

7. Effects on Other Issues

Comment: Several commenters stated that pharmaceutical manufacturers are not impacted by the proposed rule and that Medicaid would achieve more savings if the pharmaceutical manufacturers would offer lower drug pricing as they do in other countries. The commenters also suggested that CMS should mandate more controls on drug payments to manufacturers and issue regulations that require lower payments to drug manufacturers.

Response: The purpose of this regulation is to implement the Medicaid drug pricing provisions of the DRA. These comments are outside the scope of this rulemaking.

Comment: Several commenters suggested that pharmacies under Medicaid and Medicare should have the same negotiating price and contract opportunities that HMOs and PBMs have under Medicare Part D. HMOs and PBMs negotiate cheaper drug prices, insist on mail order for maintenance drugs and sign yearly contracts where the net prices are at least ten times lower than the prices offered to independent pharmacies.

Response: This comment is not within the scope of this rulemaking document.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

■ 1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart F—Payment Methods for Other Institutional and Non-Institutional Services

■ 2. Section 447.300 is revised to read as follows:

§ 447.300 Basis and purpose.

In this subpart, § 447.302 through § 447.325 and § 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care. Section 447.371 implements section 1902(a)(15) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

§ 447.301 [Removed]

■ 3. Section 447.301 is removed.

§ 447.331 through § 447.334 [Removed]

■ 4. Sections 447.331 through 447.334 are removed.

■ 5. Subpart I is revised to read as follows:

Subpart I—Payment for Drugs

Sec.

Subpart I—Payment for Drugs

§ 447.500 Basis and purpose.

(a) *Basis.* This subpart—

(1) Interprets those provisions of section 1927 of the Act that set forth

requirements for drug manufacturers' calculating and reporting average manufacturer prices (AMPs) and that set upper payment limits for covered outpatient drugs.

(2) Implements section 1903(i)(10) of the Act with regard to the denial of Federal financial participation (FFP) in expenditures for certain physician-administered drugs.

(3) Implements section 1902(a)(54) of the Act with regard to a State plan that provides covered outpatient drugs.

(b) *Purpose.* This subpart specifies certain requirements in the Deficit Reduction Act of 2005 and other requirements pertaining to Medicaid payment for drugs.

§ 447.502 Definitions.

Bona fide service fees mean fees paid by a manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Brand name drug means a single source or innovator multiple source drug.

Bundled sale means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle.

Consumer Price Index—Urban (CPI–U) means the index of consumer prices developed and updated by the U.S. Department of Labor. It is the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

Dispensing fee means the fee which—

(1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Estimated acquisition cost (EAC) means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.

Innovator multiple source drug means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA), including an authorized generic drug. It includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a product license approval (PLA), establishment license approval (ELA) or antibiotic drug approval (ADA).

Lagged price concession means any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts.

Manufacturer means any entity that possesses legal title to the NDC for a covered drug or biological product and—

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(3) With respect to authorized generic products, the term ''manufacturer'' will also include the original holder of the NDA.

(4) With respect to drugs subject to private labeling arrangements, the term ''manufacturer'' will also include the entity that does not possess legal title to the NDC.

Multiple source drug means, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent. For the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.fda.gov/cder/orange/default.htm* or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the United States during the rebate period.

National drug code (NDC) means the 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in this part as being without respect to package size (that is, the 9-digit numerical code).

National rebate agreement means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his designee and a manufacturer to implement section 1927 of the Act.

Nominal price means a price that is less than ten percent of the AMP in the same quarter for which the AMP is computed.

Noninnovator multiple source drug means (1) a multiple source drug that is not an innovator multiple source drug or a single source drug, (2) a multiple source drug that is marketed under an abbreviated NDA or an abbreviated antibiotic drug application, or (3) a drug that entered the market before 1962 that was not originally marketed under an original NDA.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug that is produced or distributed under an original NDA approved by the FDA, including a drug

product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biological license application, PLA, ELA, or ADA.

States means the 50 States and the District of Columbia.

§ 447.504 Determination of AMP.

(a) *AMP* means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)) for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation.

(b) *Average unit price* means a manufacturer's quarterly sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

(c) *Customary prompt pay discount* means any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified timeframe and consistent with customary business practices for payment.

(d) *Net sales* means quarterly gross sales revenue less cash discounts allowed, except customary prompt pay discounts extended to wholesalers, and all other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by statute or regulation) which reduce the amount received by the manufacturer.

(e) *Retail pharmacy class of trade* means any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.

(f) *Wholesaler* means any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug.

(g) *Sales, rebates, discounts, or other price concessions included in AMP.* Except with respect to those sales identified in paragraph (h) of this section, AMP for covered outpatient drugs shall include the following sales and associated rebates, discounts, or other price concessions—

(1) Sales to wholesalers, except for those sales that can be identified with adequate documentation as being subsequently sold to any of the excluded entities as specified in paragraph (h) of this section;

(2) Sales to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements;

(3) Direct and indirect sales to hospitals, where the drug is used in the outpatient pharmacy, except those sales that cannot be identified with adequate documentation as being used in the outpatient pharmacy for outpatient use (for example hospital outpatient department, clinic, or affiliated entity);

(4) Sales at nominal prices to any entity except a covered entity described in section 340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR) providing services as set forth in § 440.150 of this chapter, or a State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter;

(5) Sales to retail pharmacies including discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs to the retail pharmacy class of trade;

(6) Sales including discounts, rebates, or other price concessions provided to pharmacy benefit managers (PBMs) for their mail order pharmacy purchases;

(7) Sales directly to patients;

(8) Sales to outpatient facilities (for example, clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers);

(9) Sales to mail order pharmacies;

(10) Sales to home infusion providers;

(11) Sales to specialty pharmacies;

(12) Sales to home health care providers;

(13) Sales to physicians;

(14) Rebates, discounts, or other price concessions (other than rebates under section 1927 of the Act or as otherwise specified in the statute or regulations) associated with sales of drugs provided to the retail pharmacy class of trade; and

(15) Sales of drugs reimbursed by third party payers including the Medicare Part D Program, a Medicare Advantage prescription drug plan (MA–PD), a Qualified Retiree Prescription Drug Plan under section 1860D–22(a)(2) of the Act, State Children's Health Insurance Program (SCHIP), State pharmaceutical assistance programs (SPAPs), health maintenance organizations (HMOs) (including managed care organizations (MCOs)) that do not purchase or take possession of drugs, TRICARE Retail Pharmacy Program (TRRx), and Medicaid Programs that are associated with sales of drugs provided to the retail pharmacy class of trade (except for rebates under section 1927 of the Act or as otherwise specified in the statute or regulations).

(h) *Sales, rebates, discounts, or other price concessions excluded from AMP.* AMP excludes—

(1) Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds under 38 U.S.C. 1741, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA);

(2) Any prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA);

(3) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(4) Direct and indirect sales to hospitals, where the drug is used in the inpatient setting or in the outpatient pharmacy for outpatient use where the sales cannot be identified with adequate documentation;

(5) Sales to HMOs (including MCOs, and HMO/MCO-operated pharmacies) that purchase or take possession of drugs;

(6) Sales to long-term care facilities, including nursing facility pharmacies, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities;

(7) Sales to hospices (inpatient and outpatient);

(8) Sales to veterinarians;

(9) Sales to prisons;

(10) Sales outside the 50 States and the District of Columbia;

(11) Sales to State, county, and municipal entities;

(12) Sales to patient assistance programs;

(13) Sales to wholesalers where the drug is distributed to the non-retail pharmacy class of trade;

(14) Sales to wholesalers or distributors where the drug is relabeled under the wholesalers' or distributors' NDC number;

(15) Manufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession;

(16) Manufacturer vouchers;

(17) Manufacturer-sponsored drug discount card programs;

(18) Free goods, not contingent upon any purchase requirement;

(19) Bona fide service fees;

(20) Customary prompt pay discounts extended to wholesalers;

(21) Returned or replaced goods when accepted or replaced in good faith;

(22) Discounts, rebates, or other price concessions to PBMs, except for their mail order pharmacy's purchases.

(23) Associated rebates, discounts, or other price concessions to third party payers including the Medicare Part D Program, an MA–PD, Qualified Retiree Prescription Drug Plan under section 1860D–22(a)(2) of the Act, SCHIP, SPAPs, HMOs (including MCOs that do not take possession of drugs) the TRICARE Retail Pharmacy Program, and Medicaid Programs; and

(24) Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(i) *Further clarification of AMP calculation.* (1) AMP includes cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks, incentives, administrative fees, service fees, distribution fees, (except bona fide service fees), and any other rebates, discounts or other price concessions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

(2) Quarterly AMP is calculated as a weighted average of monthly AMPs in the quarter.

(3) The manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized.

§ 447.505 Determination of best price.

(a) *Best price* means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including any drug sold under an NDA approved under section 505(c) of the FFDCA), the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price shall be calculated to include all sales and associated rebates, discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation from the rebate calculation.

(b) For purposes of this section, *provider* means a hospital, HMO, including an MCO or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care.

(c) *Prices included in best price.* Except with respect to those prices identified in paragraph (d) of this section, best price for covered outpatient drugs includes the following prices and associated rebates, discounts, or other price concessions that adjust prices either directly or indirectly—

(1) Prices to wholesalers;

(2) Prices to any retailer, including rebates, discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs;

(3) Prices to providers (for example, hospitals, HMOs/MCOs, physicians, nursing facilities, and home health agencies);

(4) Prices available to non-profit entities;

(5) Prices available to governmental entities within the United States;

(6) Prices of authorized generic drugs, sold by the primary manufacturer in accordance with § 447.506(d) of this subpart;

(7) Prices of sales directly to patients;

(8) Prices available to mail order pharmacies;

(9) Prices available to outpatient clinics;

(10) Prices to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements; and

(11) Prices to entities that repackage/relabel under the purchaser's NDC, including private labeling agreements, if that entity also is an HMO or other non-excluded entity.

(d) *Prices excluded from best price.* Best price excludes:

(1) Any prices on or after October 1, 1992, charged to the IHS, the DVA, a State home receiving funds under 38 U.S.C. 1741, the DoD, the PHS, or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA);

(2) Any prices charged under the FSS of the GSA;

(3) Any prices provided to a designated SPAP;

(4) Any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(5) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA–PD plan under Part C of such title with respect to covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D–22(a)(2) of the Act) with respect to such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare;

(6) Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act;

(7) Prices negotiated under a manufacturer-sponsored drug discount card program;

(8) Manufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession;

(9) Goods provided free of charge under a manufacturer's patient assistance programs;

(10) Free goods, not contingent upon any purchase requirement;

(11) Nominal prices to certain entities as set forth in § 447.508 of this subpart;

(12) Bona fide service fees; and

(13) PBM rebates, discounts, or other price concessions except their mail order pharmacy's purchases or where such rebates, discounts, or other price concessions are designed to adjust prices at the retail or provider level.

(e) *Further clarification of best price.* (1) Best price shall be net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, service fees (except bona fide service fees), distribution fees,

and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer.

(2) Best price must be determined on a unit basis without regard to package size, special packaging, labeling or identifiers on the dosage form or product or package, and must not take into account prices that are nominal in amount as described in § 447.508 of this subpart.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.

§ 447.506 Authorized generic drugs.

(a) *Authorized generic drug defined.* For the purposes of this subpart, an authorized generic drug means any drug sold, licensed, or marketed under an NDA approved by the FDA under section 505(c) of the FFDCA; and marketed, sold, or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand drug.

(b) *Inclusion of authorized generic drugs in AMP.* A manufacturer holding title to the original NDA of the authorized generic drug must include the sales of this drug in its AMP only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler.

(c) *Inclusion of authorized generic drugs in best price.* A manufacturer holding title to the original NDA must include best price of an authorized generic drug in its computation of best price for a single source or innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding title to the original NDA.

§ 447.508 Exclusion from best price of certain sales at a nominal price.

(a) *Exclusion from best price.* Sales of covered outpatient drugs by a manufacturer at nominal prices are excluded from best price when purchased by the following entities:

(1) A covered entity described in section 340B(a)(4) of the PHSA;

(2) An ICF/MR providing services as set forth in § 440.150 of this chapter; or

(3) A State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter.

(b) *Nonapplication.* This restriction shall not apply to sales by a manufacturer of covered outpatient drugs that are sold under a master agreement under 38, U.S.C. 8126.

§ 447.510 Requirements for manufacturers.

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include:

(1) AMP, calculated in accordance with § 447.504 of this subpart;

(2) Best price, calculated in accordance with § 447.505 of this subpart;

(3) Customary prompt pay discounts, which shall be reported as an aggregate dollar amount for each covered outpatient drug at the nine-digit NDC level, provided to all wholesalers in the rebate period; and

(4) Prices that fall within the nominal price exclusion, which shall be reported as an aggregate dollar amount and shall include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) of this subpart for the rebate period.

(b) *Reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices.* (1) A manufacturer must report to CMS revisions to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due.

(2) A manufacturer must report revisions to AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) *Base date AMP report.* (1) A manufacturer may report a revised base date AMP to CMS within the first four full calendar quarters following [OFR: insert publication date of the final rule].

(2) *Recalculation of base date AMP.* (i) A manufacturer's recalculation of the base date AMP must only reflect the revisions to AMP as provided for in § 447.504 of this subpart.

(ii) A manufacturer may choose to recalculate base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating base date AMP.

(d) *Monthly AMP*—(1) *Definition of Monthly AMP.* Monthly AMP means the AMP that is calculated on a monthly basis. A manufacturer must submit a monthly AMP to CMS not later than 30 days after the last day of each prior month.

(2) *Calculation of monthly AMP.* Monthly AMP should be calculated based on the methodology in section 447.504 of this subpart, except the period covered should be based on monthly, as opposed to quarterly, sales. The monthly AMP should be calculated based on the weighted average of prices for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month. It is calculated as net sales divided by number of units sold, excluding goods or any other items given away unless contingent on any purchase requirements. Monthly AMP should be calculated based on the best data available to the manufacturer at the time of submission. In calculating monthly AMP, a manufacturer must estimate the impact of its lagged price concessions using a 12-month rolling average to estimate the value of those discounts.

(3) *Timeframe for reporting revised monthly AMP.* A manufacturer must report to CMS revisions to monthly AMP for a period not to exceed 36 months from the month in which the data were due.

(4) *Exception.* A manufacturer must report revisions to monthly AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(5) *Terminated products.* A manufacturer must not report a monthly AMP for a terminated product beginning with the first month after the expiration date of the last lot sold.

(e) *Certification of pricing reports.* Each report submitted under paragraphs (a) through (d) of this section must be certified by one of the following:

(1) The manufacturer's chief executive officer (CEO);

(2) The manufacturer's chief financial officer (CFO);

(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in subsections (1) through (3).

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for ten years from the date the manufacturer reports data to CMS for that rebate period. The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations. The ten-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the ten-year period if both of the following circumstances exist:

(i) The records are the subject of an audit or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format.

§ 447.512 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance with § 447.514 of this subpart. If a specific limit has not been established under § 447.514 of this subpart, then the rule for ''other drugs'' set forth in paragraph (b) of this section applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.514 of this subpart must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the—

(1) EAC plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.* (1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.514 of this subpart does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like ''brand necessary'' is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§ 447.514 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.* (1) CMS will establish and issue listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) The FDA has rated two or more drug products as therapeutically and pharmaceutically equivalent in its most current edition of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (including supplements or in successor publications), regardless of whether all such formulations are rated as such and only such formulations shall be used when determining any such upper limit.

(ii) At least two suppliers meet the criteria in paragraph (a)(1)(i) of this section.

(2) CMS publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid Program issuances.

(b) *Specific upper limits.* The agency's payments for multiple source drugs identified and listed periodically by CMS in Medicaid Program issuances must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the State agency plus an amount established by CMS that is equal to 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent.

(c) *Ensuring a drug is for sale nationally.* To assure that a drug is for sale nationally, CMS will consider the following additional criteria:

(1) The AMP of a terminated NDC will not be used to set the Federal upper limit (FUL) beginning with the first day of the month after the actual termination date reported by the manufacturer to CMS.

(2) Except as set forth in paragraph (c)(3) of this section, the AMP of the lowest priced therapeutically and pharmaceutically equivalent drug that is not less than 40 percent of the next highest AMP will be used to establish the FUL.

(3) When the FUL group includes only the brand name drug and the first new generic or authorized generic drug which has entered the market, the criteria in paragraph (c)(2) of this section will not apply.

§ 447.516 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

§ 447.518 State plan requirements, findings and assurances.

(a) *State plan.* The State plan must describe comprehensively the agency's payment methodology for prescription drugs.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.514(a) of this subpart, are in accordance with the upper limits specified in § 447.514(b) of this subpart; and

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.512 of this subpart.

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in §§ 447.512 and 447.514 of this subpart concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) *Recordkeeping.* The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

§ 447.520 FFP: Conditions relating to physician-administered drugs.

(a) No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers in order to secure rebates.

(2) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the

Secretary as having the highest dollar value under the Medicaid Program using NDC numbers in order to secure rebates.

(b) As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 27, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 29, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–3356 Filed 7–6–07; 4:00 pm]

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Peck's Cave Amphipod, Comal Springs Dryopid Beetle, and Comal Springs Riffle Beetle; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AU75

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Peck's Cave Amphipod, Comal Springs Dryopid Beetle, and Comal Springs Riffle Beetle

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are designating critical habitat for the Peck's cave amphipod (*Stygobromus pecki*), Comal Springs dryopid beetle (*Stygoparnus comalensis*), and Comal Springs riffle beetle (*Heterelmis comalensis*) in areas of occupied, spring-related aquatic habitat in Texas under the Endangered Species Act of 1973, as amended (Act). The three listed species are known only from four spring systems in central Texas: Comal Springs and Hueco Springs in Comal County, and Fern Bank Springs and San Marcos Springs in Hays County. The total area designated as critical habitat for the amphipod is about 38.5 acres (ac) (15.6 hectares (ha)), for the dryopid beetle it is about 39.5 ac (16.0 ha), and for the riffle beetle it is about 30.3 ac (12.3 ha).

DATES: This rule becomes effective on August 16, 2007.

FOR FURTHER INFORMATION CONTACT: Adam Zerrenner, Field Supervisor, Austin Ecological Services Office, 10711 Burnet Road, Suite 200, Austin, TX 78758 (telephone 512–490–0057; facsimile 512–490–0974).

SUPPLEMENTARY INFORMATION:

Background

It is our intent to discuss only those topics directly relevant to the designation of critical habitat in this rule. For more information on these species, refer to the final rule listing the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle that was published in the **Federal Register** on December 18, 1997 (62 FR 66295).

All three of the listed species included in this final rule for critical habitat designation are freshwater invertebrates. The Peck's cave amphipod is an eyeless, subterranean (below ground) arthropod that has been found in Comal Springs and Hueco Springs (also spelled Waco Springs). Both spring systems are located in Comal County, Texas. The Comal Springs dryopid beetle is a subterranean insect with vestigial (poorly developed, non-functional) eyes. The species has been found in two spring systems, Comal Springs and Fern Bank Springs, that are located in Comal and Hays Counties, respectively. The Comal Springs riffle beetle is an aquatic insect that is found in and primarily restricted to surface water associated with Comal Springs in Comal County and with San Marcos Springs in Hays County.

The four spring systems (Comal, Fern Bank, Hueco, and San Marcos) designated as critical habitat units are produced by discharge of aquifer spring water along the Balcones fault zone at the edge of the Edwards Plateau in central Texas. The source of water flows for Comal Springs and San Marcos Springs is the San Antonio segment of the Edwards Aquifer. This aquifer is characterized by highly varied, below ground spaces that have been hollowed out within limestone bedrock through dissolution by rainwater. Groundwater is held and conveyed within these hollowed-out spaces, which range in size from honeycomb-like pores to large caverns. The San Antonio segment of the aquifer occurs in a crescent-shaped section over a distance of 176 miles (mi) (283 kilometers (km)), from the town of Brackettville in Kinney County on the segment's west side over to the town of Kyle in Hays County at the segment's northeast side. Groundwater generally moves from recharge areas in the southwest part of the San Antonio segment and travels toward discharge areas in the northeast part of the segment, which includes Comal Springs and San Marcos Springs. The area that recharges groundwater coming to Comal Springs may occur as much as 62 mi (100 km) away from the springs (Brune 1981, p. 130). Hueco Springs is recharged locally from the local watershed basin and possibly by the San Antonio segment of the Edwards Aquifer (Guyton and Associates 1979, p. 2). The source of water for Fern Bank Springs has not been determined. Fern Bank Springs discharges water from the upper member of the Glen Rose Formation, and its flow could originate primarily from that unit; however, water discharged from the springs could also be (1) Drainage from the nearby Edwards Aquifer recharge zone, (2) water lost from the Blanco River, or (3) a combination of all three sources (Veni 2006, p.1).

Comal Springs and San Marcos Springs are the two largest spring systems in Texas with respective mean annual flows of 284 and 170 cubic feet per second (8 and 5 cubic meters per second) (Fahlquist and Slattery 1997, p. 1; Slattery and Fahlquist 1997, p. 1). Both spring systems emerge as a series of spring outlets along the Balcones fault that follows the edge of the Edwards Plateau in Texas. Fern Bank Springs and Hueco Springs have considerably smaller flows and consist of one main spring with several satellite springs or seep areas.

The four spring systems designated for critical habitat are characterized by high water quality and relatively constant water flows, with temperatures that range from 68 to 75 °F (Fahrenheit) (20 to 24 °C (Celsius)). Due to the underlying limestone aquifer, discharged water from these springs has a carbonate chemistry (Ogden *et al.* 1986, p. 103). Although flows from San Marcos Springs can vary according to fluctuations in the source aquifer, records indicate that this spring system has never ceased flowing. San Marcos Springs has been monitored since 1894, and has exhibited the greatest flow dependability of any major spring system in central Texas (Puente 1976, p. 27). Comal Springs has a flow record nearly comparable to that of San Marcos Springs; however, Comal Springs ceased flowing from June 13 to November 3, 1956, during a severe drought (U.S. Army Corps of Engineers 1965, p. 59). Water pumping from the aquifer contributed to cessation of flow at Comal Springs during the drought period (U.S. Army Corps of Engineers 1965, p. 59). Hueco Springs has gone dry a number of times in the past during drought periods (Puente 1976, p. 27; Guyton and Associates 1979, p. 46). Although flow records are unavailable for Fern Bank Springs, the spring system is considered to be perennial (Barr 1993, p. 39).

Each of the four spring systems and related subterranean aquifers typically provide adequate resources to sustain life cycle functions for resident populations of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. However, a primary threat to the three invertebrate species is the potential failure of spring flow due to drought or excessive groundwater pumping, which could result in loss of aquatic habitat for the species. Although these invertebrate species persisted at Comal Springs in the 1950s despite drought conditions (Bowles *et al.* 2003, p. 379), all three species are aquatic and require water to complete their individual life cycles.

Bowles *et al.* (2003, p. 379) pointed out that the mechanism by which the Comal Springs riffle beetle survived the drought and the extent to which its population was negatively impacted are

uncertain. Bowles *et al.* (2003, p. 379) speculated that the riffle beetle may be able to retreat back into spring openings or burrow down to wet areas below the surface of the streambed.

Barr (1993, p. 55) found Comal Springs dryopid beetles in spring flows with low volume discharge as well as high volume discharge and suggested that presence of the species did not necessarily depend on a high spring flow. However, Barr (1993, p. 61) noted that effects on both subterranean species (dryopid beetle and amphipod) from extended loss of spring flow and low aquifer levels could not be predicted due to limited knowledge about their life cycles.

Previous Federal Actions

Information about previous Federal actions for Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle can be found in our proposal to designate critical habitat for these species published in the **Federal Register** on July 17, 2006 (71 FR 40588). On March 16, 2007, we announced the availability of our draft economic analysis, and we reopened the public comment period on the proposed rule (72 FR 12585). The reopened public comment period ended on April 16, 2007.

Summary of Comments and Recommendations

We requested written comments from the public on the proposed designation of critical habitat for Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle in the proposed rule published on July 17, 2006 (71 FR 40588) and in our March 16, 2007, **Federal Register** notice (72 FR 12585). We also contacted appropriate Federal, State, and local agencies; scientific organizations; and other interested parties and invited them to comment on the proposed rule.

During the comment period that opened on July 17, 2006, and closed on September 15, 2006, we received eight responses directly addressing the proposed critical habitat designation: four from peer reviewers, one from a State agency, and three from organizations or individuals. The response we received from the State agency, the Texas Department of Transportation, indicated that the proposed critical habitat designations for these species were ''prudently identified'' by the Service. However, that agency did not offer any other comments. After completing the draft economic analysis, we reopened the comment period between March 16, 2007, and April 16, 2007 (72 FR 12585). During the second comment period, we received one comment from a peer reviewer and four from organizations; two of which included comments on the economic analysis. Responses to all comments were grouped by those from peer reviewers, followed by public comments. These comments are addressed in the following summary and incorporated into the final rule as appropriate. We did not receive any requests for a public hearing and thus no public hearing was held.

Peer Review

In accordance with our policy published on July 1, 1994 (59 FR 34270), we solicited expert opinions from nine knowledgeable individuals with scientific expertise that included familiarity with the species, the geographic region in which the species occur, and conservation biology principles. We received responses from four of the peer reviewers. Although none of the peer reviewers disagreed with our methods in designating critical habitat for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle, three of the responses indicated that the critical habitat designation failed to address the broader issue of maintaining spring flows, ecosystem functioning, and groundwater levels within the Edwards Aquifer. Also, two of the peer reviewers disagreed with the reasoning we presented in our determination of Primary Constituent Element (PCE) 4. Three of the peer reviewers' responses provided additional information, clarifications, and suggestions to improve the final critical habitat rule. We address peer reviewer comments in the following summary and have incorporated them into the final rule as appropriate.

We reviewed all comments received from the peer reviewers and the public for substantive issues and new information regarding critical habitat for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle, and address them in the following summary.

Peer Reviewer Comments

1. *Comment:* One of the critical factors affecting the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle is continued natural spring flows. Adequate or minimum spring flows should be included as a PCE.

Our Response: We agree that adequate water quantity is necessary for the survival of the three invertebrate species. We indicated that availability and access to water at the spring sites are important factors in maintaining the life history functions of the Peck's cave amphipod, the Comal Springs dryopid beetle, and the Comal Springs riffle beetle by highlighting the role of water in the descriptions of PCEs 1, 2, and 3 of this final rule. We clarified the language for PCE 3 to highlight the importance of spring flows in maintaining adequate dissolved oxygen levels. We also state in the Special Management Considerations section of this rule that prolonged cessation of spring flows as a result of the loss of hydrological connectivity within the aquifer may require special management considerations, such as maintenance of sustainable groundwater use and subsurface flows.

2. *Comment:* PCE 5 should be corrected to indicate that the substrate habitat of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle should also be free of sand and silt.

Our Response: We incorporated this suggestion into PCE 5.

3. *Comment:* Riparian vegetation in the immediate vicinity of the spring openings are likely not the food source for any of the three invertebrate species, as described in PCE 4. Aquatic invertebrates typically feed on plant material well after it has been mechanically broken down. Flow in the vicinity of spring openings would quickly carry away leaf litter and other plant material before it could become mechanically broken down. The detritus that comprises the food source for the Comal Springs dryopid beetle is most likely introduced into the aquifer at recharge points far upstream of the spring openings (*i.e.*, within the recharge area of the aquifer). Similarly, the food source for the Peck's cave amphipod is likely found within the Edwards Aquifer. Specifically, the food source may be composed of material that enters through the recharge area of the aquifer and the many other organisms that co-occur within the aquifer. Aquatic macrophyte (*i.e.*, large plant) roots may be a source of detritus for invertebrates in a spring-run downstream of a spring opening. However, the roots are likely not the food sources for the Peck's cave amphipod, because the amphipod is found only near the spring openings and within the aquifer. Because the riparian habitats around the springs are likely not influencing these three species, the critical habitat designations only represent the smallest part of their habitats or range.

Our Response: The Comal Springs dryopid beetle has only been observed near spring outlets. Adults have been

found on rocks and cotton cloth lures in spring openings. They have also been observed on rotting wood above spring upwellings near tree roots growing just under the gravel substrate more than 16 feet (ft) (5 meters (m)) from the shore of Landa Lake (Gibson *et al.* 2006, p. 3). Larvae of this species do not have gills and are considered terrestrial, as they typically inhabit moist soil along stream banks (Brown 1987, p. 253; Ulrich 1986, p. 325). Because of these characteristics, we believe Comal Springs dryopid beetle larvae feed on roots and decaying vegetation in areas just above the aquifer (*i.e.*, subsurface area) water line. We believe the Peck's cave amphipod likely consumes both animals and plants, and feeds both within the aquifer and on detritus in areas near spring outlets where plant roots interface with spring water (Gibson 2006, p. 1). Therefore, we believe critical habitat should include the riparian vegetation as a food source for the Peck's cave amphipod and Comal Springs dryopid beetle.

4. *Comment:* The designation of 50–ft distances around spring openings seems reasonable to protect and maintain the subsurface vegetation profile in the immediate area of the springs; however, the detrital food base could come from sources at greater distances.

Our Response: Although there may be some contribution of detrital food sources from greater distances within the aquifer, we are unaware of any data that indicate this. As explained in our response to Comment 3 above, there is available information that suggests that riparian vegetation near the spring openings is an important habitat component for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle, and may provide a source of food for these species.

5. *Comment:* Under PCE 1, the pesticides mentioned only refer to classes such as organochlorines, organophosphates, and chlorinated hydrocarbons. The Service should consider pesticide classes such as insect growth regulators as well as pharmaceuticals that could enter groundwater sources. The Service should clarify the differences between these compounds and their potential effects on the listed species.

Our Response: We have added pharmaceuticals to the list of potential pollutants discussed under PCE 1 in response to this comment. There are no scientific studies available on the potential effects that each of these pollutants have on the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle, so we are unable to address the potential effects of these pollutants in the final rule. We acknowledge the importance of maintaining high water quality within the Edwards Aquifer, and we will work to evaluate and address the effects of pollutants during the recovery planning and implementation processes for these species.

6. *Comment:* With regard to PCE 1, Hueco Springs and Fern Bank Springs may be influenced by storm water. Can the claim be made that the spring systems are characterized by high water quality?

Our Response: Spring systems in general may have some short-term changes in water quality after storm events. Hueco Springs and Fern Bank Springs are smaller in size and may have more local recharge features than Comal Springs and San Marcos Springs. Although these characteristics may make them more susceptible to short-term changes in water quality after storm events, the Service has no data to indicate that these temporary changes negatively affect the species that occur near the spring openings. Comal and San Marcos Springs may also be affected by local runoff from storm events based on tracer tests by the Edwards Aquifer Authority. We consider all of the spring systems occupied by the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle to have high water quality.

7. *Comment:* There is a strong likelihood that additional populations of the Comal Springs riffle beetle occur in or around the various spring outlets in the bottoms of Spring Lake and Landa Lake, where substrate is sufficiently coarse to serve as habitat.

Our Response: We believe this is addressed through the designation of all aquatic habitat within Landa Lake where springs are present and PCEs are known to exist for the Peck's cave amphipod and Comal Springs dryopid beetle. However, this point was clarified in the Critical Habitat Designation section of this final rule describing the designated critical habitat areas within Landa Lake for the Comal Springs Unit in Comal County, Texas.

8. *Comment:* Paragraph 8 under ''Adverse Modification Standard'' states that ''ongoing human activities that occur outside the proposed critical habitat are unlikely to threaten the physical and biological features of the proposed critical habitat.'' However, if there is an increase in pumping water from the aquifer prior to the ruling on critical habitat, then that new pumping may impact PCEs 2, 3, and 5.

Our Response: We agree with the commenter and have clarified the language in the Effects of Critical Habitat Designation section that groundwater pumping from the Edwards Aquifer may affect critical habitat and require section 7 consultation.

9. *Comment:* The critical habitat designations may provide benefits to the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle on a local scale (*i.e.*, in the immediate area of the spring openings), but they do not offer protections to the Edwards Aquifer ecosystem. Critical habitat for these species should be extended to include the entire Edwards Aquifer, including subsurface areas. Until parts of the Edwards Aquifer can be shown to not have populations of these two species, the most sensible solution is to assume that the entire aquifer is critical habitat. Also, there are ecosystem processes (*e.g.*, organic matter inputs, interactions with other species, nutrient availability) that are not addressed by the PCEs and may be addressed by designating the entire Edwards Aquifer.

Our Response: Organic matter and nutrient availability are addressed in PCE 4. We recognize the importance of maintaining ecosystem integrity and functionality and implementing strategies to protect the entire Edwards Aquifer. However, we reviewed all available information that pertains to the occurrence of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. Although the Peck's cave amphipod and the Comal Springs dryopid beetle are believed to be subterranean, we have no information available to show that the entire Edwards Aquifer ecosystem is occupied by the species. Nor do we believe the PCEs are found throughout the aquifer. We cannot demonstrate that the entire aquifer is essential to the conservation of the species. Although the entire aquifer has not been designated as critical habitat, Federal activities outside of designated critical habitat areas are subject to review under section 7 of the Act if these activities may adversely affect the PCEs within the critical habitat designation.

10. *Comment:* The PCEs do nothing to safeguard the source of the water—the Edwards Aquifer, upon which the invertebrates depend. A comprehensive plan for the Edwards Aquifer with constraints on groundwater pumping and pollution of recharge should be developed.

Our Response: Designating critical habitat is only one means to aid in the habitat conservation of listed species. Efforts to address threats to the Edwards Aquifer can be undertaken through the

recovery implementation process for these and the other federally-listed species that depend on the aquifer for their survival. For example, we are working with a large number of partner agencies and organizations, including the Edwards Aquifer Authority, to develop an Edwards Aquifer Recovery Implementation Program (RIP) to address threats to the Edwards Aquifer. The Edwards Aquifer Authority (EAA) is the agency with the responsibility to manage, enhance, and protect the Edwards Aquifer system through a variety of mechanisms including the issuing of pumping permits for use of water from the aquifer. We intend to continue our close work with the EAA and others for conservation of the springs that flow from the Edwards Aquifer.

Public Comments

11. *Comment:* It seems imprudent to designate critical habitat for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle, when this would provide no benefit to the species beyond that provided by listing of the species and any subsequent evaluation of activities in light of section 7 consultation requirements.

Our Response: The Role of Critical Habitat in Actual Practice of Administering and Implementing the Act section in the proposed rule has been removed from this final rule. We recognize some benefits to critical habitat designations. Federal activities outside of designated critical habitat areas are subject to review under section 7 of the Act if these activities may adversely affect the PCEs within the critical habitat designation. The Ninth Circuit Court's decision in *Gifford Pinchot Task Force* v. *United States Fish and Wildlife Service*, 378 F.3d 1059 (9th Cir 2004) (hereinafter *Gifford Pinchot*) requires consideration of the recovery of species. Thus, under this court ruling, and our implementation of Section 7 of the Act, critical habitat designations may provide greater benefits to the recovery of a species. Also, we have found that critical habitat designations serve to educate landowners, State and local governments, and the public regarding the potential conservation value of the areas designated.

12. *Comment:* This critical habitat designation is not beneficial, especially in light of a recent initiation of a RIP for the endangered species of the Edwards Aquifer under the encouragement of the Service.

Our Response: In designating critical habitat areas, we have reviewed the overall approach to the conservation of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle undertaken by local, Federal, and State agencies; and by private organizations operating within the species' range since their listing. As noted above, we are very supportive of the RIP process; however, this process is in its initial stages of development, and therefore we were not able to consider the potential conservation benefits of the RIP to these species in our critical habitat determination. Also, as stated in our response to Comment 11 above, we recognize several benefits to designating critical habitat.

13. *Comment:* In the Critical Habitat section of the proposed rule, the Service understates the extent to which critical habitat designations provide additional protection for species above and beyond the prohibition of take that comes with federally listing species as endangered or threatened. This approach is legally and scientifically unsubstantiated, and it shortchanges the goals of the Act to provide for the conservation and recovery of listed species.

Our Response: As discussed above, we agree that the designation of critical habitat can serve positive purposes, but we also believe it is only one tool for managing listed species' habitat. In addition to the designation of critical habitat, we have determined that other conservation mechanisms, including the recovery planning process, section 6 funding to States, section 7 consultations, management plans, Safe Harbor agreements, and other on-the-ground strategies, contribute to species' conservation. We will continue to work with local partner organizations (such as the Edwards Aquifer Authority, San Antonio Water System, local municipalities, Texas Parks and Wildlife Department, and others) through the RIP, to develop means for voluntary conservation of habitats for these listed species. We believe these other conservation measures often provide incentives for project planners and greater conservation benefits than critical habitat designation.

14. *Comment:* There does not appear to be a clear correlation between the needs of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle and particular spring flow conditions to require such special management considerations.

Our Response: There is information to indicate that availability and access to water at the spring sites are important factors in maintaining the life history functions (*i.e.*, those functions that are dependent on high water quality, adequate water temperature, and adequate dissolved oxygen levels) of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle, as described under PCEs 1, 2, and 3. We believe that prolonged cessation of spring flows as a result of the loss of hydrological connectivity within the aquifer may require special management considerations, such as maintenance of sustainable groundwater use and subsurface flows.

15. *Comment:* The proposed rule only designates as critical habitat the aquatic areas where the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle are found, plus a 50-ft distance from the spring outlets. The proposed rule does nothing to control water quality impacts from activities occurring in the contributing and recharge zones of the aquifer, limiting the critical habitat to only a 50-ft buffer beyond the spring outlets to protect the species' food sources. Such a buffer would fail to protect the water quality in the aquatic habitat. Typical buffers to protect water quality tend to be at least 100 ft on each side of sensitive waters. The critical habitat should likewise at least accommodate such extended buffers to help protect water quality in the aquatic habitat.

Our Response: We proposed designating critical habitat in areas that we have determined are occupied by the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle; contain sufficient PCEs to support life-history functions essential for the conservation of the species; and require special management or protection. The 50-ft (15.2-m) distances define the lateral extent of critical habitat that contains PCEs with respect to food sources in root/water interfaces. Use of a 100-ft (30.4-m) buffer for this critical habitat designation would extend the boundary to include areas not known to contain the PCEs; therefore, use of this larger buffer is not consistent with the criteria used to identify critical habitat.

The designation of critical habitat requires Federal agencies to consult with us when activities they fund, authorize, or carry out may affect the critical habitat of a listed species. Consultation is required where projects may (indirectly or directly) adversely affect critical habitat, even if those projects occur outside designated critical habitat (e.g., the contributing and recharge zones of the aquifer).

16. *Comment:* The final rule should include the minimal spring flow rates provided in the EAA's 2005 Draft Habitat Conservation Plan.

Our Response: The EAA's 2005 Draft Habitat Conservation Plan (HCP) has not

been finalized, nor have we issued a permit for the EAA. We have not analyzed spring flow rates from the 2005 Draft HCP for effects to the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. In addition, flow from Fern Bank Springs is from the Trinity Aquifer, not the Edwards Aquifer. Thus, the draft EAA HCP does not address the maintenance of Fern Bank Springs habitat and that population of the Comal Springs dryopid beetle.

17. *Comment:* The economic analysis should include the benefits of designating critical habitat for the invertebrate species. Without estimating the benefits to designation, the costs seem unreasonably high, and therefore paint the conservation effort in a negative light. A full benefits analysis should include direct, indirect, and non-use benefits.

Our Response: As stated in Chapter 1 of the final economic analysis, a potential direct benefit of the rulemaking is the potential to enhance conservation of the species. The published economics literature has documented that social welfare benefits can result from the conservation and recovery of endangered and threatened species. However, in its guidance for implementing Executive Order 12866, OMB acknowledges that it may not be feasible to monetize, or even quantify, the benefits of environmental regulations due to either an absence of defensible, relevant studies or a lack of resources on the implementing agency's part to conduct new research. Rather than rely on economic measures, we believe that the direct benefits of the proposed rule are best expressed in biological terms that can be weighed against the expected cost impacts of the rulemaking.

Where data are available, the economic analysis does discuss and attempt to measure the net economic impacts of this rulemaking. For example, Chapter 2 discusses the reduction in net economic benefit to municipal and industrial water users that may occur with pumping restrictions. The analysis also discusses the fact that higher springflow levels are anticipated to contribute to river flows downstream of the aquifer, which will make more water available to municipalities, industries, and farmers who use river water. Whether the users will use the water to an economic benefit depends on a myriad of factors that are beyond the scope of the economic analysis; however, the analysis notes that increased springflows are likely to generate potentially significant ecological and/or recreational benefits.

18. *Comment:* Section 1.34(c) of the EAA Act of 1993, as amended, notes that a ''holder of a permit for irrigation use may not lease more than 50 percent of the irrigation rights initially permitted. The user's remaining irrigation water rights must be used in accordance with the original permit and must pass with transfer of the irrigated land.'' Paragraph 83 of the economic analysis makes it unclear whether this restriction on irrigation transfers was considered in the analysis.

Our Response: The analysis predicts that water users, when faced with lowered water permit availability, will sell or lease their water rights to higher-valued uses. The value of water in the planning area is assumed to rise faster than the profitability of irrigated crops, and thus agricultural water will be traded from agriculture to municipal and industrial use, as has been common in the western United States. Despite the current restriction on the sale and lease of irrigation rights in the Edwards Aquifer, the analysis assumes that the Edwards Aquifer Authority will be able to purchase and retire sufficient agricultural water rights for the purposes of maintaining aquifer levels in the future. While this assumption was implicit in the draft economic analysis, it is now stated explicitly in the final economic analysis.

19. *Comment:* PCE 5 concludes that a gravel substrate is necessary for the Comal Springs riffle beetle because specimens were not found in Spring Run 4 where the substrate was primarily sand and not gravel. The Service has drawn this conclusion from a preliminary correlation reported in a study done by Bowles *et al.* (2003), and therefore, a definitive conclusion may inaccurately represent the findings. A number of abiotic and biotic factors, including flow rates, competition with other species, and other life-history traits may all have been contributing factors to the absence of the beetle in Spring Run 4.

Our Response: In reviewing the best available information, we found that additional searches for the Comal Springs riffle beetle in Spring Run 3 and the western shoreline habitat of Landa Lake yielded results similar to those found by Bowles *et al.* (2003) with regard to the occurrence of this species on gravel, cobble, and rock substrates outside of areas with sedimentation or silt buildup (BIO–WEST 2002a, p. 11). We included this additional reference within the discussion of PCE 5. By referencing the survey results of Bowles *et al.* (2003), it was not our intention to imply that the Comal Springs riffle beetle could never be found in smaller sized substrates. Although we cannot determine the full scope of substrate habitat restrictions for the Comal Springs riffle beetle from the information provided in the above referenced reports, it does indicate that gravel, cobble, and rock substrates that are free of silt and sedimentation are essential features of the habitat for this species.

20. *Comment:* ''Global warming'' is another impact to consider in protecting water quantity in the habitat of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. At least one science team has predicted higher temperatures, and thus, higher evaporation rates, and reduced rainfall for central Texas as a result of global warming.

Our Response: We recognize that global climate change may affect global temperatures, and that this in turn can cause other climatic changes, such as changes in the amount and pattern of precipitation. However, the consequences of such changes to the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle are unknown. We therefore believe this issue to be outside the scope of the critical habitat designation for these species.

Summary of Changes From Proposed Rule

Based upon our review of the peer review and public comments, economic analysis, and any new relevant information that may have become available since the publication of the proposal, we reevaluated our proposed critical habitat designation for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. We made no changes to the critical habitat designation as described in the proposed rule. Other than minor clarifications and incorporation of additional information on the species' biology, status, and threats, this final rule differs from the proposal by the following:

(1) We modified the primary constituent elements for clarity and to reflect additional information received during the public comment period. Specifically we added, ''other compounds containing surfactants'' and ''pharmaceuticals and veterinary medicines,'' under the list of potential pollutants under PCE 1. Under PCE 3, we added the phrase, ''that allows for adequate spring flows'' to clarify the intent of the hydrologic regime. For PCE 4, we added, ''living plant material, algae, fungi, bacteria and other

microorganisms,'' to the list of potential food items.

(2) We made technical corrections to some of the information found in the Primary Constituent Elements, Background, and Criteria Used to Identify Critical Habitat sections of this rule.

Critical Habitat

Critical habitat is defined in section 3 of the Act as—(i) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) Essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. Conservation, as defined under section 3 of the Act means to use and the use of all methods and procedures that are necessary to bring any endangered species or threatened species to the point at which the measures provided under the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the prohibition against destruction or adverse modification of critical habitat with regard to actions carried out, funded, or authorized by a Federal agency. Section 7 of the Act requires consultation on Federal actions that are likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow government or public access to private lands. Section 7 of the Act is a purely protective measure and does not require implementation of restoration, recovery, or enhancement measures.

To be included in a critical habitat designation, the habitat within the area occupied by the species must first have features that are essential to the conservation of the species. Critical habitat designations identify, to the extent known using the best scientific data available, habitat areas that provide essential life cycle needs of the species (*i.e.*, areas on which are found the primary constituent elements (PCEs), as defined at 50 CFR 424.12(b)).

Occupied habitat may be included in critical habitat only if the essential features thereon may require special management or protection. Furthermore, when the best available scientific data do not demonstrate that the conservation needs of the species require additional areas, we cannot designate critical habitat in areas outside the geographical area occupied by the species at the time of listing. However, an area currently occupied by the species but not occupied at the time of listing, will likely be essential to the conservation of the species and, therefore, may be included in the critical habitat designation.

The Service's Policy on Information Standards Under the Endangered Species Act, published in the **Federal Register** on July 1, 1994 (59 FR 34271), and Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658) and the associated Information Quality Guidelines issued by the Service, provide criteria, establish procedures, and provide guidance to ensure that decisions made by the Service represent the best scientific data available. They require Service biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat. When determining which areas are critical habitat, a primary source of information is generally the listing package for the species. Additional information sources may include the recovery plan for the species, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, or other unpublished materials and expert opinion or personal knowledge. All information is used in accordance with the provisions of Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658) and the associated Information Quality Guidelines issued by the Service.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific and commercial data available. Habitat is often dynamic, and species may move from one area to another over time. Furthermore, we recognize that designation of critical habitat may not include all of the habitat areas that may eventually be determined to be necessary for the recovery of the species. For these reasons, critical habitat designations do not signal that habitat outside the designation is unimportant or may not be required for recovery.

Areas that support populations, but are outside the critical habitat designation, will continue to be subject to conservation actions implemented under section 7(a)(1) of the Act and to the regulatory protections afforded by the section 7(a)(2) jeopardy standard, as determined on the basis of the best available information at the time of the action. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available to these planning efforts calls for a different outcome.

Primary Constituent Elements

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, in determining which areas to designate as critical habitat, we consider those physical and biological features (known as primary constituent elements) that are essential to the conservation of the species, and within areas occupied by the species at the time of listing, that may require special management considerations or protection. These include, but are not limited to: (1) Space for individual and population growth, and for normal behavior; (2) food, water, air, light, minerals, or other nutritional or physiological requirements; (3) cover or shelter; (4) sites for breeding, reproduction, and rearing (or development) of offspring; and (5) habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species.

The specific primary constituent elements required for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle are derived from the biological needs of these species as described in the Background section of this final rule and in the December 18, 1997, final rule listing these species (62 FR 66295).

Pursuant to the Act and its implementing regulations, we are required to identify the known physical

and biological features (PCEs) within the geographical area occupied at the time of listing that are essential to the conservation of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle, which may require special management considerations or protections. All areas designated as critical habitat for Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle are occupied, within the species' historic geographic ranges, and contain sufficient PCEs to support at least one life history function.

Based on our current knowledge of the life history, biology, and ecology of these species, and the habitat requirements for sustaining the essential life history functions of these species, we have determined that the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle require the PCEs described below. The PCEs apply to all three species unless otherwise noted.

PCE 1. High-quality water with no or minimal levels of pollutants, such as soaps and detergents (Brown 1987, p. 261) and other compounds containing surfactants, heavy metals, pesticides, fertilizer nutrients, petroleum hydrocarbons, pharmaceuticals and veterinary medicines, and semi-volatile compounds, such as industrial cleaning agents, and including:

(a) Low salinity with total dissolved solids that generally range from about 307 to 368 milligrams per liter (mg/L); and

(b) Low turbidity that generally is less than 5 nephelometric (measurement of turbidity in a water sample by passing light through the sample and measuring the amount of the light that is deflected) turbidity units (NTUs).

These spring-adapted aquatic species live in high-quality unpolluted groundwater and spring outflows that have low levels of salinity and turbidity. High-quality discharge water from springs and adjacent subterranean areas also help sustain habitat components, such as riparian vegetation, that are essential to the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. The two beetle species are thought to require water with adequate levels of dissolved oxygen for respiration (Brown 1987, p. 260; Arsuffi 1993, p. 18). Amphipods generally require relatively high concentrations of oxygen and may serve as an indicator of good water quality (Arsuffi 1993, p. 15). While definitive studies on the limits of tolerance and preference for these aquatic invertebrates have not been completed, the aquatic invertebrates are exclusively found in aquatic habitats with constant temperature, low salinity, low turbidity, and extremely low levels of pollutants. In particular, respiration in the riffle beetle may be inhibited by pollutants such as soaps and detergents that can affect its respiratory mechanism (Brown 1987, p. 261). The dryopid beetle may also be affected by these particular pollutants, since this species shares a similar respiratory structure (Arsuffi 1993, p. 18). However, biological tolerances for this species are not understood due to its existence within a subterranean habitat.

Based on available literature, we believe that the PCE for high water quality in the critical habitat for these species should have an approximate range of salinity of about 307 to 368 mg/L and a turbidity of less than 5 NTUs. Fahlquist and Slattery (1997, p. 3) reported a low salinity (as measured by total dissolved solids) as low as 307 mg/L at Comal Springs, and Slattery and Fahlquist (1997, p. 4) found that San Marcos Springs had a low salinity of 328 mg/L. The two springs also have a low turbidity of less than 5 NTUs (Fahlquist and Slattery 1997, p. 3; Slattery and Fahlquist 1997, p. 4). Brune (1975, p. 94) reported a salinity for Hueco Springs of 322 mg/L. The highest salinity (as determined by analysis of total dissolved solids) that we have found associated with any of these invertebrates was 368 mg/L, which was reported from Fern Bank Springs on April 28, 2005 (Texas Water Development Board 2006, p. 1).

PCE 2. Aquifer water temperatures that range from approximately 68 to 75 °F (20 to 24 °C).

The three listed invertebrate species complete their life cycle functions within a relatively narrow temperature range; water temperatures outside of this range could be harmful to these invertebrates. The temperature of spring water emerging from the Edwards Aquifer at Comal Springs and San Marcos Springs ordinarily occurs within a narrow range of approximately 72 to 75 °F (22 to 24 °C) (Fahlquist and Slattery 1997, pp. 3–4; Groeger *et al.* 1997, pp. 282–283). Hueco Springs and Fern Bank Springs have temperature records of 68 to 71 °F (20 to 22 °C) (George 1952, p. 52; Brune 1975, p. 94; Texas Water Development Board 2006, p. 1).

PCE 3. A hydrologic regime that allows for adequate spring flows that provide levels of dissolved oxygen in the approximate range of 4.0 to 10.0 mg/L for respiration of the Comal Springs riffle beetle and Comal Springs dryopid beetle.

Respiration in most beetle species belonging to the family Elmidae (which includes the Comal Springs riffle beetle) typically requires flowing waters highly saturated with dissolved oxygen (Brown 1987, p. 260). As a consequence, riffle beetles are most commonly associated with flowing water that has shallow riffles (small waves) or rapids (Brown 1987, p. 253). Although there are not available data to support a correlation between minimum spring flows and survival or other sublethal, adverse effects of low or no spring flows on these species, there is information to indicate that availability and access to water at the spring sites are important factors in their respiration. For example, riffle beetles are known to be restricted to waters with high dissolved oxygen due to their reliance on a plastron (a thin sheet of air) that is held next to the underside of the body surface by a mass of minute, hydrophobic (tending to repel and not absorb water) hairs. The plastron functions as a gill by allowing oxygen to diffuse passively from water into the plastron and replace oxygen absorbed during respiration (Brown 1987, p. 260). Beetle species in the Elmidae family are generally limited to well-aerated water environments since gaseous exchange with a plastron can actually be reversed in oxygen-depleted waters (Brown 1987, p. 260; Ward 1992, p. 130). The Comal Springs dryopid beetle also relies on a plastron for respiration, and this beetle species may also be affected by changes in oxygen levels caused by habitat modification (Arsuffi 1993, pp. 17–18).

PCE 4. Food supply that includes detritus (decomposed materials), leaf litter, living plant material, algae, fungi, bacteria and other microorganisms, and decaying roots.

Feeding ecology in the Elmidae family varies among species, but most riffle beetles, as larvae and adults, feed on algae and detritus scraped from the substrates within their habitat (Brown 1987, p. 262). Specific food requirements for each of the three invertebrate species are unknown. However, the Peck's cave amphipod and dryopid beetle are most commonly found in areas where plant roots are inundated or otherwise influenced by aquifer water. Potential food sources for all three species in these areas include detritus (decomposed materials), leaf litter, and decaying roots; however, it is possible that these species feed on bacteria and fungi associated with decaying plant material. Both beetle species may be detritivores (detritus-feeding animals) that consume detrital materials in spring-influenced riparian zones (Brown 1987, p. 262; Randy

Gibson 2006, pp. 1–2). The best information available indicates the Peck's cave amphipod is an omnivore (a species capable of consuming both animals and plants), which would enable the amphipod to exist as a scavenger or predator inside the aquifer in addition to using detritus in areas near spring outlets where plant roots interface with spring water (Gibson 2006, p. 1).

Trees and shrubs in riparian areas adjacent to the spring system may provide plant growth necessary to maintain food sources such as decaying material for these invertebrates. Roots from trees and shrubs in proximity to spring outlets are most likely to penetrate underground down to the water pools, where these roots can serve as habitat for the amphipod and dryopid beetle. We believe relatively intact riparian areas with trees and shrubs may provide an important function within areas designated for critical habitat of the two subterranean species. According to patterns of plant canopies as determined from aerial photographs, trees and shrubs (and their root systems) are generally within 50 ft (15.2 m) of the edge of water in these spring systems.

PCE 5. Bottom substrate in surface water habitat of the Comal Springs riffle beetle that is free of sand and silt, and is composed of gravel and cobble ranging in size between 0.3 to 5.0 inches (in) (8–128 millimeters (mm)).

Although Comal Springs riffle beetles occur in conjunction with a variety of bottom substrates in surface water habitat, Bowles *et al.* (2003, p. 372) found that these beetles mainly occurred in areas with gravel and cobble ranging between 0.3 to 5.0 in (8–128 mm). Collection efforts in areas of high sedimentation generally do not yield riffle beetles (Bowles *et al.* 2003, p. 376). Similarly, BIO-WEST (2002, p. 11) conducted surveys for the Comal Springs riffle beetle in the Comal system and found that individuals of this species were restricted to habitat areas that consisted of rocks and gravel. They also observed that riffle beetles were only found in areas that were largely silt-free (BIO-WEST 2002, p.11).

This designation is designed for the conservation of PCEs necessary to support the life history functions that were the basis for the proposal and the areas containing those PCEs. Because not all life history functions require all of the PCEs, not all of the designated critical habitat may contain all the PCEs.

Units are designated based on sufficient PCEs being present to support at least one of each of the species' life history functions. Some units contain all PCEs and support multiple life processes, while some units contain only a portion of the PCEs necessary to support the species' particular use of that habitat. Where a subset of the PCEs is present at the time of designation, this rule protects those PCEs and thus the conservation function of the habitat.

Special Management Considerations or Protections

When designating critical habitat, we assess whether the areas determined to be occupied at the time of listing contain the features essential to the conservation that may require special management considerations or protections. Primary threats to the spring systems designated as critical habitat for the three invertebrate species that may require special management are summarized in Table 2. The threats for individual springs vary according to the degree of urbanization and availability of aquifer source water, but possible threats generally include prolonged cessation of spring flows (in 1956, Comal Springs at New Braunfels did not flow from mid-June to November (U.S. Army Corps of Engineers 1965)) as a result of the loss of hydrological connectivity within the aquifer (*e.g.*, groundwater pumping, excavation, concrete filling), pollutants (*e.g.*, stormwater drainage, pesticide use), and non-native species (*e.g.*, biological control, sport fish stocking). To address the threats affecting these three invertebrate species, certain special management actions may be required—for example, maintenance of sustainable groundwater use and subsurface flows, use of adequate buffers for water quality protection, selection of appropriate pesticides, and implementation of integrated pest management plans.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(1)(A) of the Act, we use the best scientific and commercial data available in determining areas that contain the features that are essential to the conservation of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle.

We reviewed available information that pertains to the presence and habitat requirements of these three invertebrate species, such as research published in peer-reviewed articles, data in reports submitted during section 7 consultations, contracted surveys, agency reports and databases, and aerial photographs. Information that has been reviewed includes, but is not limited to: Holsinger (1967), Bosse *et al.* (1988), Barr and Spangler (1992), Arsuffi (1993), Barr (1993), BIO-WEST (2001, 2002a, 2002b, 2003, 2004), Bowles *et al.* (2003), Fries *et al.* (2004), and Krejca (2005). As part of the process, we also reviewed the overall approach to conservation of these species undertaken by local, State, and Federal agencies, and private and non-governmental organizations operating within the species' range since their listing in 1997.

Peck's cave amphipod—The Peck's cave amphipod has been found in Comal Springs and Hueco Springs, which are both located in Comal County. While limited data have been collected on the extent to which this subterranean species exists below ground away from outlets of spring systems, other species within the genus *Stygobromus* are known to be widely distributed in groundwaters and cave systems (Holsinger 1972, p. 65). Although this species could possibly range throughout the 4-mile (mi) (8-kilometer (km)) distance between the two habitat spring systems through the ''honeycomb'' pores and conduits of the Edwards Aquifer, it is not known to what extent below-ground connections between Comal Springs and Hueco Springs are inhabited by the amphipod. The only specific location information we have for this species regarding its distribution in the aquifer, aside from where they exit the aquifer via spring openings, is an observation of Peck's cave amphipods at the bottom of a well (Panther Canyon well) that is located approximately 360 ft (110 m) away from the head outlet of Spring Run No. 1 (as designated in Barr and Spangler 1992, Fig. 1 on p. 42) in the Comal Springs complex (Krejca 2005, p. 83).

We are designating critical habitat for the Peck's cave amphipod in aquatic habitat associated with both Comal Springs and Hueco Springs. To include amphipod food sources in root/water interfaces around spring outlets, we also are designating an area consisting of a 50-ft (15.2-m) distance from spring outlets of both Comal Springs and Hueco Springs (including several satellite springs that are located between the main outlet of Hueco Springs and the Guadalupe River). We believe that this 50-ft distance defines the lateral extent of critical habitat that contains PCEs necessary to provide for life functions of the Peck's cave amphipod with respect to roots that can penetrate into the aquifer. Based on the 50-ft distance, the areas designated for the amphipod critical habitat are about 38.1 ac (15.4 ha) at Comal Springs and 0.4 ac (0.2 ha) at Hueco Springs. The acreages were calculated with a computer-based Geographical Information System (GIS). Designated critical habitat does not

include areas where PCEs do not occur for this species, such as buildings, roads, sidewalks, campgrounds, and lawns. Where lakes are designated, critical habitat is only designated in a radius of 50 ft (15.2 m) around springs and does not include other areas of the lake bottom where springs do not occur.

Comal Springs dryopid beetle—The Comal Springs dryopid beetle has been found in only two spring systems, Comal Springs and Fern Bank Springs, located in Comal and Hays Counties, respectively. The subterranean species is primarily collected near spring outlets (Barr and Spangler 1992, p. 41). While the extent to which the dryopid beetle inhabits subterranean areas away from spring outlets is unknown, this species does not swim and may be limited to relatively short ranges within the aquifer. In addition, immature stages of the species are thought to be terrestrial (Barr 1993, p. 56); however, they may also exist in spring outlets and in subterranean, air-filled chambers, such as caves (Barr and Spangler 1992, pp. 51–52). Barr and Spangler (1992, p. 41) collected larvae of the dryopid beetle near spring outlets of Comal Springs and believed that the larvae were associated with ceilings of spring orifices. Extension of the dryopid beetle into the aquifer may also be limited by the lack of food materials associated with decaying plant roots that occur near spring orifices.

For critical habitat of the Comal Springs dryopid beetle, we are designating aquatic habitat and a 50-ft (15.2-m) distance from spring outlets of Comal Springs and Fern Bank Springs. The 50-ft (15.2-m) distance is based on evaluations of aerial photographs showing tree and shrub canopies occurring in proximity to spring outlets at both spring systems. These plant canopies reflect approximate distances where plant root systems interface with water flows of the two spring systems. Based on the 50-ft (15.2-m) distance, the area designated for dryopid beetle critical habitat at Comal Springs is about 38.1 ac (15.4 ha), and 1.4 ac (0.6 ha) at Fern Bank Springs. These acreages include occupied areas that contain PCEs necessary for life history functions of the Comal Springs dryopid beetle. The acreages were calculated with GIS. Designated critical habitat does not include areas where PCEs do not occur for this species, such as lawns, buildings, roads, parking lots, and sidewalks. Where lakes are designated, critical habitat is only designated in a radius of 50 ft (15.2 m) around springs and does not include other areas of the lake bottom where springs do not occur.

Comal Springs riffle beetle—For the Comal Springs riffle beetle, habitat is primarily restricted to surface water in two impounded spring systems that are located within Comal and Hays Counties in central Texas. In Comal County, the aquatic beetle species is found in various spring outlets and seeps of Comal Springs that occur within the spring runs of Landa Lake and within Landa Lake itself, over a linear distance of about 0.9 mi (1.4 km). The species has also been found in outlets of San Marcos Springs in the upstream portion of Spring Lake in Hays County. However, populations of Comal Springs riffle beetles may exist elsewhere in Spring Lake since spring systems within the lake are interconnected, and sampling to date for the species within the lake has been limited.

For critical habitat of the Comal Springs riffle beetle, we are designating an area that encompasses all of the spring outlets that are found within the same lake (excluding a slough (slack water) portion that lacks spring outlets). Apart from the slough portion, the approximate linear distance of Spring Lake at its greatest length is 0.2 mi (0.3 km). We are designating about 19.8 ac (8.0 ha) of aquatic habitat in Landa Lake and about 10.5 ac (4.3 ha) of aquatic habitat in Spring Lake as critical habitat. These areas contain PCEs necessary for life-history functions of the Comal Springs riffle beetle. We did not include the 50-ft (15.2-m) lateral extent around springs because, unlike the other two species, the riffle beetle is believed to occur on the surface and not subterranean. The acreages were estimated by calculating the cross-hatched polygon area in two map figures of these lakes using GIS. Designated critical habitat does not include areas where PCEs do not occur for this species, such as lawns, buildings, roads, parking lots, and sidewalks.

When determining critical habitat boundaries, we made every effort to avoid including within those boundaries of the maps contained within this final rule developed areas such as buildings, paved areas, and other structures that lack PCEs for the Peck's cave amphipod, Comal Springs dryopid beetle, or Comal Springs riffle beetle. These efforts included overlaying critical habitat boundaries onto aerial photos to determine the percentage of buildings, lawns, and paved areas that were located within the critical habitat designations. In the few instances that this occurred, these areas were excluded in the text of the critical habitat unit descriptions in the Critical Habitat Designation section of this final rule. The estimated acreages for these areas were so small (i.e., approximately 2 percent or less of the critical habitat units involved), it was not practical to exclude them from the GIS coordinates provided for the designated critical habitat units in this final rule. We believe that eliminating buildings, lawns, and paved areas in the text of the critical habitat descriptions was the most feasible means of excluding these areas from the designations and provided a clearer indication of the exclusions for the public. The scale of the maps prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed areas. Any such structures and the surface under them inadvertently left inside critical habitat boundaries shown on the maps of this final rule have been excluded by text in the final rule and are not designated as critical habitat. Therefore, Federal actions limited to these areas would not trigger section 7 consultation, unless they may affect the species or PCEs in adjacent critical habitat.

We are designating critical habitat in areas that we have determined were occupied at the time of listing and contain sufficient PCEs to support life-history functions essential for the conservation of the species. Units of Comal Springs, Fern Bank Springs, Hueco Springs, and San Marcos Springs were designated based on sufficient PCEs being present to support at least one life process for the Peck's cave amphipod, Comal Springs dryopid beetle, and/or Comal Springs riffle beetle. A brief discussion of each area designated as critical habitat is provided in the unit descriptions below.

Critical Habitat Designation

We are designating four units as critical habitat for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. The critical habitat areas described below constitute our best assessment of areas determined to be occupied at the time of listing, that contain the PCEs essential for the conservation of these species and may require special management, and those additional areas that were not known to be occupied at the time of listing but were found to be essential to the conservation of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. The four spring systems designated as critical habitat are: (1) The Comal Springs Unit, (2) the Fern Bank Springs Unit, (3) the Hueco Springs Unit, and (4) the San Marcos Springs Unit. Table 1 shows the occupied units,

as well as provides approximate areas (ac/ha) of these spring units that have been determined to meet the definition of critical habitat for the three listed invertebrates.

TABLE 1.—SPRING SYSTEM UNITS, OCCUPANCY, DISTANCES FROM SPRING OUTLETS, AND ACREAGES OF CRITICAL HABITAT DESIGNATED FOR THE PECK'S CAVE AMPHIPOD, COMAL SPRINGS DRYOPID BEETLE, AND COMAL SPRINGS RIFFLE BEETLE IN COMAL AND HAYS COUNTIES, TEXAS

Species	Spring systems designated as critical habitat areas	Occupied at time of listing	Currently occupied	Distance from spring outlets for designated critical habitat ft (m)	Designated critical habitat acreage ac (ha)
Peck's cave amphipod	Comal Springs Unit	Yes	Yes	50 (15.2)	38.1 (15.4)
	Hueco Springs Unit	Yes	Yes	50 (15.2)	0.4 (0.2)
Comal Springs dryopid beetle	Comal Springs Unit	Yes	Yes	50 (15.2)	38.1 (15.4)
	Fern Bank Springs Unit	Yes	Yes	50 (15.2)	1.4 (0.6)
Comal Springs riffle beetle	Comal Springs Unit	Yes	Yes	(1)	19.8 (8.0)
	San Marcos Springs Unit	Yes	Yes	(1)	10.5 (4.3)

[1] Not applicable.

Table 2 summarizes land ownership and threats for the four spring systems designated for critical habitat. Land ownership for these spring systems involves only the State of Texas, municipalities, and private landowners, and does not involve Federal or Tribal holdings. Comal Springs and San Marcos Springs are surrounded, respectively, by the cities of New Braunfels and San Marcos. Both Comal Springs and San Marcos Springs have been impounded with dams to form Landa Lake and Spring Lake, respectively. Possible threats to these urban spring systems include, but are not limited to, water withdrawals, pesticide use, and stormwater runoff of pollutants that have accumulated on impervious cover (paved driveways, parking lots, sidewalks, etc.) in urban areas. A thorough threats discussion is found in the December 18, 1997, final rule listing these species (62 FR 66295).

TABLE 2.—OWNERSHIP AND THREATS TO SPRINGS OR LISTED SPECIES FOR CRITICAL HABITAT UNITS

Designated critical habitat units	Ownership of critical habitat by listed species ac (ha)	Threats to spring system or listed species
Comal Springs Unit, Comal County.	Peck's cave amphipod State—19.8 (8.0) Municipal—7.3 (3.0) Private—11.0 (4.5) Comal Springs dryopid beetle State—19.8 (8.0) Municipal—7.3 (3.0) Private—11.0 (4.5) Comal Springs riffle beetle State—19.8 (8.0)	Water withdrawals, hazardous materials spills, pesticide use, excavation/construction, stormwater pollutants, invasive species, and well entrainment.
Fern Bank Springs Unit, Hays County.	Comal Springs dryopid beetle Private—1.4 (0.6)	Water withdrawals, excavation/construction, and pesticide use.
Hueco Springs Unit, Comal County.	Peck's cave amphipod Private—0.4 (0.2)	Water withdrawals, hazardous materials spills, pesticide use, excavation/construction, stormwater pollutants, and well entrainment.
San Marcos Springs Unit, Hays County.	Comal Springs riffle beetle State—10.5 (4.3)	Water withdrawals, hazardous materials spills, pesticide use, excavation/construction, stormwater pollutants, and invasive species.

We present brief descriptions of all units and reasons why they meet the definition of critical habitat for Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle below. Maps of the designated critical habitat units are provided in the Regulation Promulgation section of this rule.

Comal Springs Unit—Comal County, Texas

The Comal Springs system provides habitat for all three listed invertebrate species, along with a federally listed fish, the endangered fountain darter (*Etheostoma fonticola*). No other critical habitat has been designated at this spring system. Comal Springs provides all of the PCEs necessary for conservation of the three invertebrate species. The spring system primarily occurs as a series of spring outlets that lie along the west shoreline of Landa Lake and within the lake itself. This nearly L-shaped lake is surrounded by the City of New Braunfels. Practically all of the spring outlets and spring runs associated with Comal Springs occur within the upper part of the lake above the confluence of Spring Run No. 1 with the lake. The land ownership of Comal Springs consists of private, municipal, and State holdings. The surface water and bottom of Landa Lake are State-owned. The City of New Braunfels owns approximately 40 percent of the land surface adjacent to the lake, and private landowners own approximately 60 percent. Approximate acreages of surface land ownership within the designated critical habitat unit and

threats to the unit are shown in Table 2.

Critical habitat for the three listed invertebrate species in the Comal Springs Unit is as follows:

(1) Landa Lake (Comal Springs riffle beetle only)—aquatic habitat within the lake and outlying spring runs that occur from the confluence of Blieders Creek at the upstream end of Landa Lake down to the lake's lowermost point of confluence with Spring Run No. 1. The part of Landa Lake that lies below the confluence with Spring Run No. 1 down to the impounding dams at the downstream end of the lake is not included.

(2) Aquatic habitat and shoreline areas of Landa Lake (Peck's cave amphipod and Comal Springs dryopid beetle only)—aquatic habitat within the lake and outlying spring runs that occur from the confluence of Blieders Creek at the upstream end of Landa Lake down to the lake's lowermost point of confluence with Spring Run No. 1. The part of Landa Lake that lies below the confluence with Spring Run No. 1 down to the impounding dams at the downstream end of the lake is not included. Land areas along the shoreline of Landa Lake and on small islands inside the lake that are within a 50-ft (15.2-m) distance from habitat spring outlets are included in the critical habitat. These shoreline areas in proximity to spring outlets provide trees and shrubs with roots that penetrate underground to serve as habitat for the Peck's cave amphipod and Comal Springs dryopid beetle. The critical habitat designated for the Peck's cave amphipod and Comal Springs dryopid beetle includes only aquatic and shoreline areas where PCEs exist for these two species and does not include areas where these features do not occur, such as lawns, buildings, roads, parking lots, and sidewalks. Where lakes are included, critical habitat is only designated for areas within a radius of 50 ft (15.2 m) around springs and does not include other areas of the lake bottom in areas where springs are absent.

Fern Bank Springs Unit—Hays County, Texas

The Fern Bank Springs system provides habitat for only the Comal Springs dryopid beetle. No other critical habitat has been designated at this spring system. Fern Bank Springs provides all of the PCEs necessary for conservation of this species. The spring system is located approximately 0.2 mi (0.4 km) east of the junction of Sycamore Creek with the Blanco River in Hays County. This spring system occurs in a rural area and is relatively unaffected by current urban activities in the vicinity of the springs. It consists of a main outlet and a number of seep springs that occur at the base of a high bluff overlooking the Blanco River. This spring system is located entirely on land that is privately owned. Approximate acreages of land ownership encompassed within the designated critical habitat unit and threats to the unit are shown in Table 2.

Critical habitat for the Comal Springs dryopid beetle in the Fern Bank Springs Unit as follows: Fern Bank Springs—aquatic habitat and land areas that are within a 50-ft (15.2-m) distance from spring outlets, including the main outlet of Fern Bank Springs and its associated seep springs. These land areas in proximity to spring outlets provide trees and shrubs with roots that penetrate underground to serve as habitat for the Comal Springs dryopid beetle. The critical habitat designated for the Comal Springs dryopid beetle includes only areas where PCEs exist for this species and does not include areas where these features do not occur, such as buildings, lawns, or paved areas.

Hueco Springs Unit—Comal County, Texas

The Hueco Springs system provides habitat for only the Peck's cave amphipod. No other critical habitat has been designated at this spring system. Hueco Springs provides all of the PCEs necessary for conservation of this species. This spring system occurs in a rural area and is relatively unaffected by current urban activities in the vicinity of the springs. It has a main outlet that is located approximately 0.1 mi (0.2 km) south of the junction of Elm Creek with the Guadalupe River in Comal County. The main outlet itself lies approximately 500 ft (152 m) from the west bank of the Guadalupe River. Several satellite springs lie further south between the main outlet and the river. This spring system is located entirely on private land. The main outlet of Hueco Springs is located on undeveloped land, but the satellite springs occur within undeveloped areas of a privately owned campground. Approximate acreages of land ownership encompassed within the designated critical habitat unit and threats to the unit are indicated in Table 2.

We designate critical habitat for the Peck's cave amphipod within the Hueco Springs Unit as follows:

(1) Hueco Springs—aquatic habitat and land areas that are within 50 ft (15.2 m) from habitat spring outlets, including the main outlet of Hueco Springs and its associated satellite springs. These land areas in proximity to spring outlets provide trees and shrubs with roots that penetrate underground to serve as habitat for the Peck's cave amphipod. The critical habitat designated for the Peck's cave amphipod includes only aquatic habitat and land areas where PCEs exist for this species. Areas consisting of buildings, roads, sidewalks, campgrounds, and lawns are excluded from this designation.

San Marcos Springs Unit—Hays County, Texas

The San Marcos Springs system provides habitat only for the Comal Springs riffle beetle. However, the San Marcos Springs system provides habitat for five other federally listed species: (1) The endangered fountain darter, (2) the endangered San Marcos gambusia (*Gambusia georgei*), (3) the threatened San Marcos salamander (*Eurycea nana*), (4) the endangered Texas blind salamander (*Eurycea* (formerly *Typhlomolge*) *rathbuni*), and (5) endangered Texas wild-rice (*Zizania texana*) (Service 1996, p. 6). However, the San Marcos gambusia has not been found in surveys during recent years and is presumed to be extinct (Edwards 1999, p. 3). Critical habitat has been designated for the fountain darter, San Marcos gambusia, San Marcos salamander, and Texas wild-rice within Spring Lake and portions of the San Marcos River that lie downstream from Spring Lake (45 FR 47355, July 14, 1980). The San Marcos Springs unit provides all of the PCEs necessary for conservation of the Comal Springs riffle beetle. The spring system primarily occurs as a series of spring outlets that lie at the bottom of Spring Lake and along its shoreline. The lake is surrounded by the City of San Marcos in Hays County. The spring outlets associated with San Marcos Springs occur within the main part of the lake, excluding the slough portion that exists as an arm of the lake. The land ownership involving San Marcos Springs consists entirely of State holdings. The surface water and bottom of Spring Lake are State-owned; the State-affiliated Texas State University owns the adjacent land surface. Approximate acreages of surface land ownership in the designated critical habitat unit and threats to the unit are shown in Table 2.

We designate critical habitat for the Comal Springs riffle beetle in the San Marcos Springs unit as: Spring Lake—aquatic habitat areas within the lake upstream of Spring Lake dam, with the exception of the slough portion of the lake upstream of its confluence with the main body.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7 of the Act requires Federal agencies, including the Service, to ensure that actions they fund, authorize, or carry out are not likely to destroy or adversely modify critical habitat. In our regulations at 50 CFR 402.02, we define destruction or adverse modification as ''a direct or indirect alteration that appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species. Such alterations include, but are not limited to, alterations adversely modifying any of those physical or biological features that were the basis for determining the habitat to be critical.'' However, recent decisions by the 5th and 9th Circuit Courts of Appeal have invalidated this definition. Pursuant to current national policy and the statutory provisions of the Act, destruction or adverse modification is determined on the basis of whether, with implementation of the proposed Federal action, the affected critical habitat would remain functional (or retain the current ability for the PCEs to be functionally established) to serve the intended conservation role for the species.

Section 7(a) of the Act requires Federal agencies, including the Service, to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is proposed or designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402.

If a species is listed or critical habitat is designated, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. As a result of this consultation, compliance with the requirements of section 7(a)(2) will be documented through the Service's issuance of: (1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or (2) a biological opinion for Federal actions that may affect, but are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to result in jeopardy to a listed species or the destruction or adverse modification of critical habitat, we also provide reasonable and prudent alternatives to the project, if any are identifiable. ''Reasonable and prudent alternatives'' are defined at 50 CFR 402.02 as alternative actions identified during consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that the Director believes would avoid jeopardy to the listed species or destruction or adverse modification of critical habitat. Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where a new species is listed or critical habitat is subsequently designated that may be affected and the Federal agency has retained discretionary involvement or control over the action or such discretionary involvement or control is authorized by law. Consequently, some Federal agencies may request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions may affect subsequently listed species or designated critical habitat or adversely modify or destroy proposed critical habitat.

Federal activities that may affect the Peck's cave amphipod, Comal Springs dryopid beetle, or Comal Springs riffle beetle or their designated critical habitat will require section 7 consultation under the Act. Activities on State, Tribal, local, or private lands requiring a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act or a permit under section 10(a)(1)(B) of the Act from the Service) or involving some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or Federal Emergency Management Agency) will also be subject to the section 7 consultation process. Federal actions requiring section 7 consultation also include pumping of Edwards Aquifer water by Federal agencies, such as the Department of Defense or Service. Federal actions not affecting listed species or critical habitat, and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or permitted, do not require section 7 consultations.

Application of the Jeopardy and Adverse Modification Standards for Actions Involving Effects to the Peck's Cave Amphipod, Comal Springs Dryopid Beetle, and Comal Springs Riffle Beetle and Their Critical Habitat

Jeopardy Standard

The Service has applied an analytical framework for jeopardy analyses of Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle that relies heavily on the importance of habitat conditions to the survival and recovery of these species. The section 7(a)(2) analysis is focused on the habitat conditions necessary to support them.

The jeopardy analysis usually expresses the survival and recovery needs of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle in a qualitative fashion without making distinctions between what is necessary for survival and what is necessary for recovery. Generally, if a proposed Federal action is incompatible with the viability of the affected species, inclusive of associated habitat conditions, a jeopardy finding is warranted because of the relationship of each core area population to the survival and recovery of the species as a whole.

Adverse Modification Standard

For the reasons described in the Director's December 9, 2004, memorandum, the key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical habitat would remain functional (or retain the current ability for the PCEs to be functionally established) to serve the intended conservation role for the species. Generally, the conservation role of critical habitat units for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle is to have each unit support viable populations.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe in any proposed or final regulation that designates critical habitat those activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation. Activities that may destroy or adversely modify critical habitat may also jeopardize the continued existence of the species.

Activities that may destroy or adversely modify critical habitat are

those that alter the PCEs to an extent that the conservation value of critical habitat for Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle is appreciably reduced. Activities that, when carried out, funded, or authorized by a Federal agency, may affect critical habitat and, therefore, should result in consultation for these listed species include, but are not limited to:

(1) Actions that can negatively affect the PCEs of the Peck's cave amphipod, Comal Springs dryopid beetle, or Comal Springs riffle beetle;

(2) Activities that would significantly and detrimentally alter the water quality in any of the spring systems listed above and would thereby destroy or adversely modify the critical habitat for any of theses species. These activities include, but are not limited to, sedimentation from construction or release of chemical or biological pollutants into the surface water or connected groundwater at a point source or by dispersed release (non-point source); such activities could also alter water conditions to a point that negatively affects these invertebrate species;

(3) Actions that change the existing and historic flow regimes and would thereby significantly and detrimentally alter the PCEs necessary for conservation of these species. Such activities could include, but are not limited to, water withdrawal, impoundment, and water diversions. These activities could eliminate or reduce the habitat necessary for the growth, reproduction, or survival of these invertebrate species; and

(4) Actions that remove hydraulic connectivity of the aquifer and the spring areas where it exists and would thereby negatively affect the PCEs of the designated critical habitat of these species and the population dynamics of the species. Alteration of subsurface water flows through destruction of geologic features (for example, excavation) or creation of impediments to flow (for example, concrete filling), especially in proximity to spring outlets, could negatively alter the hydraulic connectivity necessary to sustain these species. It is necessary for subsurface habitat to remain intact with sufficient hydraulic connectivity of flow paths and conduits to ensure that PCEs (water quality, water quantity, and food supply) for the designated critical habitat remain adequate for all three listed invertebrates.

Due in large part to the nature of the aquifer and spring systems, ongoing human activities that occur outside the designated critical habitat may threaten the physical and biological features of the designated critical habitat. While we are only designating critical habitat in occupied areas where PCEs exist and are in need of special management (*i.e.*, areas meeting the Service's criteria for defining critical habitat), consultation may also be needed outside of designated areas in order to avoid adverse modification of the PCEs within the designation. Federal activities outside of critical habitat (such as groundwater pumping, pollution, issuance of a section 10(a)(1)(B) permit, highway construction, etc.) are subject to review under section 7 of the Act if they may affect these species or adversely affect their critical habitat.

We consider all of the units designated as critical habitat to contain features essential to the conservation of the Peck's cave amphipod, Comal Springs dryopid beetle, or Comal Springs riffle beetle. All units are within the geographic range of the species, all were occupied by the species at the time of listing (based on observations made within the last 9 years), and are likely to be used by these listed invertebrates. Federal agencies already consult with us on activities in areas currently occupied by these listed invertebrates, or if the species may be affected by the action, to ensure that their actions do not jeopardize the continued existence of the Peck's cave amphipod, Comal Springs dryopid beetle, or Comal Springs riffle beetle.

Application of Section 4(a)(3) of the Act—Approved Integrated Natural Resource Management Plans

The Sikes Act Improvement Act of 1997 (Sikes Act) (16 U.S.C. 670a) required each military installation that includes land and water suitable for the conservation and management of natural resources to complete, by November 17, 2001, an Integrated Natural Resource Management Plan (INRMP). An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found on the base.

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108–136) amended the Act to limit areas eligible for designation as critical habitat. Specifically, section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) now provides: The Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.

There are no Department of Defense lands within the designated critical habitat that have completed an INRMP.

Application of Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that critical habitat shall be designated, and revised, on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact, of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the Secretary is afforded broad discretion, and the Congressional record is clear that, in making a determination under the section, the Secretary has discretion as to which factors and how much weight will be given to any factor.

Under section 4(b)(2), in considering whether to exclude a particular area from the designation, we must identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, determine whether the benefits of exclusion outweigh the benefits of inclusion. If an exclusion is contemplated, then we must determine whether excluding the area would result in the extinction of the species. In the following sections, we address a number of general issues that are relevant to the exclusions we considered.

Pursuant to section 4(b)(2) of the Act, we must consider relevant impacts in addition to economic ones. We determined that the lands within the designation of critical habitat for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle are not owned or managed by the Department of Defense; there are currently no habitat conservation plans for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle; and the designation does not include any Tribal lands or trust resources.

We have considered a number of programs that exist at the State and local levels (*e.g.*, EAA and Texas Commission for Environmental Quality) to protect the Edwards Aquifer and manage spring flows. As a result of a ruling in a 1991 court case (*Sierra Club* v. *Secretary of the Interior, No. MO–91–CA–069*), we

identified minimum spring flows from Comal and San Marcos springs likely to cause take, jeopardy, and adverse modification of critical habitat for other listed aquatic species. As a result of the Sierra Club lawsuit, the State legislature created the EAA through Senate Bill 1477 to regulate groundwater withdrawals. The EAA has issued withdrawal permits and created drought response plans that help protect the PCEs related to water quantity and temperature. The EAA has prepared a draft Habitat Conservation Plan (HCP) to provide for water quantity in the aquifer and protect spring dependent species. If finalized and permitted, the HCP is expected to help protect the aquifer. However, at this time the HCP has not been completed and the EAA is continuing to develop aquifer management strategies to permit appropriate pumping levels and conserve downstream spring flows. The full effects of future pumping strategies on spring flows remain uncertain and do not allow us to exclude any areas from critical habitat based on the benefits of the Edwards Aquifer management.

Other programs that provide some aquifer protection are Edwards Aquifer Rules and Phase I optional water quality measures of the Texas Commission on Environmental Quality (TCEQ). The Edwards Aquifer Rules provide protection for drinking water, and the Phase I measures provide protection for fountain darter, Texas wild-rice, San Marcos salamander, and San Marcos gambusia. The Edwards Aquifer Rules protect water quality by reducing pollutant loading through the implementation of best management practices that can help prevent degradation of groundwater. The Phase I optional water quality measures include enhanced best management practices that protect sensitive karst features. These measures also contain other protective actions that can be applied to many types of new projects. The Edwards Aquifer Rules and Phase I optional measures provide some benefits for the three Comal Springs invertebrates. However, the Phase I optional measures are not mandated for every project. Therefore we have considered excluding but have not excluded any lands from this designation based on the potential benefits from these planned or existing aquifer and water quality management initiatives.

We anticipate no impact to national security, Tribal lands, partnerships, or habitat conservation plans from this critical habitat designation. Based on the best available information, including the prepared economic analysis, we believe that all of these units contain the features that are essential for the conservation of the species. Our economic analysis does not indicate any areas within the critical habitat designation will bear a disproportionate cost of the designation. Therefore, we have found no areas for which the benefits of exclusion outweigh the benefits of inclusion, and so have not excluded any areas from this designation of critical habitat for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle based on economic impacts. As such, we have considered but not excluded any lands from this designation based on the potential impacts to economic factors.

Economics

Section 4(b)(2) of the Act requires us to designate critical habitat on the basis of the best scientific information available and to consider the economic and other relevant impacts of designating a particular area as critical habitat. We may exclude areas from critical habitat upon a determination that the benefits of such exclusions outweigh the benefits of specifying such areas as critical habitat. We cannot exclude such areas from critical habitat when such exclusion will result in the extinction of the species concerned.

Following the publication of the proposed critical habitat designation, we conducted an economic analysis to estimate the potential economic effect of the designation. The draft analysis was made available for public review on March 16, 2007 (72 FR 12585). We accepted comments on the draft analysis until April 16, 2007.

The primary purpose of the economic analysis is to estimate the potential economic impacts associated with the conservation of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. This economic analysis considers the economic efficiency effects that may result from the designation, including habitat protections that may be co-extensive with the listing of the species. It also addresses distribution of impacts, including an assessment of the potential effects on small entities and the energy industry. This information can be used by the Secretary to assess whether the effects of the designation might unduly burden a particular group or economic sector.

This analysis focuses on the direct and indirect costs of the rule. However, economic impacts to land use activities can exist in the absence of critical habitat. These impacts may result from, for example, section 7 consultations under the jeopardy standard, local zoning laws, State and natural resource laws, and enforceable management plans and best management practices applied by other State and Federal agencies.

Under scenarios 1 and 2 in the draft economic analysis, impacts associated with water use changes comprised the vast majority, or between 91 and 99 percent, of the total quantified impacts in the areas we proposed for designation. Economic impacts were based on the total permitted withdrawals from the Edwards Aquifer that are planned to be reduced in part to provide spring flows that were identified in a 1993 lawsuit concerning five endangered species in the Edwards Aquifer that share habitat with the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. The analysis considered that as soon as 2008, total permitted water withdrawals in the Edwards Aquifer may be further limited from the present 549,000 acre-feet per year to 400,000 acre-feet per year (scenario 1). It is also possible that, in dry years, additional restrictions may be imposed that will further limit aquifer withdrawals to 340,000 acre-feet (scenario 2). The draft economic analysis examined social welfare and regional economic impacts that could result from these limits to water withdrawals in the aquifer. It should be noted that the majority of economic impacts quantified in the draft economic analysis are jointly caused by eight endangered species, including the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. Because all of these species reside in the same habitat, separating future impacts of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle from those of the other listed species in the aquifer was not attempted.

We estimated costs related to conservation activities for the area proposed for designation of critical habitat for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle under sections 4, 7, and 10 of the Act to be approximately $24.5 million over the next 20 years under scenario 1, or $154.3 million under scenario 2 in undiscounted dollars (annualized dollars are estimated to be $1.2 million under scenario 1 and $7.7 million under scenario 2). Future economic impacts associated with conservation activities in areas designated as critical habitat at a 3 percent discount rate are estimated to be $18 million over the next 20 years

under scenario 1, or $113 million under scenario 2 (annualized dollars are estimated to be $1.2 million under scenario 1 and $7.6 million under scenario 2). Future economic impacts associated with conservation efforts in areas proposed as critical habitat at a 7 percent discount rate were estimated to be $12.5 million over the next 20 years under scenario 1, or $78.5 million under scenario 2 (annualized dollars are estimated to be $1.3 million under scenario 1 and $7.4 million under scenario 2). No areas were excluded from this designation as a result of the economic analysis. The economic analysis did not consider recent changes to the Edwards Aquifer Authority passed by the Texas Legislature in May 2007 (Senate Bill 3).

A copy of the final economic analysis with supporting documents may be obtained by contacting U.S. Fish and Wildlife Service, Branch of Endangered Species (see **FOR FURTHER INFORMATION CONTACT**) or by download from the Internet at *http://www.fws.gov/southwest/es/Library/*.

Required Determinations

Regulatory Planning and Review

In accordance with Executive Order (E.O.) 12866, this document is a significant rule in that it may raise novel legal and policy issues, but will not have an annual effect on the economy of $100 million or more or affect the economy in a material way. Due to the tight timeline for publication in the **Federal Register**, the Office of Management and Budget (OMB) has not formally reviewed this rule. As explained above, we prepared an economic analysis of this action. We used this analysis to meet the requirement of section 4(b)(2) of the Act to determine the economic consequences of designating the specific areas as critical habitat. We also used it to help determine whether to exclude any area from critical habitat, as provided for under section 4(b)(2) of the Act, if we determine that the benefits of such exclusion outweigh the benefits of specifying an area as part of the critical habitat, unless we determine, based on the best scientific data available, that the failure to designate such an area as critical habitat will result in the extinction of the species.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA) (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a statement of factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA also amended the RFA to require a certification statement.

Small entities include small organizations, such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; as well as small businesses. Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we consider the types of activities that might trigger regulatory impacts under this rule, as well as the types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

To determine if the rule could significantly affect a substantial number of small entities, we consider the number of small entities affected within particular types of economic activities (such as housing development, grazing, oil and gas production, timber harvesting). We apply the ''substantial number'' test individually to each industry to determine if certification is appropriate. However, the SBREFA does not explicitly define ''substantial number'' or ''significant economic impact.'' Consequently, to assess whether a ''substantial number'' of small entities is affected by this designation, this analysis considers the relative number of small entities likely to be impacted in an area. In some circumstances, especially with critical habitat designations of limited extent, we may aggregate across all industries and consider whether the total number of small entities affected is substantial. In estimating the number of small entities potentially affected, we also consider whether their activities have any Federal involvement.

Designation of critical habitat only affects activities conducted, funded, or permitted by Federal agencies. Some kinds of activities are unlikely to have any Federal involvement and so will not be affected by critical habitat designation. In areas where the species is present, Federal agencies already are required to consult with us under section 7 of the Act on activities they fund, permit, or implement that may affect the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. Federal agencies also must consult with us if their activities may affect critical habitat. Designation of critical habitat, therefore, could result in an additional economic impact on small entities due to the requirement to reinitiate consultation for ongoing Federal activities.

The draft economic analysis examined the potential for Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle conservation efforts to affect small entities. This analysis was based on the estimated impacts associated with the proposed critical habitat designation and evaluated the potential for economic impacts related to water use for agricultural activities, construction or development, and aquatic restoration. Aquatic restoration activities were not anticipated to affect small entities, as these activities will be carried out by a Federal agency (U.S. Army Corps of Engineers). Accordingly, the small business analysis focused on economic impacts resulting from potential water use changes for agricultural activities and construction or development activities. Future restrictions on groundwater pumping are expected to cause irrigated crop acreage to shift to dryland production. Under Scenario 1, where future groundwater pumping is restricted to 400,000 acre-feet per year, approximately 33,000 acres of irrigated cropland are expected to shift to dryland production, and 507 farms are likely to experience a reduction in output valued between $8,000 and $44,000. Under Scenario 2, where future groundwater pumping is restricted to 340,000 acre-feet per year, approximately 35,000 acres of irrigated cropland are expected to shift to dryland production, and 532 farms are likely to experience a reduction in

output valued between $9,000 and $45,000. However, these costs are associated with the conservation of the species, and may result from desirable management, but not necessarily management that can be required under the Act. For those development projects likely to be undertaken by a small entity, Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle conservation costs are estimated to be between $1,340 and $1,710. Assuming the annual revenues of an average small developer are $18.0 million, the average annualized cost per project is about 0.1 percent of typical annual sales.

In general, two different mechanisms in section 7 consultations could lead to additional regulatory requirements for the approximately four small businesses, on average, that may be required to consult with us each year regarding their project's impact on the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle and its habitat. First, if we conclude, in a biological opinion, that a proposed action is likely to jeopardize the continued existence of a species or adversely modify its critical habitat, we can offer ''reasonable and prudent alternatives.'' Reasonable and prudent alternatives are alternative actions that can be implemented in a manner consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that would avoid jeopardizing the continued existence of listed species or result in adverse modification of critical habitat. A Federal agency and an applicant may elect to implement a reasonable and prudent alternative associated with a biological opinion that has found jeopardy or adverse modification of critical habitat. An agency or applicant could alternatively choose to seek an exemption from the requirements of the Act or proceed without implementing the reasonable and prudent alternative. However, unless an exemption were obtained, the Federal agency or applicant would be at risk of violating section 7(a)(2) of the Act if it chose to proceed without implementing the reasonable and prudent alternatives.

Second, if we find that a proposed action is not likely to jeopardize the continued existence of a listed animal or plant species, we may identify reasonable and prudent measures designed to minimize the amount or extent of take and require the Federal agency or applicant to implement such measures through non-discretionary terms and conditions. We may also identify discretionary conservation recommendations designed to minimize or avoid the adverse effects of a proposed action on listed species or critical habitat, help implement recovery plans, or to develop information that could contribute to the recovery of the species.

Based on our experience with consultations pursuant to section 7 of the Act for all listed species, virtually all projects—including those that, in their initial proposed form, would result in jeopardy or adverse modification determinations in section 7 consultations—can be implemented successfully with, at most, the adoption of reasonable and prudent alternatives. These measures, by definition, must be economically feasible and within the scope of authority of the Federal agency involved in the consultation. We can only describe the general kinds of actions that may be identified in future reasonable and prudent alternatives. These are based on our understanding of the needs of the species and the threats it faces, as described in the final listing rule and this critical habitat designation. Within the final critical habitat units, the types of Federal actions or authorized activities that we have identified as potential concerns are:

(1) Regulation of activities affecting waters of the United States by the U.S. Army Corps of Engineers under section 404 of the Clean Water Act;

(2) Regulation of water flows, damming, diversion, and channelization implemented or licensed by Federal agencies;

(3) Activities that may lead to storm water runoff that are regulated under the National Pollution Discharge Elimination System of the Clean Water Act by the Environmental Protection Agency;

(4) Activities authorized, carried out, or funded by any Federal agency that may result in point source storm water pollutant discharges, including excavation, site development, construction, and other surface disturbing activities;

(5) Activities authorized, carried out, or funded by the Federal Highway Administration that could lead to the introduction of pollutants into receiving waters from highway runoff; and

(6) Activities authorized, carried out, or funded by any Federal agency that could result in a reduction of groundwater supplies that support the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle.

It is likely that a developer or other project proponent could modify a project or take measures to protect the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. The kinds of actions that may be included if future reasonable and prudent alternatives become necessary include conservation set-asides, management of competing nonnative species, restoration of degraded habitat, and regular monitoring. These are based on our understanding of the needs of the species and the threats it faces, as described in the final listing rule and proposed critical habitat designation. These measures are not likely to result in a significant economic impact to project proponents.

In summary, we have considered whether this would result in a significant economic effect on a substantial number of small entities. We have determined, for the above reasons and based on currently available information, that it is not likely to affect a substantial number of small entities. Federal involvement, and thus section 7 consultations, would be limited to a subset of the area designated. The most likely Federal involvement could include actions needing a section 404 permit under the Clean Water Act, actions receiving Federal Highway Administration funding, and actions needing a section 10(a)(1)(B) permit under the Endangered Species Act of 1973, as amended. A regulatory flexibility analysis is not required.

Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 et seq.)

Under SBREFA, this rule is not a major rule. Our detailed assessment of the economic effects of this designation is described in the economic analysis. Based on the effects identified in the economic analysis, we believe that this rule will not have an annual effect on the economy of $100 million or more, will not cause a major increase in costs or prices for consumers, and will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. Refer to the final economic analysis for a discussion of the effects of this determination.

Executive Order 13211

On May 18, 2001, the President issued Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This final rule to designated critical habitat for the

Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle is not expected to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(a) This rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments,'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. (At the time of enactment, these entitlement programs were: Medicaid; AFDC work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement.) ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) A condition of Federal assistance; or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities who receive Federal funding, assistance, permits or otherwise require approval or authorization from a Federal agency for an action may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above on to State governments.

(b) We do not believe that this rule will significantly or uniquely affect small governments because it will not produce a Federal mandate of $100 million or greater in any year; that is, it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. The designation of critical habitat imposes no obligations on State or local governments. As such, a Small Government Agency Plan is not required.

Takings

In accordance with Executive Order 12630 (''Government Actions and Interference with Constitutionally Protected Private Property Rights''), we have analyzed the potential takings implications of designating 38.5 ac (15.6 ha) of lands in Comal County, Texas, as critical habitat for the Peck's cave amphipod, 39.5 ac (16.0 ha) of lands in Comal and Hays Counties, Texas, as critical habitat for the Comal Springs dryopid beetle, and 30.3 ac (12.3 ha) of lands in Comal and Hays counties, Texas, as critical habitat for the Comal Springs riffle beetle in a takings implication assessment. The takings implications assessment concludes that this final designation of critical habitat does not pose significant takings implications for lands within or affected by the designation.

Federalism

In accordance with Executive Order 13132 (Federalism), the rule does not have significant Federalism effects. A Federalism assessment is not required. In keeping with the Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of, this final critical habitat designation with appropriate State resource agencies in Texas. The designation may have some benefit to these governments in that the areas that contain the features essential to the conservation of the species are more clearly defined, and the primary constituent elements of the habitat necessary to the conservation of the species are specifically identified. While making this definition and identification does not alter where and what federally sponsored activities may occur, it may assist these local governments in long-range planning (rather than waiting for case-by-case section 7 consultations to occur).

Civil Justice Reform

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. We are designating critical habitat in accordance with the provisions of the Endangered Species Act. This final rule uses standard property descriptions and identifies the primary constituent elements within the designated areas to assist the public in understanding the habitat needs of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act. This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the Tenth Federal Circuit, we do not need to prepare environmental analyses as defined by NEPA in connection with designating critical habitat under the Endangered Species Act of 1973, as amended. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This assertion was upheld in the courts of the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. Ore. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive

Order 13175, and the Department of Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997, ''American Indian Tribal Rights, Federal—Tribal Trust Responsibilities, and the Endangered Species Act,'' we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes. We have determined that there are no Tribal lands occupied at the time of listing that contain the features essential for the conservation and no Tribal lands that are unoccupied areas that are essential for the conservation of the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle. Therefore, we have not designated critical habitat for the Peck's cave amphipod, Comal Springs dryopid beetle, and Comal Springs riffle beetle on Tribal lands.

References Cited

A complete list of all references cited in this rulemaking is available upon request from the Field Supervisor, Austin Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Author(s)

The primary authors of this final rule are staff of the Ecological Services Office in Austin, Texas (see **FOR FURTHER INFORMATION CONTACT**).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

■ Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

■ 2. Amend § 17.11(h), the List of Endangered and Threatened Wildlife, as follows:

■ a. Under ''INSECTS,'' revise the entries for ''Beetle, Comal Springs dryopid'' and ''Beetle, Comal Springs riffle'' to read as set forth below; and

■ b. Under ''CRUSTACEANS,'' revise the entry for ''Amphipod, Peck's cave'' to read as set forth below.

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
* * *	*	*	*		*	*	
INSECTS							
* * *	*	*	*		*	*	
Beetle, Comal Springs dryopid.	*Stygoparnus comalensis*	U.S.A. (TX)	NA	E	629	17.95(i)	NA
Beetle, Comal Springs riffle	*Heterelmis comalensis*	U.S.A. (TX)	NA	E	629	17.95(i)	NA
* * *	*	*	*		*	*	
CRUSTACEANS							
* * *	*	*	*		*	*	
Amphipod, Peck's cave	*Stygobromus (=Stygonectes) Pecki.*	U.S.A. (TX)	NA	E	629	17.95(h)	NA
* * *	*	*	*		*	*	

■ 3. Amend § 17.95 as follows:

■ a. In paragraph (h), add an entry for ''Peck's cave amphipod (*Stygobromus pecki*)'', in the same alphabetical order in which the species appears in the table at 50 CFR 17.11(h), to read as set forth below; and

■ b. In paragraph (i), add entries for ''Comal Springs dryopid beetle (*Stygoparnus comalensis*)'' and ''Comal Springs riffle beetle (*Heterelmis comalensis*)'', in the same alphabetical order in which these species appear in the table at 50 CFR 17.11(h), to read as set forth below.

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(h) *Crustaceans.*

* * * * *

Peck's cave amphipod (*Stygobromus pecki*).

(1) Critical habitat units are depicted for Comal County, Texas, on the maps below.

(2) The primary constituent elements of critical habitat for Peck's cave amphipod are:

(i) High-quality water with no or minimal levels of pollutants, such as soaps and detergents (Brown 1987, p. 261) and other compounds containing surfactants, heavy metals, pesticides, fertilizer nutrients, petroleum hydrocarbons, pharmaceuticals and veterinary medicines, and semi-volatile compounds, such as industrial cleaning agents, and including:

(A) Low salinity with total dissolved solids that generally range from 307 to 368 mg/L; and

(B) Low turbidity that generally is less than 5 nephelometric turbity units;

(ii) Aquifer water temperatures that range from approximately 68 to 75 °F (20 to 24 °C); and

(iii) Food supply that includes detritus (decomposed materials), leaf litter, living plant material, algae, fungi,

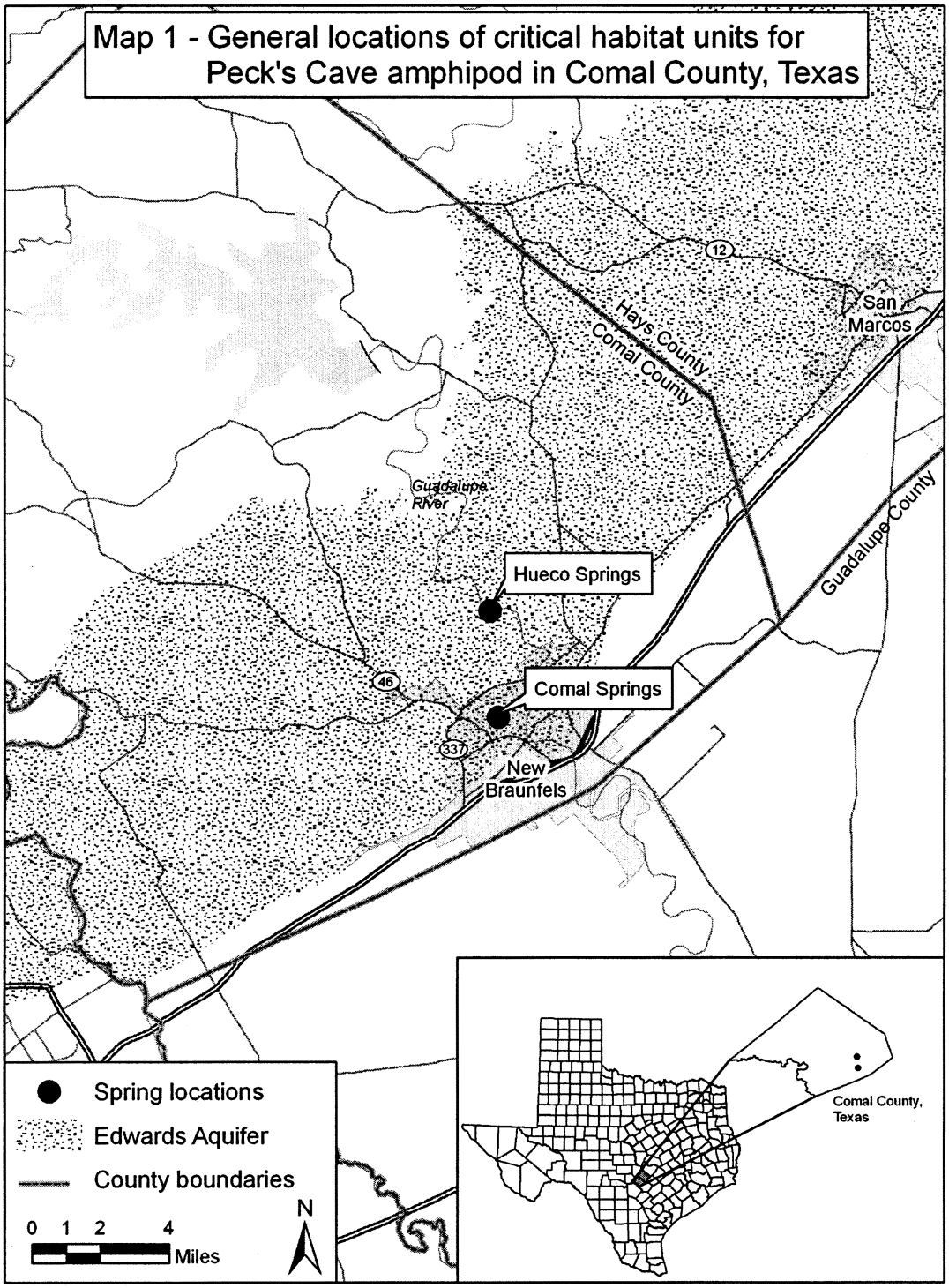
bacteria and other microorganisms, and decaying roots.

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of this rule. Where lakes are designated, critical habitat is only designated for areas where springs occur and does not include areas of the lake bottom beyond a radius of 50 ft (15.2 m) from the spring outlet.

(4) *Critical habitat map units.* Data layers defining map units were created by using ArcGIS. All coordinates are UTM zone 14 coordinate pairs, referenced to North American Horizontal Datum 1983. Coordinates were derived from 2004 digital orthophotographs. All acreage and mileage calculations were performed using GIS.

(5) Note: Index map (Map 1) follows:

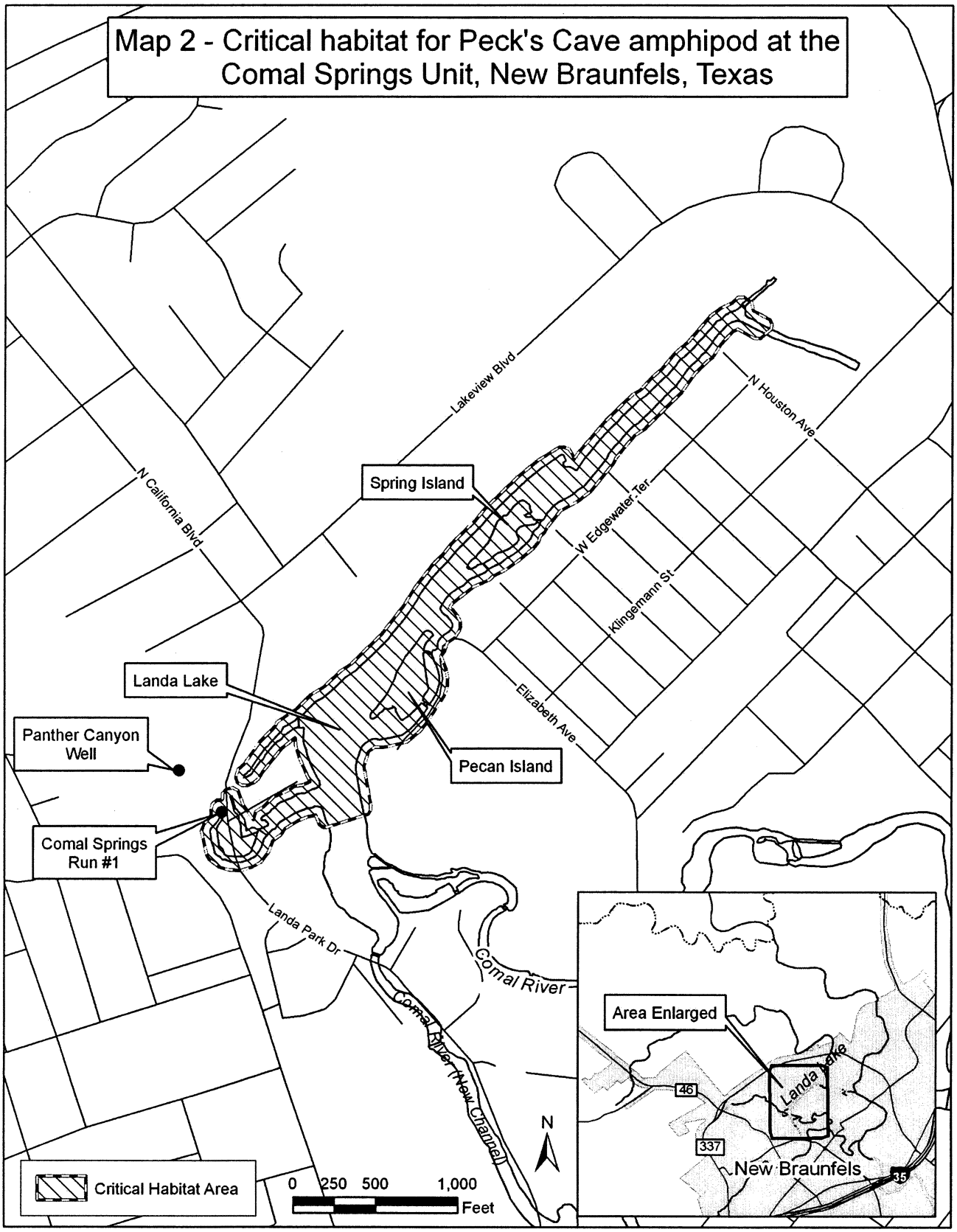
BILLING CODE 4310–55–P



(6) Comal Springs Unit, Comal County, Texas.

(i) Aquatic habitat areas bounded by the UTM Zone 14 NAD 83 coordinates (meters E, meters N): 583387, 3287251; 583392, 3287264; 583405, 3287280; 583404, 3287290; 583407, 3287301; 583414, 3287307; 583425, 3287308; 583425, 3287320; 583433, 3287328; 583444, 3287330; 583454, 3287325; 583463, 3287301; 583482, 3287272; 583486, 3287286; 583501, 3287296; 583520, 3287314; 583547, 3287326; 583557, 3287333; 583572, 3287335; 583586, 3287342; 583567, 3287387; 583560, 3287408; 583559, 3287423; 583534, 3287403; 583499, 3287359; 583491, 3287347; 583484, 3287340; 583471, 3287334; 583461, 3287334; 583452, 3287340; 583450, 3287350; 583454, 3287364; 583465, 3287374; 583494, 3287415; 583521, 3287443; 583526, 3287453; 583563, 3287477; 583589, 3287503; 583613, 3287519; 583643, 3287547; 583662, 3287561; 583719, 3287617; 583759, 3287669; 583780, 3287701; 583811, 3287743; 583833, 3287764; 583848, 3287784; 583892, 3287826; 583911, 3287850; 583970, 3287907; 584008, 3287938; 584047, 3287963; 584055, 3287964; 584065, 3287960; 584073, 3287948; 584074, 3287941; 584081, 3287952; 584131, 3288011; 584164, 3288044; 584183, 3288062; 584197, 3288071; 584216, 3288093; 584236, 3288110; 584258, 3288138; 584284, 3288161; 584325, 3288209; 584343, 3288223; 584364, 3288233; 584375, 3288243; 584386, 3288244; 584401, 3288234; 584403, 3288218; 584433, 3288201; 584437, 3288193; 584436, 3288184; 584416, 3288167; 584405, 3288167; 584375, 3288184; 584365, 3288180; 584344, 3288156; 584329, 3288131; 584320, 3288125; 584298, 3288103; 584273, 3288067; 584204, 3287997; 584187, 3287985; 584176, 3287973; 584152, 3287943; 584147, 3287933; 584105, 3287880; 584080, 3287862; 584049, 3287844; 584026, 3287815; 584021, 3287805; 584013, 3287798; 584009, 3287787; 583999, 3287775; 583971, 3287751; 583947, 3287735; 583927, 3287725; 583920, 3287718; 583890, 3287704; 583850, 3287673; 583845, 3287665; 583851, 3287662; 583860, 3287650; 583865, 3287640; 583865, 3287629; 583863, 3287622; 583854, 3287609; 583840, 3287600; 583836, 3287584; 583829, 3287576; 583838, 3287552; 583841, 3287535; 583841, 3287520; 583835, 3287501; 583804, 3287452; 583790, 3287435; 583766, 3287416; 583727, 3287406; 583706, 3287406; 583695, 3287398; 583686, 3287370; 583699, 3287298; 583698, 3287288; 583694, 3287282; 583617, 3287257; 583610, 3287258; 583605, 3287262; 583597, 3287280; 583584, 3287277; 583565, 3287270; 583541, 3287255; 583534, 3287244; 583518, 3287233; 583510, 3287211; 583496, 3287192; 583480, 3287183; 583459, 3287177; 583436, 3287178; 583419, 3287184; 583400, 3287198; 583396, 3287205; 583387, 3287251.

(ii) Note: Comal Springs Unit (Map 2) follows:



(7) Hueco Springs Unit, Comal County, Texas.

(i) Aquatic habitat areas bounded by the UTM Zone 14 NAD 83 coordinates (meters E, meters N): 583113, 3292498; 583114, 3292498; 583115, 3292498; 583116, 3292498; 583117, 3292498; 583118, 3292497; 583119, 3292497; 583120, 3292497; 583120, 3292496; 583121, 3292496; 583122, 3292495; 583123, 3292495; 583124, 3292494; 583124, 3292493; 583125, 3292493;

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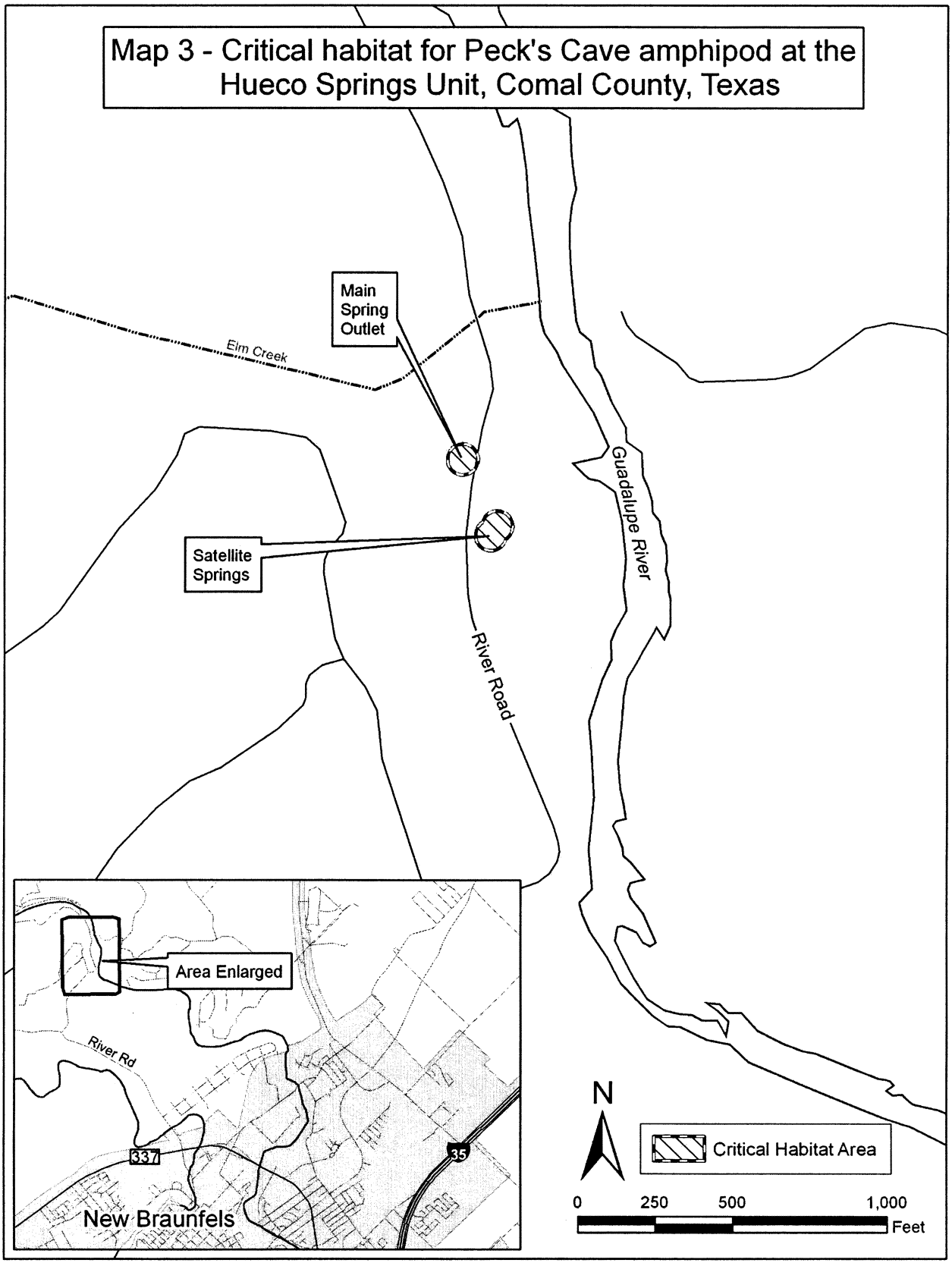
(ii) Aquatic habitat areas bounded by the UTM Zone 14 NAD 83 coordinates (meters E, meters N): 583132, 3292420; 583133, 3292421; 583133, 3292421; 583133, 3292422; 583134, 3292423; 583134, 3292424; 583134, 3292425; 583135, 3292426; 583136, 3292426; 583136, 3292427; 583137, 3292428; 583138, 3292428; 583138, 3292429; 583139, 3292430; 583140, 3292430; 583141, 3292430; 583142, 3292431; 583143, 3292431; 583143, 3292431; 583144, 3292432; 583145, 3292432; 583146, 3292432; 583147, 3292432; 583148, 3292432; 583149, 3292432; 583150, 3292432; 583151, 3292432; 583152, 3292431; 583153, 3292431; 583154, 3292431; 583155, 3292430; 583155, 3292430; 583156, 3292429; 583157, 3292429; 583158, 3292428; 583158, 3292427; 583159, 3292427; 583160, 3292426; 583160, 3292425; 583161, 3292424; 583161, 3292423; 583162, 3292422; 583162, 3292422; 583162, 3292421; 583162, 3292420; 583163, 3292419; 583163, 3292418; 583163, 3292417; 583163, 3292416; 583163, 3292415; 583162, 3292414; 583162, 3292413; 583162, 3292412; 583162, 3292411; 583161, 3292410; 583161, 3292409; 583160, 3292409; 583160, 3292408; 583159, 3292407; 583159, 3292406; 583158, 3292406; 583157, 3292405; 583156, 3292404; 583156, 3292404; 583156, 3292403; 583155, 3292402; 583155, 3292402; 583155, 3292401; 583154, 3292400; 583154, 3292399; 583153, 3292398; 583152, 3292398; 583152, 3292397; 583151, 3292396; 583150, 3292396; 583149, 3292395; 583149, 3292395; 583148, 3292394; 583147, 3292394; 583146, 3292393; 583145, 3292393; 583144, 3292393; 583143, 3292393; 583142, 3292393; 583141, 3292393; 583140, 3292393; 583139, 3292393; 583138, 3292393; 583137, 3292393; 583137, 3292393; 583136, 3292394; 583135, 3292394; 583134, 3292395; 583133, 3292395; 583132, 3292396; 583132, 3292396; 583131, 3292397; 583130, 3292397; 583129, 3292398; 583129, 3292399; 583128, 3292400; 583128, 3292400; 583127, 3292401; 583127, 3292402; 583127, 3292403; 583126, 3292404; 583126, 3292405; 583126, 3292406; 583126, 3292407; 583126, 3292408; 583126, 3292409; 583126, 3292410; 583126, 3292411; 583126, 3292412; 583127, 3292413; 583127, 3292413; 583127, 3292414; 583128, 3292415; 583128, 3292416; 583129, 3292417; 583129, 3292418; 583130, 3292418; 583131, 3292419; 583131, 3292420; 583132, 3292420.

(iii) Note: Hueco Springs Unit (Map 3) follows:



* * * * *

(i) *Insects.*

* * * * *

Comal Springs dryopid beetle (*Stygoparnus comalensis*).

(1) Critical habitat units are depicted for Comal and Hays Counties, Texas, on the maps below.

(2) The primary constituent elements of critical habitat for the Comal Springs dryopid beetle are:

(i) High-quality water with no or minimal levels of pollutants, such as soaps and detergents (Brown 1987, p. 261) and other compounds containing surfactants, heavy metals, pesticides, fertilizer nutrients, petroleum hydrocarbons, pharmaceuticals and veterinary medicines, and semi-volatile compounds, such as industrial cleaning agents, and including:

(A) Low salinity with total dissolved solids that generally range from 307 to 368 mg/L; and

(B) Low turbidity that generally is less than 5 nephelometric turbidity units;

(ii) Aquifer water temperatures that range from approximately 68 to 75 °F (20 to 24 °C);

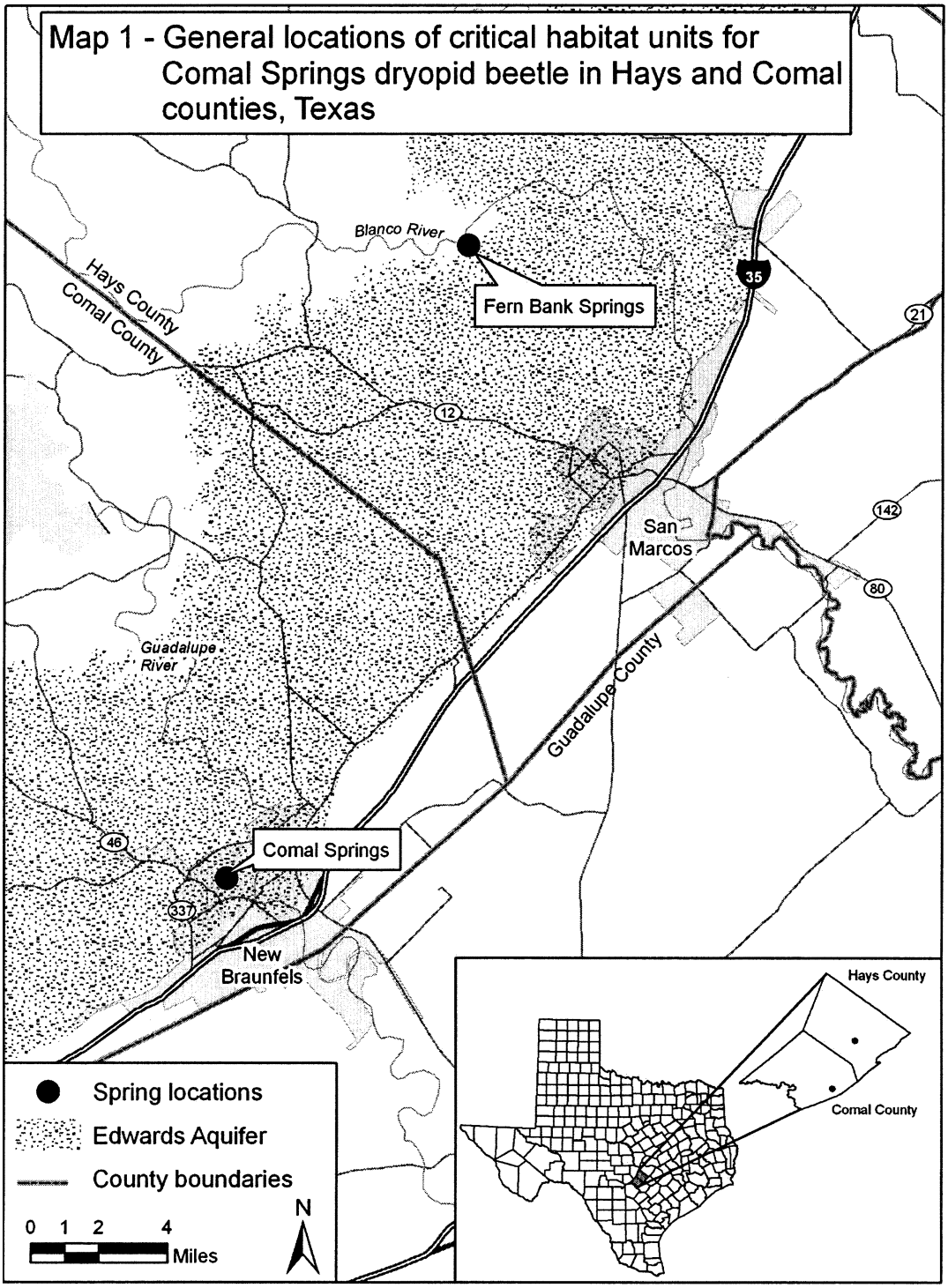
(iii) A hydrologic regime that allows for adequate spring flows that provide levels of dissolved oxygen in the approximate range of 4.0 to 10.0 mg/L for respiration of the Comal Springs dryopid beetle; and

(iv) Food supply that includes detritus (decomposed materials), leaf litter, living plant material, algae, fungi, bacteria and other microorganisms, and decaying roots.

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, roads, and other paved areas) and the land on which they are located existing with the legal boundaries on the effective date of this rule. Where lakes are designated, critical habitat is only designated for areas where springs occur and does not include areas of the lake bottom beyond a radius of 50 ft (15.2 m) from the spring outlet.

(4) *Critical habitat map units.* Data layers defining map units were created by using ArcGIS. All coordinates are UTM zone 14 coordinate pairs, referenced to North American Horizontal Datum 1983. Coordinates were derived from 2004 digital orthophotographs. All acreage and mileage calculations were performed using GIS.

(5) Note: Index map of the critical habitat units for Comal Springs dryopid beetle (Map 1) follows:

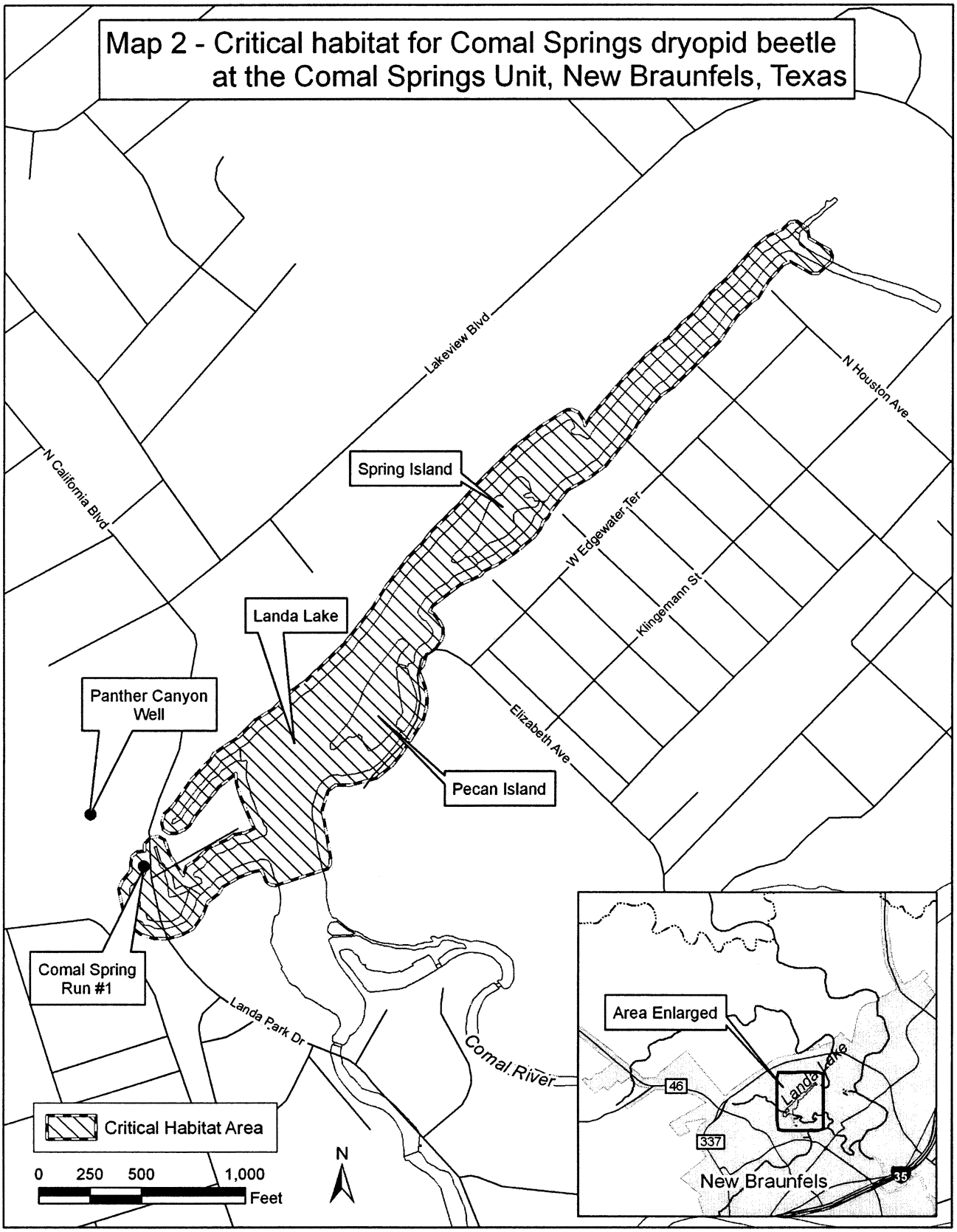


(6) Comal Springs Unit, Comal County, Texas.

(i) Aquatic habitat areas bounded by the UTM Zone 14 NAD 83 coordinates (meters E, meters N): 583387, 3287251; 583392, 3287264; 583405, 3287280; 583404, 3287290; 583407, 3287301; 583414, 3287307; 583425, 3287308; 583425, 3287320; 583433, 3287328; 583444, 3287330; 583454, 3287325; 583463, 3287301; 583482, 3287272; 583486, 3287286; 583501, 3287296; 583520, 3287314; 583547, 3287326; 583557, 3287333; 583572, 3287335; 583586, 3287342; 583567, 3287387; 583560, 3287408; 583559, 3287423; 583534, 3287403; 583499, 3287359; 583491, 3287347; 583484, 3287340; 583471, 3287334; 583461, 3287334; 583452, 3287340; 583450, 3287350; 583454, 3287364; 583465, 3287374; 583494, 3287415; 583521, 3287443; 583526, 3287453; 583563, 3287477; 583589, 3287503; 583613, 3287519; 583643, 3287547; 583662, 3287561; 583719, 3287617; 583759, 3287669; 583780, 3287701; 583811, 3287743; 583833, 3287764; 583848, 3287784; 583892, 3287826; 583911, 3287850; 583970, 3287907; 584008, 3287938; 584047, 3287963; 584055, 3287964; 584065, 3287960; 584073, 3287948; 584074, 3287941; 584081, 3287952;

584131, 3288011; 584164, 3288044; 584183, 3288062; 584197, 3288071; 584216, 3288093; 584236, 3288110; 584258, 3288138; 584284, 3288161; 584325, 3288209; 584343, 3288223; 584364, 3288233; 584375, 3288243; 584386, 3288244; 584401, 3288234; 584403, 3288218; 584433, 3288201; 584437, 3288193; 584436, 3288184; 584416, 3288167; 584405, 3288167; 584375, 3288184; 584365, 3288180; 584344, 3288156; 584329, 3288131; 584320, 3288125; 584298, 3288103; 584273, 3288067; 584204, 3287997; 584187, 3287985; 584176, 3287973; 584152, 3287943; 584147, 3287933; 584105, 3287880; 584080, 3287862; 584049, 3287844; 584026, 3287815; 584021, 3287805; 584013, 3287798; 584009, 3287787; 583999, 3287775; 583971, 3287751; 583947, 3287735; 583927, 3287725; 583920, 3287718; 583890, 3287704; 583850, 3287673; 583845, 3287665; 583851, 3287662; 583860, 3287650; 583865, 3287640; 583865, 3287629; 583863, 3287622; 583854, 3287609; 583840, 3287600; 583836, 3287584; 583829, 3287576; 583838, 3287552; 583841, 3287535; 583841, 3287520; 583835, 3287501; 583804, 3287452; 583790, 3287435; 583766, 3287416; 583727, 3287406; 583706, 3287406; 583695, 3287398; 583686, 3287370; 583699, 3287298; 583698, 3287288; 583694, 3287282; 583617, 3287257; 583610, 3287258; 583605, 3287262; 583597, 3287280; 583584, 3287277; 583565, 3287270; 583541, 3287255; 583534, 3287244; 583518, 3287233; 583510, 3287211; 583496, 3287192; 583480, 3287183; 583459, 3287177; 583436, 3287178; 583419, 3287184; 583400, 3287198; 583396, 3287205; 583387, 3287251.

(ii) Note: Comal Springs Unit (Map 2) follows:



(7) Fern Bank Springs Unit, Hays County, Texas.

(i) Aquatic habitat areas bounded by the UTM Zone 14 NAD 83 coordinates (meters E, meters N): 595131, 3317374; 595131, 3317375; 595132, 3317376; 595132, 3317377; 595132, 3317378; 595132, 3317379; 595133, 3317380; 595133, 3317381; 595133, 3317382; 595134, 3317383; 595135, 3317383; 595135, 3317384; 595136, 3317385; 595137, 3317386; 595137, 3317386;

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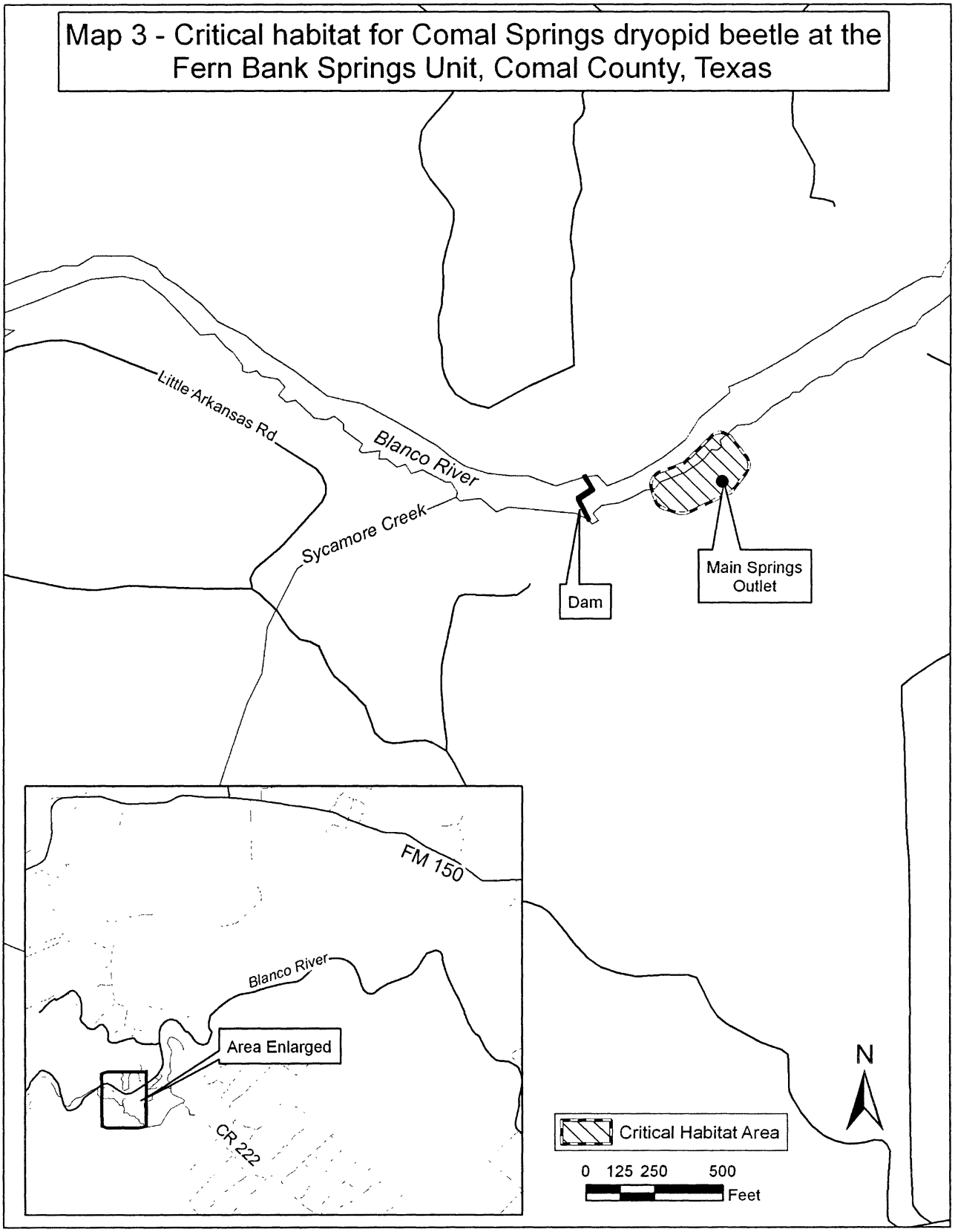
(ii) Note: Fern Bank Springs Unit (Map 3) follows:



* * * * *

Comal Springs riffle beetle (*Heterelmis comalensis*).

(1) Critical habitat units are depicted for Comal and Hays Counties, Texas, on the maps below.

(2) The primary constituent elements of critical habitat for Comal Springs riffle beetle are:

(i) High-quality water with no or minimal levels of pollutants, such as soaps and detergents (Brown 1987, p. 261) and other compounds containing surfactants, heavy metals, pesticides, fertilizer nutrients, petroleum hydrocarbons, pharmaceuticals and veterinary medicines, and semi-volatile compounds, such as industrial cleaning agents, and including:

(A) Low salinity with total dissolved solids that generally range from 307 to 368 mg/L; and

(B) Low turbidity that generally is less than 5 nephelometric turbidity units;

(ii) Aquifer water temperatures that range from approximately 68 to 75 °F (20 to 24 °C);

(iii) A hydrologic regime that allows for adequate spring flows that provide levels of dissolved oxygen in the approximate range of 4.0 to 10.0 mg/L for respiration of the Comal Springs riffle beetle;

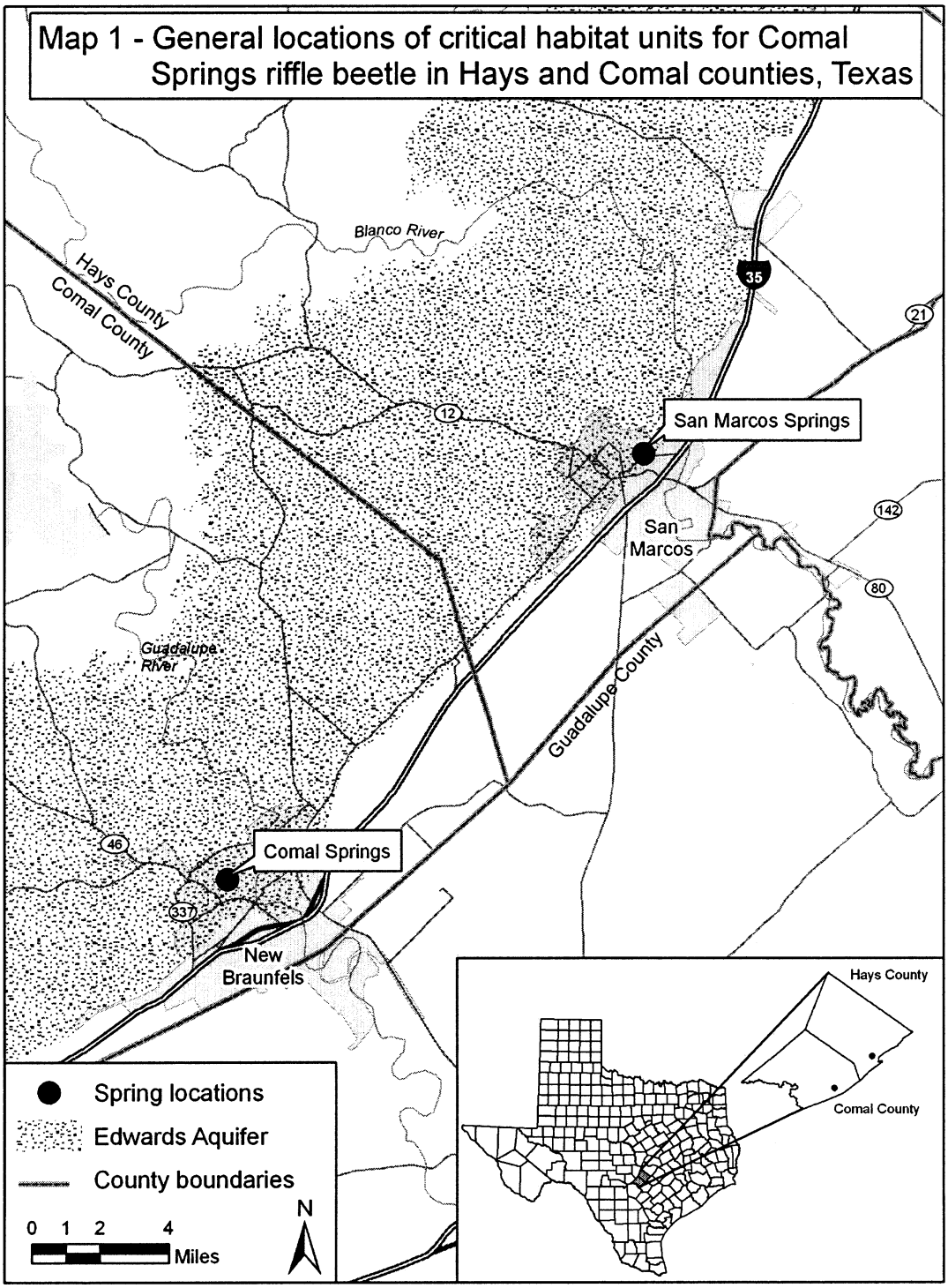
(iv) Food supply that includes detritus (decomposed materials), leaf litter, living plant material, algae, fungi, bacteria and other microorganisms, and decaying roots; and

(v) Bottom substrate in surface water habitat of the Comal Springs riffle beetle that is free of sand and silt, and is composed of gravel and cobble ranging in size from 0.3 to 5.0 inches (8 to 128 millimeters).

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of this rule.

(4) *Critical habitat map units.* Data layers defining map units were created by using ArcGIS. All coordinates are UTM zone 14 coordinate pairs, referenced to North American Horizontal Datum 1983. Coordinates were derived from 2004 digital orthophotographs. All acreage and mileage calculations were performed using GIS.

(5) Note: Index map of the critical habitat units for Comal Springs riffle beetle (Map 1) follows:



(6) Comal Springs Unit, Comal County, Texas.

(i) Aquatic habitat areas bounded by the UTM Zone 14 NAD 83 coordinates (meters E, meters N): 583420, 3287293; 583423, 3287293; 583426, 3287293; 583428, 3287290; 583429, 3287285; 583428, 3287280; 583426, 3287273; 583422, 3287268; 583416, 3287259; 583415, 3287255; 583415, 3287249; 583417, 3287238; 583418, 3287233; 583419, 3287228; 583418, 3287222; 583421, 3287221; 583427, 3287216; 583429, 3287207; 583435, 3287204; 583442, 3287203; 583455, 3287203; 583464, 3287203; 583468, 3287205; 583475, 3287209; 583479, 3287213; 583479, 3287217; 583483, 3287224; 583486, 3287232; 583490, 3287246; 583491, 3287248; 583485, 3287247; 583481, 3287245; 583476, 3287243; 583471, 3287241; 583461, 3287239; 583460, 3287242; 583460, 3287248; 583459, 3287255; 583459, 3287261; 583458, 3287266; 583455, 3287272; 583455, 3287277; 583452, 3287282; 583449, 3287284; 583446, 3287288; 583445, 3287295; 583441, 3287307; 583439, 3287314; 583443, 3287315; 583444, 3287309; 583446, 3287303; 583449, 3287293; 583450, 3287291; 583453, 3287288; 583457, 3287284; 583461, 3287278; 583466, 3287271; 583468, 3287263; 583469, 3287255; 583470, 3287251; 583480, 3287257; 583484, 3287256; 583488, 3287254;

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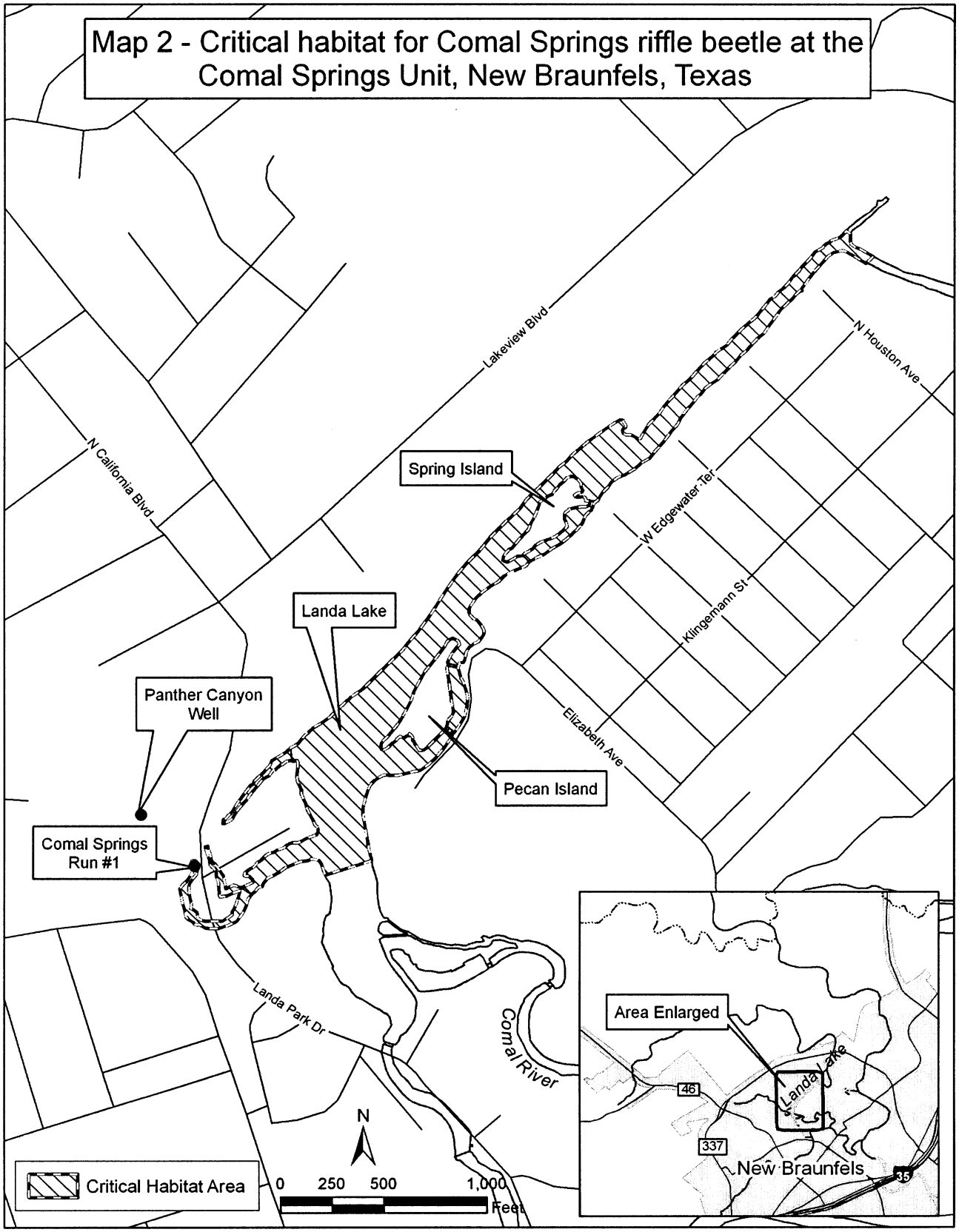
(ii) Note: Comal Springs Unit (Map 2) follows:

BILLING CODE 4310–55–P

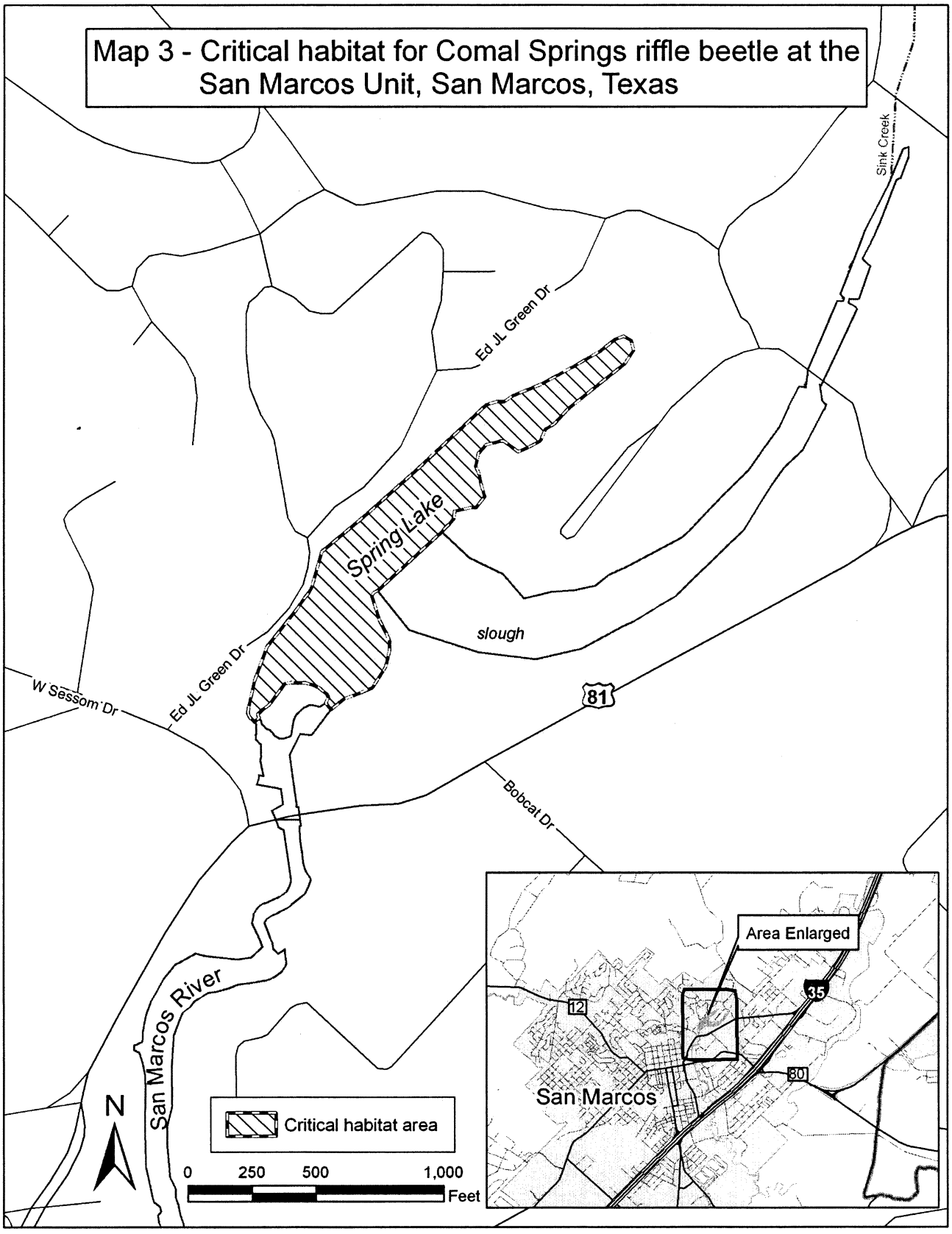


(7) San Marcos Springs Unit, Hays County, Texas.

(i) Aquatic habitat areas bounded by the UTM Zone 14 NAD 83 coordinates (meters E, meters N): 602869, 3307092; 602870, 3307100; 602877, 3307131; 602892, 3307172; 602926, 3307215; 602936, 3307229; 602942, 3307237; 602945, 3307243; 602957, 3307286; 603007, 3307329; 603072, 3307386; 603154, 3307462; 603158, 3307463; 603166, 3307466; 603175, 3307465;

603186, 3307473; 603219, 3307486; 603258, 3307508; 603288, 3307526; 603307, 3307541; 603317, 3307544; 603326, 3307539; 603329, 3307527; 603319, 3307512; 603251, 3307456; 603234, 3307439; 603224, 3307433; 603218, 3307419; 603206, 3307412; 603192, 3307406; 603175, 3307418; 603170, 3307419; 603153, 3307414; 603144, 3307404; 603141, 3307389; 603145, 3307379; 603147, 3307369; 603152, 3307352; 603141, 3307339; 603135, 3307339; 603124, 3307337; 603120, 3307336; 603116, 3307335; 603114, 3307325; 603109, 3307318; 603105, 3307315; 603104, 3307314; 603100, 3307310; 603024, 3307239; 603023, 3307240; 603019, 3307237; 603017, 3307233; 603026, 3307203; 603035, 3307187; 603038, 3307178; 603038, 3307166; 603033, 3307148; 603027, 3307138; 603018, 3307123; 603002, 3307117; 602983, 3307109; 602968, 3307097; 602962, 3307105; 602962, 3307105; 602965, 3307112; 602963, 3307116; 602958, 3307119; 602954, 3307123; 602946, 3307126; 602938, 3307129; 602928, 3307129; 602921, 3307129; 602913, 3307128; 602896, 3307105; 602894, 3307101; 602887, 3307097; 602881, 3307091; 602883, 3307087; 602877, 3307082; 602875, 3307084; 602872, 3307087; 602869, 3307092.

(ii) Note: San Marcos Springs Unit (Map 3) follows:


Map 3 - Critical habitat for Comal Springs riffle beetle at the San Marcos Unit, San Marcos, Texas
Sink Creek
Ed JL Green Dr
Spring Lake
slough
W Sessom Dr
Ed JL Green Dr
81
Bobcat Dr
San Marcos River
N
Critical habitat area
0 250 500 1,000
Feet
Area Enlarged
12
35
80
San Marcos

* * * * *

Dated: June 28, 2007.

David M. Verhey,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 07–3267 Filed 7–16–07; 8:45 am]

BILLING CODE 4310–55–C

Federal Register

Tuesday,
July 17, 2007

Part IV

Department of Housing and Urban Development

48 CFR Part 2409
HUD Acquisition Regulation (HUDAR) Debarment and Suspension Procedures; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

48 CFR Part 2409

[Docket No. FR–5098–P–01]

RIN 2535–AA28

HUD Acquisition Regulation (HUDAR) Debarment and Suspension Procedures

AGENCY: Office of the Chief Procurement Officer, HUD.

ACTION: Proposed rule.

SUMMARY: This rule proposes to amend HUD's Acquisition Regulation (HUDAR) to codify the suspension and debarment procedures applicable to HUD's procurement contracts. Such an amendment would affirm that the suspension and debarment procedures in 24 CFR part 24 apply to procurement as well as nonprocurement contracts. The contracting community is familiar with the suspension and debarment procedures in part 24 and this rule is limited to amending the HUDAR regulations to reflect the applicability of these requirements to procurement contracts.

DATES: *Comment Due Date:* September 17, 2007.

ADDRESSES: Interested persons are invited to submit comments regarding this rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410–0500. Interested persons also may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically so that HUD can make them immediately available to the public. Commenters should follow the instructions provided on that site to submit comments electronically. Facsimile (FAX) comments are not acceptable. In all cases, communications must refer to the docket number and title. All comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.* Hearing-or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Frederick Graves, Office of Policy and Systems, Office of the Chief Procurement Officer (Seattle Outstation), Department of Housing and Urban Development, Seattle Federal Office Building, 909 First Avenue, Seattle, WA 98104–1000; telephone (206) 220–5259, FAX (206) 220–5247 (these are not toll-free numbers). Persons with hearing or speech impairments may access the telephone number via TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The uniform regulation for the procurement of supplies and services by Federal departments and agencies, the Federal Acquisition Regulation (FAR), was promulgated on September 19, 1983 (48 FR 42102). The FAR is codified in title 48, chapter 1, of the Code of Federal Regulations (CFR). HUD promulgated its regulation to implement the FAR on March 1, 1984 (49 FR 7696). The HUDAR (title 48, chapter 24 of the CFR) is prescribed under section 7(d) of the Department of HUD Act (42 U.S.C. 3535(d)); section 205(c) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 486(c)); and the general authorization in FAR 1.301.

II. This Proposed Rule

This proposed rule makes one change to 48 CFR 2409.7001 to clarify that HUD's suspension and debarment procedures, found at 24 CFR part 24, apply to procurement contracts. (On March 23, 2007, HUD published a proposed rule (72 FR 14015) that would redesignate 24 CFR part 24 to 2 CFR part 2424. The proposed rule published in today's **Federal Register** refers to the current regulations at 24 CFR part 24. A conforming change will be made at the final rule stage to reflect the redesignation.)

On November 26, 2003, HUD adopted, with minor revisions, the governmentwide nonprocurement debarment and suspension common rule (68 FR 66534). The governmentwide rule sets forth the common policies and procedures that federal executive branch agencies must use in taking suspension or debarment actions. The amendments made by the November 26, 2003, rule limited covered transactions to nonprocurement contracts. For many years prior to the promulgation in 2003 of the governmentwide debarment and suspension common rule, HUD applied, to procurement contracts, the same suspension and debarment procedures that it uses for nonprocurement contracts. HUD is unable to amend the governmentwide debarment and suspension procedures. Therefore, to reflect the applicability of debarment and suspension requirements to procurement contracts, HUD is proposing to revise the HUDAR to affirm that the suspension and debarment rules in 24 CFR part 24 apply to procurement contracts. This regulatory clarification does not impose any additional requirements because the suspension and debarment procedures in part 24 are well established and the contracting community is already familiar with the requirements.

III. Findings and Certifications

Paperwork Reduction Act Statement

The information collection requirements contained in this proposed rule are currently approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and assigned OMB control number 2535–0091. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid OMB control number.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1531–1538) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This rule does not impose any federal mandate on any state, local, or tribal government or the private sector within the meaning of UMRA.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This proposed rule makes clarifying changes to existing governmentwide suspension and debarment procedures and does not make any major changes that would significantly impact small entities. Accordingly, the undersigned certifies that this rule will not have a significant

economic impact on a substantial number of small entities.

Notwithstanding HUD's determination that this rule will not have a significant economic impact on a substantial number of small entities, HUD specifically invites comments regarding less burdensome alternatives to this rule that will meet HUD's objectives as described in this preamble.

Environmental Impact

This proposed rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this proposed rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This proposed rule would not have federalism implications and would not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

List of Subjects for 48 CFR Part 2409

Government procurement.

For the reasons discussed in the preamble, HUD proposes to amend 48 CFR part 2409 to read as follows:

PART 2409—CONTRACTOR QUALIFICATIONS

1. The authority citation for part 2409 continues to read as follows:

Authority: 40 U.S.C. 486(c); 42 U.S.C. 3535(d).

2. Revise 2409.7001 to read as follows:

2409.7001 HUD regulations on debarment, suspension, and ineligibility.

HUD's policies and procedures concerning debarment and suspension are contained in 24 CFR part 24 and, notwithstanding 24 CFR 24.220(a)(1), apply to procurement contracts.

Dated: June 7, 2007.

Joseph A. Neurauter,

Chief Procurement Officer.

[FR Doc. E7–13745 Filed 7–16–07; 8:45 am]

BILLING CODE 4210–67–P

Federal Register

Tuesday,
July 17, 2007

Part V

Securities and Exchange Commission

17 CFR Parts 232, 239, 270 and 274
Extension of Interactive Data Voluntary Reporting Program on the Edgar System to Include Mutual Fund Risk/Return Summary Information; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 232, 239, 270 and 274

[Release Nos. 33–8823; IC–27884; File Number S7–05–07]

RIN 3235–AJ59

Extension of Interactive Data Voluntary Reporting Program on the Edgar System To Include Mutual Fund Risk/Return Summary Information

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: We are adopting rule amendments to extend the current interactive data voluntary reporting program to enable mutual funds voluntarily to submit supplemental tagged information contained in the risk/return summary section of their prospectuses. A mutual fund choosing to tag its risk/return summary information also would continue to file this information in HTML or ASCII format, as currently required. This extension of the voluntary program is intended to help us evaluate the usefulness to investors, third-party analysts, registrants, the Commission, and the marketplace of data tagging and, in particular, of tagging mutual fund information.

DATES: *Effective Date:* August 20, 2007.

FOR FURTHER INFORMATION CONTACT: Alberto H. Zapata, Senior Counsel, or Brent J. Fields, Assistant Director, Office of Disclosure Regulation, Division of Investment Management, at (202) 551–6784, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549–5720. If you have questions about the EDGAR system, contact Richard Heroux, EDGAR Program Manager, at (202) 551–8800, in the Office of Information Technology.

SUPPLEMENTARY INFORMATION: The Securities and Exchange Commission (''Commission'') is adopting amendments to rules 401 [1] and 402 [2] of Regulation S–T [3] , rule 8b–33 [4] under the Investment Company Act of 1940 (''Investment Company Act''), and Form N–1A [5] under the Investment Company Act and the Securities Act of 1933 (''Securities Act''). [6]

[1] 17 CFR 232.401.

[2] 17 CFR 232.402.

[3] 17 CFR 232.10 *et seq.*

[4] 17 CFR 270.8b–33.

[5] 17 CFR 239.15A and 274.11A.

[6] The Commission proposed these amendments in February 2007. Securities Act Release No. 8781 (Feb. 6, 2007) [72 FR 6676 (Feb. 12, 2007)] (''Proposing Release'').

Table of Contents

I. Background

A. Interactive Data and XBRL

For the past several years, the Commission has been evaluating the use of interactive data tagging as a tool to improve the timeliness and accessibility of the information contained in filings with the Commission under the federal securities laws.[7] Data tagging uses standard definitions (or data tags) to translate text-based information into data that is interactive, that is, data that can be retrieved, searched, and analyzed through automated means.[8]

Interactive data has enormous potential to enable investors and other market participants to analyze and compare data from different sources more efficiently and effectively and to exchange information across various platforms automatically. Through interactive data, static text-based information can be transformed into dynamic databases that can readily be searched and analyzed, facilitating the comparison of information across companies, reporting periods, and industries. Interactive data also provides a significant opportunity to automate information processing throughout the business and reporting cycle, with the potential to increase accuracy and reduce costs. By ensuring that information is classified properly at each step of the cycle, and minimizing the need for human intervention and, therefore, human error, interactive data may improve the quality of information at decreased cost.

Tags are defined in taxonomies, which are essentially data dictionaries that describe individual items of information and mathematical and definitional relationships among the items. As tagging has continued to gain prominence in recent years, there has been substantial progress in developing data tagging taxonomies related to a language for the electronic communication of business and financial data known as eXtensible Business Reporting Language (''XBRL''). XBRL was developed as an open source specification that describes a standard format for tagging financial and other information to facilitate the preparation, publication, and analysis of that information by software applications.[9] XBRL was developed and continues to be supported by XBRL International, a collaborative consortium of approximately 450 organizations representing many perspectives in the financial reporting community.[10] XBRL International and its related entities have been developing standard taxonomies that are designed to classify and define financial information in accordance with U.S. Generally Accepted Accounting Principles (''GAAP'') and Commission regulations. The Commission has contracted with XBRL US, Inc., the U.S. based jurisdiction of XBRL International, to help complete the writing of XBRL taxonomies that would enable companies in all industries to file financial reports with the Commission using XBRL.[11]

[7] *See SEC to Rebuild Public Disclosure System to Make It 'Interactive,'* Securities and Exchange Commission Press Release, Sept. 25, 2006, available at: *http://www.sec.gov/news/press/2006/2006–158.htm* (''September 25 Press Release''); *Commission Announces Roundtable Series Giving Investors and Analysts Better Financial Data via Internet*, Securities and Exchange Commission Press Release, Mar. 9, 2006, available at: *http://www.sec.gov/news/press/2006–34.htm; SEC Offers Incentives for Companies to File Financial Reports with Interactive Data*, Securities and Exchange Commission Press Release, Jan. 11, 2006, available at: *http://www.sec.gov/news/press/2006–7.htm* (''January 11 Press Release''); *SEC Announces Initiative to Assess Benefits of Tagged Data in Commission Filings*, Securities and Exchange Commission Press Release, July 22, 2004, available at: *http://www.sec.gov/news/press/2004–97.htm.*

[8] The Commission's Electronic Data Gathering, Analysis, and Retrieval System (''EDGAR'') has allowed certain tagged data since its inception, for example, by using Standard Generalized Markup Language and Extensible Markup Language (''XML'') to tag form-specific information (such as the form type, central index key, and file number) that accompanies electronic documents submitted on EDGAR. More recently, EDGAR has employed HyperText Markup Language (''HTML'') to format documents and made limited use of XML related to financial and business information contained within certain EDGAR submissions.

[9] ''Open Source'' means that the software can be used by anyone without charge and is being developed in an open and collaborative setting. For a more detailed discussion about XBRL, see ''How XBRL Works'' on the XBRL International Web site available at: *http://www.xbrl.org/HowXBRLWorks/.*

[10] *See* ''About the Organisation'' page and subpages on the XBRL International Web site, available at: *http://www.xbrl.org/AboutTheOrganisation/.*

[11] September 25 Press Release, *supra* note 7.

B. The Voluntary Program and Tagging of Mutual Fund Information

As part of our evaluation of the potential of interactive data tagging technology, the Commission adopted rules in 2005 instituting a program that permits filers, on a voluntary basis, to submit financial information tagged in XBRL format as an exhibit to certain filings on the Commission's Electronic Data Gathering, Analysis and Retrieval System (''EDGAR'').[12] The Commission adopted the voluntary program to help evaluate the usefulness of data tagging and XBRL to registrants, investors, the Commission, and the marketplace.[13] In 2006, the Commission initiated an interactive data test program, in which companies, including investment companies, voluntarily agree to furnish financial data in XBRL format for at least one year and provide feedback on their experiences, including the costs and benefits.[14] The data currently permitted in XBRL exhibits is limited to financial information.

The current voluntary program extends to financial information for investment companies, including open end management investment companies (''mutual funds'').[15] In February of this year, we proposed amendments to the voluntary program that would permit mutual funds to tag the information in the risk/return summary section of their prospectuses using a taxonomy developed by the Investment Company Institute (''ICI'').[16]

The risk/return summary section of the mutual fund prospectus contains important information about investment objectives and strategies, risks, and costs,[17] and tagging this information could provide powerful tools for investors. With almost half of all U.S. households owning mutual funds,[18] typically to fund their education, retirement, and other basic needs, improving the quality of mutual fund disclosure is important to millions of Americans. Tagging of key mutual fund information could help to streamline the delivery of mutual fund information and provide investors, analysts, and others with improved tools to compare funds based upon, among other things, costs, investment objectives, strategies, and risks. In addition, the risk/return summary information is largely narrative in format, and exploring the viability of tagging this information will provide us with valuable insights as we assess the potential for tagging other primarily narrative information.

The Commission received eight comment letters on the proposed rule amendments, including comments from software vendors, an accounting firm, a trade association, and several individuals.[19] These commenters generally supported the proposed rules to extend the interactive data voluntary reporting program to the risk/return summary section of mutual fund prospectuses. We are adopting the proposed amendments, with minor modifications to address commenters' recommendations. The rule amendments are intended to help us evaluate the usefulness to investors, third-party analysts, registrants, the Commission, and the marketplace of data tagging and, in particular, of tagging mutual fund information.

II. Discussion

As part of our ongoing effort to evaluate the usefulness of data tagging, we are adopting amendments to extend the voluntary program to enable mutual funds to submit exhibits containing tagged risk/return summary information attached to EDGAR filings.[20] Any mutual fund may participate, without pre-approval, merely by submitting the risk/return summary information in the required manner. As we continue to gain experience with interactive data, we will evaluate the benefits of data tagging to investors, analysts, and others. If, in the future, we consider requiring filers to tag the risk/return summary information, that would be the subject of a separate rulemaking proposal.

A. Expansion of Voluntary Program Content

Currently, the XBRL data furnished under the voluntary program must consist of at least one item from a list of enumerated mandatory content (''Mandatory Content''), including financial statements, earnings information, and, for registered management investment companies, financial highlights or condensed financial information.[21] We are adding the risk/return summary information set forth in Items 2 and 3 of Form N–1A as a new item of Mandatory Content, with two modifications to our proposal that address commenters' recommendations.

Our proposal, like the current voluntary program, would have required that Mandatory Content ''consist of a complete set of information for all periods presented in the corresponding official EDGAR filing.'' [22] First, the adopted amendments clarify that, in the case of a Form N 1A filing that includes more than one series,[23] a filer may tag a complete set of risk/return summary information for any one or more series.[24] For example, if a filing contains information about four series, a filer could tag information for one, two,

[12] *See* Securities Act Release No. 8529 (Feb. 3, 2005) [70 FR 6556 (Feb. 8, 2005)] (''XBRL Adopting Release''); Securities Act Release No. 8496 (Sept. 27, 2004) [69 FR 59094 (Oct. 1, 2004)] (''XBRL Proposing Release''). *See also* Securities Act Release No. 8497 (Sept. 27, 2004) [69 FR 59111 (Oct. 1, 2004)] (concept release soliciting comment on data tagging).

[13] XBRL Adopting Release, *supra* note 12, 70 FR at 6556–57.

[14] January 11 Press Release, *supra* note 7. For more information about the Commission's interactive data initiatives, see the Commission Web page ''Spotlight On: Interactive Data and XBRL Initiatives,'' available at: *http://www.sec.gov/spotlight/xbrl.htm*.

[15] *See SEC XBRL Voluntary Program Extends to Investment Companies*, Securities and Exchange Commission Press Release, Aug. 8, 2005, available at: *http://www.sec.gov/news/press/2005–112.htm*.

[16] The ICI is a national association of the American investment company industry. In March 2006, the ICI announced an initiative to create a taxonomy to cover the risk/return summary information. *See Stevens Calls for Greater Use of Internet; Announces Initiative to Develop XBRL Data Tagging Technology*, ICI Press Release, Mar. 20, 2006, available at: *http://ici.org/statements/nr/2006/06_news_mfimc.html#TopOfPage; ICI Unveils Draft XBRL Taxonomy For Public Review*, ICI Press Release, Jan. 4, 2007, available at: *http://www.ici.org/statements/nr/07_news_xbrl_txnmy.html#TopOfPage*.

In a letter to the Commission staff, dated May 18, 2007, the ICI advised that the risk/return summary taxonomy is ready for use and described its response to comments received regarding the taxonomy development. *See* Letter from Donald J. Boteler, Vice President—Operations and Continuing Education, ICI, to Andrew J. Donohue, Director, Division of Investment Management (May 18, 2007) (''Boteler Letter''), available at: *http://www.sec.gov/comments/s7–05–07/s70507–21.pdf*. The ICI also indicated that the schema files and reference materials for the taxonomy are available at: *http://xbrl.ici.org*.

[17] Items 2 and 3 of Form N–1A [17 CFR 239.15A and 274.11A].

[18] *2007 Investment Company Fact Book*, at 57–58, Investment Company Institute (2007), available at: *http://www.ici.org/home/2007_factbook.pdf*.

[19] *See* comment letters of Confluence (Mar. 14, 2007); Walter S. Hamscher (''Hamscher'') (Mar. 2, 2007); Charles S. Hoffman (''Hoffman'') (Feb. 10, 2007); ICI (Mar. 14, 2007); NewRiver, Inc. (''NewRiver'') (Mar. 14, 2007); PricewaterhouseCoopers LLP (''PWC'') (Mar. 14, 2007); Rivet Software, Inc. (''Rivet'') (Mar. 14, 2007); Ayal Rosenthal (''Rosenthal'') (Mar. 6, 2007). The ICI contracted with PWC to design and construct the risk/return taxonomy, and Hamscher was a subcontractor to PWC. The comment letters are available on the Commission's Web site at: *http://www.sec.gov/comments/s7–05–07/s70507.shtml*.

[20] The amendments do not alter the current voluntary program as it applies to the furnishing of XBRL information by non-investment companies.

[21] Rule 401(b)(1) of Regulation S–T [17 CFR 232.401(b)(1)].

[22] Rule 401(b)(1)(i) of Regulation S–T [17 CFR 232.401(b)(1)(i)].

[23] A mutual fund may issue multiple ''series'' of shares, each of which is preferred over all other series in respect of assets specifically allocated to that series. Rule 18f–2 under the Investment Company Act [17 CFR 270.18f–2]. Each series is, in effect, a separate investment portfolio.

[24] Rule 401(b)(1)(iv) of Regulation S–T [17 CFR 232.401(b)(1)(iv)].

three, or four series. Filers who choose to tag the information for a particular series would be required to tag all the information for that series, including the information for each class of the series.[25] Second, we have modified the proposed amendments, which would have required the information for each class to be separately identified, to clarify, as suggested by a commenter,[26] that this requirement applies only to information that does not relate to all of the classes in a series.[27] Thus, class-specific information, such as expenses and performance, would be required to be separately identified by class. Information that is not class-specific, such as investment objectives, would not be required to be separately identified by class.

Three commenters stated that if a mutual fund's official filing contains information for more than one series or class, the fund should be permitted to submit tagged risk/return summary information for one or more, but fewer than all, series or classes.[28] One of these commenters indicated that this approach would provide the broadest possible participation in the voluntary program.[29] We agree with these commenters that mutual funds volunteering to participate in the reporting program that include more than one series in an official filing should not be required to tag the information for all series in the filing. A mutual fund's series represent separate portfolios of securities, each with its own discrete investment objectives and strategies. Each series of a registered investment company is a distinct mutual fund though they are organized as part of a single legal entity. As a result, we have concluded that tagging one or more series should not require tagging all the series of a fund. Therefore, our rule amendments permit mutual funds to submit tagged risk/return summary information for one or more series in an official filing.[30] This flexibility should encourage participation in the voluntary program.[31]

We disagree, however, with commenters' recommendations[32] that volunteers be permitted to tag the risk/return summary information for less than all classes for any mutual fund or series selected. Permitting tagged submissions for less than all the classes of a fund or series would significantly impair the Commission's and users' ability to evaluate the effectiveness of the ICI's risk/return summary taxonomy in tagging class-specific information. In addition, it would limit the ability to assess the usefulness of the taxonomy in facilitating the comparison of class-specific information, such as expenses and performance, within a fund.

As with all tagged exhibits under the voluntary program, submissions of tagged exhibits containing risk/return summary information will be supplemental and will not replace the required HTML or ASCII version of the information called for in Form N–1A. Volunteers will be required to file their complete official registration statements to ensure that all investors have access to information upon which to base their investment decisions.[33] While tagged exhibits will be required to reflect the same information contained in the risk/return summary section of the related official Form N–1A filing, we emphasize that investors and others should continue to rely on the official filing rather than the tagged exhibit.

We are adopting, as proposed, the requirement that mutual funds submitting tagged risk/return summary information must include this information as an exhibit to an amendment to a previous filing on Form N–1A.[34] Form N–1A filings, which contain mutual fund registration statements (or amendments thereto), are often subject to revision prior to effectiveness. For this reason, the rules do not permit the submission of a tagged exhibit that is related to a registration statement or an amendment that is not yet effective. More specifically, the rules provide that a tagged exhibit to a Form N–1A filing, whether the filing is an initial registration statement or an amendment thereto, may be submitted only as an amendment to the filing to which the tagged exhibit relates and only after the effective date of such filing.[35] An exhibit containing tagged risk/return summary information may be submitted under rule 485(b) of the Securities Act, which provides for immediate effectiveness of amendments that make non-material changes, and will only need to contain the new exhibit, a facing page, a signature page, a cover letter explaining the nature of the amendment, and a revised exhibit index.

The voluntary program requires all volunteers to use the appropriate version of a standard taxonomy, supplemented with extension taxonomies as specified by the EDGAR Filer Manual. Filers submitting tagged risk/return summary information should not include the risk/return summary taxonomy in their submissions as this taxonomy will be stored as a part of the EDGAR system. Section 5.2.4 of the EDGARLink Filer Manual (Volume II): ''EDGAR Filing'' will provide instructions and guidance on the preparation, submission, and validation of EDGAR-acceptable electronic filings with attached tagged risk/return summary information.[36] The EDGAR system upgrade to Release 9.7 is scheduled to become available on August 20, 2007, to, among other things,

[25] A mutual fund may issue more than one class of shares that represent interests in the same portfolio of securities with each class, among other things, having a different arrangement for shareholder services or the distribution of securities, or both. Rule 18f–3 under the Investment Company Act [17 CFR 270.18f–3].

[26] *See* letter from ICI, *supra* note 19.

[27] Rule 8b–33 under the Investment Company Act [17 CFR 270.8b–33].

[28] *See* letters from Hamscher, ICI, and PWC, *supra* note 19.

[29] *See* letter from ICI, *supra* note 19.

[30] Rule 401(b)(1)(iv).

[31] We have previously indicated that rule 8b–33 would require investment companies to submit tagged XBRL documents separately for each series of an investment company registrant. *See* XBRL Proposing Release, *supra* note 12, 69 FR at 59097 n. 49. Under amended rule 8b–33, a mutual fund will not be required to submit tagged risk/return summary information in separate documents for each series or class, provided that the information is tagged in such a manner that the information may be separately identified by series and class.

[32] *See* letters from Hamscher, ICI, and PWC, *supra* note 19.

[33] Consistent with the current voluntary program, once received by the Commission, the official filing and the tagged risk/return summary information submitted as exhibits to the official filing will undergo technical validations. The official filing will continue to follow the normal process for receipt and acceptance. That is, it will be suspended if it fails its validation criteria. If the official filing meets its validation criteria, but any tagged risk/return summary document submitted as an exhibit to the official filing fails its own validation criteria, all tagged documents will be removed and the official filing will be accepted and disseminated without the tagged documents. The volunteer will be notified of the submission problem with the tagged documents. If the official filing fails to meet the required receipt and acceptance process and is suspended for any reason, any tagged risk/return summary information submitted with the official filing will also be suspended.

[34] *See* Rule 401(a) of Regulation S–T [17 CFR 232.401(a)]; rule 8b–33. A mutual fund submitting tagged risk/return summary information as an exhibit to Form N–1A will be required to name each document ''EX–100'' as specified in the EDGAR Filer Manual. We also are adopting a technical amendment to General Instruction B.4.(b) of Form N–1A to add rule 8b–33 to the list of general provisions that apply to the filing of registration statements on Form N–1A.

[35] Rule 401(a); rule 8b–33.

[36] Rule 301 of Regulation S–T, the regulation that governs the preparation and transmission of electronic filings on the Commission's EDGAR system, requires electronic filings to be prepared in accordance with the provisions of the EDGAR Filer Manual. The Filer Manual contains the technical formatting requirements for electronic submissions. Filers must comply with those requirements to ensure the timely receipt and acceptance of documents submitted to the Commission in an electronic format. The Commission's EDGAR Filer Manual is available at: *http://www.sec.gov/info/edgar.shtml*.

enable EDGAR to process tagged risk/return summary information when the expanded voluntary program becomes effective.

Similar to the current voluntary program, volunteers will be free to submit tagged risk/return summary information regularly or from time to time, and volunteers may stop and start as they choose. Participating in the voluntary program will not create a continuing obligation for a volunteer to submit tagged risk/return summary information as an exhibit to a subsequent post-effective amendment. A volunteer will, however, be required to amend any tagged risk/return summary exhibits that do not comply with the content and format requirements of rule 401, *e.g.*, because they do not reflect the same information as the corresponding official filing.[37]

One commenter, while agreeing that participation in the voluntary program should not create a continuing obligation to submit tagged risk/return summary information as an exhibit to a subsequent post-effective amendment, noted that rendering tools may not be able to detect that tagged data is no longer current.[38] The commenter encouraged the Commission to consider whether additional safeguards, such as the option to withdraw tagged exhibits, should be made available to ensure that there is no liability to funds or harm to investors if rendering tools utilize outdated information. As we noted in response to similar comments when the voluntary program rules were initially adopted, submissions to EDGAR cannot, as a practical matter, be withdrawn after public dissemination.[39] In order to address questions of potential harm to investors and liability to mutual funds, the rules provide for cautionary disclosures [40] and liability protections.[41]

The amendments we are adopting will, as proposed, provide mutual funds with the option to submit tagged financial highlights or condensed financial information as a tagged exhibit to an amendment to the Form N 1A filing to which the information relates.[42] Mutual funds also may continue to submit this information as an exhibit to Form N–CSR, as currently permitted, whether or not they submit tagged risk/return summary information.[43] A mutual fund submitting tagged risk/return summary information may, but is not required to, submit tagged financial highlights or condensed financial information. Similarly, a mutual fund that submits tagged financial highlights or condensed financial information may, but is not required to, submit tagged risk/return summary information.

B. Required Disclosure

The Commission is adopting, as proposed, a requirement that the exhibit index of any Form N–1A filing that includes a tagged exhibit disclose that the purpose of submitting the tagged exhibit is to test the related format and technology and, as a result, investors should not rely on the exhibit in making investment decisions.[44] In addition, we are requiring this disclosure to appear within a tagged exhibit, as recommended by some commenters.[45]

We believe that the inclusion of the cautionary disclosure within tagged risk/return summary exhibits may help to alert investors and other users that the exhibits should not be relied on in making investment decisions. We are modifying the proposed rule to require that the disclosure be included within the exhibits as a tagged data element.[46] The ICI indicated in its comment letter that an element could be added to the risk/return summary taxonomy for the display of this disclosure and has now done so. We encourage parties that are developing rendering tools for the risk/return summary taxonomy to make use of this data tag in order to display the cautionary disclosure in rendered versions of funds' risk/return summary information.

The adopted rules, like the proposed rules and consistent with one commenter's recommendation,[47] do not require a Form N–1A filing that includes tagged exhibits containing only risk/return summary information to disclose that the information in the exhibits is ''unaudited'' or ''unreviewed.'' This disclosure will be required in a Form N 1A filing with which tagged financial highlights or condensed financial information is submitted.[48]

C. Liability Issues

The two commenters who addressed liability issues supported the proposal to extend to tagged risk/return summary information limited protection from liability that is similar to the protection provided under the current voluntary program,[49] and we are adopting the liability protection as proposed. We are providing this protection because liability remains for the official filing, and because the program is experimental, it contains certain safeguards, and the program should not unnecessarily deter volunteers from participating.

Under the current voluntary program, tagged exhibits are not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 (''Exchange Act'') [50] or Section 34(b) of the Investment Company Act,[51] or otherwise subject to the liability of these sections.[52] In addition, the current rules also provide more general relief from liability under the securities laws, including the Securities Act, the Exchange Act, the Trust Indenture Act of 1939, and the Investment Company Act, for information in a tagged exhibit that complies with the content and format requirements of the voluntary program to the extent that the information in the corresponding portion of the official EDGAR filing was not materially false or misleading.[53]

The amendments we are adopting, as proposed, extend the liability protection

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[37] *See* rule 401(c)(1) of Regulation S–T [17 CFR 232.401(c)(1)] (requires tagged exhibits to reflect the same information as corresponding official filing); XBRL Adopting Release, *supra* note 12, 70 FR at 6559 n. 48.

[38] *See* letter from ICI, *supra* note 19.

[39] XBRL Adopting Release, *supra* note 12, 70 FR at 6559.

[40] *See infra* Section II.B.

[41] *See infra* Section II.C.

[42] Rule 8b–33 (permitting tagged exhibits under the voluntary program to be submitted on Form N–1A); Item 8(a) of Form N–1A (requiring mutual funds to provide financial highlights information); rule 401(a) and (b)(1)(iii) of Regulation S–T [17 CFR 232.401(a) and (b)(1)(iii)] (permitting information set forth in Item 8(a) of Form N–1A as Mandatory Content under the voluntary program).

[43] Rule 401(a) and (b)(1)(iii) (permitting financial highlights or condensed financial information set forth in Item 8(a) of Form N–1A to be submitted as Mandatory Content); rule 8b–33. Mutual funds must include their financial highlights or condensed financial information in every annual and semi-annual report transmitted to shareholders. Items 22(b)(2) and (c)(2) of Form N–1A (requiring annual or semi-annual reports to include the information required by Item 8(a) of Form N–1A). Mutual funds must include a copy of their annual or semi-annual report transmitted to shareholders with their Form N–CSR filed with the Commission. Item 1 of Form N–CSR.

[44] Rule 401(d)(1)(ii) and (d)(2)(i) of Regulation S–T [17 CFR 232.401(d)(1)(ii) and (d)(2)(i)]. Rule 483(a) of Regulation C [17 CFR 230.483(a)] requires, among other things, that a registration statement of a registered investment company ''contain an exhibit index, which should immediately precede the exhibits filed with such registration statement.''

[45] *See* letters from ICI and PWC, *supra* note 19.

[46] Rule 401(d)(2)(i).

[47] *See* letter from ICI, *supra* note 19.

[48] Rule 401(d)(1)(i) of Regulation S–T [17 CFR 232.401(d)(1)(i)].

[49] *See* letters from ICI and PWC, *supra* note 19.

[50] 15 U.S.C. 78r.

[51] 15 U.S.C. 80a–33(b).

[52] Rule 402(a)(1) under Regulation S–T [17 CFR 232.402(a)(1)]. Further, because the tagged documents are not filed under the Exchange Act, they are not incorporated by reference into registration statements filed under the Securities Act or prospectuses they contain. These protections apply regardless of whether the documents are exhibits to a document otherwise incorporated by reference into a filing.

[53] Rule 402(b) of Regulation S–T [17 CFR 232.402(b)].

under the voluntary program to include Section 11 of the Securities Act.[54] Specifically, we are amending rule 402(a) to provide that tagged exhibits are not deemed filed for purposes of Section 11 or otherwise subject to the liabilities of that section. In addition, we are amending rule 402(a) to state explicitly that tagged exhibits are not part of any registration statement to which they relate.[55] Finally, the provision in the current rules that affords volunteers general relief from liability under the federal securities laws to the extent that the information in the corresponding portion of the official EDGAR filing was not materially false or misleading includes liability protections under the Securities Act, and it will apply to tagged documents submitted as exhibits on Form N–1A.[56] We will continue to caution users on the Commission's Web site that documents submitted under the voluntary program should not be relied upon for making investment decisions, and users should continue to rely on the company's official filing.[57]

D. The Risk/Return Summary Taxonomy and Software Tools

The taxonomy for tagging the risk/return summary information was developed by the ICI. Mutual funds will be permitted to submit documents containing risk/return summary information that is tagged using the ICI's taxonomy commencing on the effective date of the rules that we are adopting. In January 2007, the ICI released a draft risk/return summary taxonomy for public review and comment.[58] The final taxonomy was submitted for acknowledgement by the ICI to XBRL International on May 16, 2007,[59] in accordance with XBRL International procedures.[60] The taxonomy received acknowledgement in June 2007.[61] The ICI also intends to seek approval of the taxonomy in accordance with the procedures of XBRL International, but has indicated that requiring the taxonomy to be approved prior to use in the voluntary program could introduce delay, the length of which is unpredictable.[62]

We have concluded that the ICI's taxonomy is sufficiently developed to permit its use in the voluntary program. Three commenters involved in the taxonomy development process stated that the risk/return summary taxonomy is sufficiently developed for use in the voluntary program, noting that the taxonomy was developed through the use of a broad working group that was given the opportunity to review and comment on the taxonomy as it was developed and that the taxonomy was subjected to a public review and comment period.[63] While some commenters suggested changes to the taxonomy, such as reducing the number of elements in the taxonomy[64] or avoiding the use of complex structures,[65] these commenters did not suggest that the voluntary program should be delayed unless the taxonomy is modified. The ICI has considered the comments it received on the taxonomy, as well as the comments on the taxonomy submitted to the Commission, and has submitted a letter to the Commission's staff summarizing its response to the commenters and the taxonomy changes that were made.[66] In its letter, the ICI asserts that the taxonomy is ready for use with the Commission's interactive data voluntary reporting program. In light of the ICI's consideration of comments related to the taxonomy, and the comments that we received favoring the expansion of the voluntary program to the risk/return summary,[67] we have concluded that it is appropriate to permit use of the taxonomy in its present state of development. Further, the purpose of the voluntary program is to test and evaluate tagging technology, and, as a result, we agree with commenters' recommendations that it is not necessary for approval of the taxonomy to be obtained before permitting volunteers to submit tagged documents.

As in the current voluntary program, filers will be permitted to use extensions to the risk/return summary taxonomy, which are additional tags created by a particular user that further refine the tags contained in a standard taxonomy. Some commenters supported permitting the use of at least some extensions with the risk/return summary taxonomy,[68] but one commenter opposed the use of extensions to the risk/return summary taxonomy, stating that the extensions would introduce complexity.[69] While we recognize that permitting the use of extensions to the risk/return summary taxonomy may affect the ability to compare or render tagged submissions, we believe that it will be helpful to permit extensions on an unrestricted basis at this time. Experimentation with extensions will permit the Commission, filers, and users of tagged filings to better assess the need for extensions to the risk/return summary taxonomy and the impact that extensions may have on tagged documents.

One commenter recommended that the Commission impose validity testing on tagged risk/return summary exhibits

[54] In addition, the current provisions of rule 402(a) will apply to tagged risk/return summary information. In particular, a tagged exhibit on Form N–1A will not be deemed incorporated by reference into another filing, regardless of whether the tagged exhibit is an exhibit to a document otherwise incorporated by reference into another filing. Rule 402(a)(2) under Regulation S–T [17 CFR 232.402(a)(2)]. All other liability and antifraud provisions of the Securities Act, Exchange Act, and Investment Company Act will apply. Rule 402(a)(3) under Regulation S–T [17 CFR 232.402(a)(3)]. For example, material misstatements or omissions in a tagged submission will continue to be subject to liability under Section 10(b) [15 U.S.C. 78j(b)] and rule 10b–5 [17 CFR 240.10b–5] under the Exchange Act.

[55] Section 11 of the Securities Act applies to ''any part of the registration statement, when such part became effective.'' The Commission takes a similar approach with unofficial PDF copies contained in electronic submissions. *See* Rule 104(d) of Regulation S–T [17 CFR 232.104(d)]. Similar to the other protections in the voluntary program, Section 11 liability relief will not extend to the information that the official filing contains.

[56] Rule 402(b). We are adopting technical amendments to rule 402(b) to replace each reference to ''Item 401'' with ''Rule 401.''

[57] *See* ''XBRL Data Submitted in the XBRL Voluntary Program on EDGAR'' page on the Commission Web site, available at: *http://www.sec.gov/Archives/edgar/xbrl.html.*

[58] *See ICI Unveils Draft XBRL Taxonomy For Public Review,* Investment Company Institute Press Release, Jan. 4, 2007, available at: *http://www.ici.org/statements/nr/07_news_xbrl_txnmy.html#TopOfPage. See also Statements of SEC Chairman Christopher Cox and Division of Investment Management Director Andrew Donohue Regarding the Investment Company Institute's Mutual Fund Interactive Data Taxonomy,* Securities and Exchange Commission Press Release, Jan. 4, 2007, available at: *http://www.sec.gov/news/press/2007/2007–2.htm.*

[59] *See* Boteler Letter, *supra* note 16.

[60] XBRL US, Inc., represents the United States to XBRL International. XBRL US, Inc., is responsible for organizing and sponsoring taxonomies from the United States, including the main accounting standards for United States business reporting. There are two levels of XBRL taxonomy recognition: (1) ''acknowledgement'' is formal recognition that a taxonomy complies with XBRL specifications, including testing by a defined set of validation tools; and (2) ''approval'' is a formal recognition requiring more detailed quality assurance and testing, including compliance with official XBRL guidelines for the type of taxonomy under review, creation of a number of instance documents, and an open review period after acknowledgement. For more information regarding the XBRL taxonomy recognition process, see ''Taxonomy Recognition Process'' on the XBRL International Web site available at: *http://www.xbrl.org/TaxonomyRecognition/.*

[61] The taxonomy is available on XBRL International's Web site at: *http://www.xbrl.org/Taxonomy/ici/ici-rr-summarydocument-20070516-acknowledged.htm.*

[62] *See* letter from ICI, *supra* note 19. *See also* letter from Hamscher, *supra* note 19.

[63] *See* letters from Hamscher, ICI, and PWC, *supra* note 19.

[64] *See* letter from NewRiver, *supra* note 19.

[65] *See* letter from Rivet, *supra* note 19.

[66] *See* Boteler Letter, *supra* note 16.

[67] *See* letters from Confluence, Hamscher, Hoffman, ICI, NewRiver, PWC, and Rosenthal, *supra* note 19.

[68] *See* letters from ICI, PWC, and Rivet, *supra* note 19.

[69] *See* letter from Confluence, *supra* note 19.

in addition to the tests currently performed under the voluntary program, but we have determined not to impose additional testing at this time.[70] The commenter stated that additional validity testing would improve the quality of tagged exhibits submitted. Currently, under the voluntary program, validity testing of tagged exhibits consists of testing for: (1) Content validation (*i.e.*, validating for invalid ASCII characters); (2) document-type validation (*e.g.*, ensuring that EX–100.INS documents have .xml extensions and ''XBRL tags''); and (3) XBRL validation (*e.g.*, ensuring that exhibits follow appropriate XBRL standards and are structured according to the taxonomy). We agree that increased validity testing of tagged submissions might improve their quality. The purpose of the voluntary program, however, is to test the technology and the taxonomy. We, therefore, believe that it is premature to impose additional validity testing upon tagged risk/return summary documents.

The Commission's Web site currently provides access to a prototype XBRL Web application that converts tagged financial information submitted in the voluntary program into a rendered, or human readable, format.[71] At present, our Web site does not provide access to any rendering or analytical tools for use with tagged risk/return summary information. Some commenters favored a tool on the Commission's Web site that would render tagged risk/return summary documents.[72] One commenter noted that such a tool could help both investors and mutual funds to better understand and explore the benefits of tagging and could stimulate the development of other, more sophisticated tools for rendering tagged data.[73] We agree that the availability of rendering and analysis tools will help investors and mutual funds, as well as third party users, to evaluate the benefits of tagged risk/return summary data.

We will continue to analyze rendering and other capabilities specifically developed for the risk/return summary taxonomy, and we may add these features to our Web site in the future. The Commission also encourages funds and third parties to develop these tools. Users of EDGAR data on the Commission's Web site will be able to download the tagged risk/return summary information to perform their own analysis if they have appropriate software. Users will continue to be able to view the official filing in ASCII or HTML format, as they can today.

E. Effective Date

The effective date of these amendments is August 20, 2007, in order to provide sufficient time to implement EDGAR system changes necessary to provide for risk/return summary functionality.

III. Paperwork Reduction Act

The rule and form amendments contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[74] Provision of information under the amendments would be voluntary and would not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (''OMB'') control number.

The title for the collection of information is ''Voluntary XBRL-Related Documents'' (OMB Control No. 3235–0611). The rule and form amendments expand the current interactive data voluntary reporting program to enable mutual funds voluntarily to submit tagged information contained in the risk/return summary section of their prospectuses on EDGAR as exhibits to Form N–1A filings. We published notice soliciting comments on the collection of information requirements in the release proposing the amendments and submitted the proposed collection of information to OMB for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11.[75] OMB pre-approved these collection requirements. We received no comments on the collection of information requirements.

The Voluntary Program

The amendments, which will expand the current interactive data voluntary reporting program to enable mutual funds voluntarily to submit tagged information contained in the risk/return summary section of their prospectuses on EDGAR as exhibits to Form N–1A filings, will increase the burden associated with the existing collection of information for Voluntary XBRL-Related Documents. The expansion of the voluntary program will be open to any mutual fund choosing to participate. We estimate that 10% of the approximately 545 fund complexes that have mutual funds, or 55 fund complexes, will each submit documents containing tagged risk/return summary information for one mutual fund.[76] This estimate is higher than the number of mutual funds participating in the current voluntary program. However, we believe that additional mutual funds will participate in the expanded voluntary program.[77]

Submission of tagged risk/return summary information will not directly affect the burden of preparing the mutual funds' registration statements or the registrants' official EDGAR filings. In order to provide tagged risk/return summary information, a participating mutual fund will have to tag the risk/return summary section of its prospectus using the risk/return summary taxonomy and potentially develop taxonomy extensions and will submit an exhibit to its filing. Based on our previous estimates and our experience with registrants who have submitted tagged financial information in the current voluntary program, we estimate that the initial creation of tagged documents containing risk/return summary information will require, on average, approximately 110 burden hours per mutual fund,[78] and the

[70] *See* comment letter from Hoffman, *supra* note 19.

[71] *See* ''Interactive Financial Report Viewer—Preview Release'' Web page on the Commission Web site, available at: *http://www.sec.gov/spotlight/xbrl/xbrlwebapp.htm.*

[72] *See* letters from Hamscher, ICI, and PWC, *supra* note 19.

[73] *See* letter from ICI, *supra* note 19.

[74] 44 U.S.C. 3501 *et seq.*

[75] *See* Proposing Release, *supra* note 6, 72 FR at 6682–83.

[76] In the case of a mutual fund with multiple series, our estimate treats each series as a separate mutual fund.

[77] The ICI is undertaking an educational effort to encourage mutual funds to use the risk/return summary taxonomy to tag the information in their EDGAR filings. *ICI Details Project to Extend XBRL to Key Investor Information,* Investment Company Institute Press Release, June 12, 2006, available at: *http://www.ici.org/statements/nr/2006/06_news_xbrl.html#TopOfPage.*

One commenter suggested that the Commission offer incentives to encourage volunteers to participate in the expanded voluntary program. *See* letter from ICI, *supra* note 19. Specifically, the commenter suggested that the Commission: (1) Offer expedited review of mutual fund exemptive applications; or (2) offer expedited review of an initial registration statement on Form N–1A or an amendment to a registration statement to add a new fund or series. *Id.* The Commission did not initially offer incentives for volunteers to submit tagged information as part of the current voluntary program. The Commission subsequently offered expedited review of registration statements and annual reports to volunteers agreeing to participate in a test group. *See* January 11 Press Release, *supra* note 7. Volunteers that participate in the test group agree to furnish financial data contained in their periodic and investment company reports in XBRL format for at least one year and provide feedback on their experiences. *Id.* At this time, we are not offering specific incentives to encourage volunteers to participate in the expanded voluntary program, however, we will continue to assess the need for incentives going forward.

[78] In the current voluntary program, we estimated that an initial set of submissions would require an average of 130 burden hours, 75% of which (or 97.5

Continued

creation of such tagged documents in subsequent years will require an average 10 burden hours per mutual fund.[79] Because the PRA estimates represent the average burden over a three-year period, we estimate the average hour burden for the submission of tagged documents containing risk/return summary information for one mutual fund to be approximately 43 hours.[80]

Based on the estimates of 55 participants submitting tagged documents containing risk/return summary information for one mutual fund per year and incurring 43 hours per submission, we estimate that, in the aggregate, the industry will incur an additional 2,365 burden hours associated with the amendments.[81] We further estimate that 75% of this burden increase, or approximately 1,774 hours, will be borne internally by the mutual fund complex. We estimate that this internal burden increase converted to dollars will amount to approximately $393,828.[82]

We also estimate that 25% of the burden, or approximately 591 hours, will be outsourced to external professionals and consultants retained by the mutual fund complex at an average cost of $256.00 per hour for a total annual increase of approximately $151,296.[83] In addition, it is our understanding that many participants will also have annual software licensing costs. We estimate that the cost of licensing software will be $333 per participant per year, for a total annual increase of $18,315.[84] Altogether, the total annual increase in external costs related to the amendments will be $169,611.[85]

Our cost estimates are intended to reflect both initial and ongoing costs over a three-year period. In calculating these costs, we have tried to take into account, among other things, the current state of reporting process automation, automation that likely will be introduced in connection with the initial cost incurred, and the efficiencies that likely will be realized over the course of three years.

Regulation S–T

Regulation S–T (OMB Control No. 3235–0424) specifies the requirements that govern the electronic submission of documents. The amendments will revise rules under Regulation S–T, but the associated increase in burden is reflected in the ''Voluntary XBRL-Related Documents'' collection of information as described above.

IV. Cost/Benefit Analysis

The Commission is sensitive to the costs and benefits imposed by its rules. The goal of the voluntary program is to increase EDGAR's efficiency and utility and to enhance the usefulness to investors of the information collected through EDGAR. In order to evaluate data tagging further, we are adopting amendments to extend the current interactive data voluntary reporting program to enable mutual funds voluntarily to submit tagged information contained in the risk/return summary section of their prospectuses on EDGAR as exhibits to Form N–1A filings.

A. Benefits

We believe that tagged information may allow more efficient and effective retrieval, research, and analysis of company information through automated means. The expansion of the voluntary program will assist us in assessing whether using interactive data tags enhances users' ability to analyze and compare mutual fund risk/return summary information included in mutual funds' filings with the Commission. The expansion of the voluntary program to include narrative, non-financial information, such as that contained in the risk/return summary, also will facilitate our ability to assess further the technical requirements of processing tagged documents using EDGAR.

Currently, a number of companies use computers and data entry staff to mine risk/return summary information provided by mutual funds on EDGAR in order to populate databases that are used to package information for sale to analysts, funds, investors, and others. Permitting funds to tag risk/return summary information in Commission filings will aid this data-mining process in that it will identify points of data at the source, which could reduce the cost to populate databases and improve the

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hours) represents the internal burden hour estimate. *See* XBRL Adopting Release, *supra* note 12, 70 FR at 6563; XBRL Proposing Release, *supra* note 12, 69 FR at 59101. Based upon our experience with filers who have submitted tagged financial information in the current voluntary program, we believe that this burden estimate for submitting an initial set of submissions may have been too high. *See, e.g.*, Indra K. Nooyi, Chief Executive Officer, PepsiCo, Inc., Webcast Archive of October 3 Interactive Data Roundtable, Oct. 3, 2006, available at: *http://www.connectlive.com/events/secinteractivedata100306/* (initial submission in voluntary program required approximately 60 to 80 total labor hours); John Stantial, Director of Financial Reporting, United Technologies Corporation, Transcript of June 12 Interactive Data Roundtable, June 12, 2006, available at: *http://www.sec.gov/spotlight/xbrl/xbrlofficialtranscript0606.pdf*, at 160 (initial submission in voluntary program required about 80 hours of effort). We, therefore, estimate that the initial creation of tagged documents containing risk/return summary information will require, on average, approximately 110 burden hours per mutual fund, 75% of which (or 82.5 hours) represents the internal burden hour estimate. These estimates more closely approximate the experience of filers in the current voluntary program.

[79] In the current voluntary program, we estimated that each set of submissions, after the initial set, would take 10 burden hours. *See* XBRL Adopting Release, *supra* note 12, 70 FR at 6563; XBRL Proposing Release, *supra* note 12, 69 FR at 59101. We continue to believe that this estimate is appropriate.

[80] (110 hours in the first year + 10 hours in the second year + 10 hours in the third year) ÷ 3 years = 43 hours. While the PRA requires an estimate based on a hypothetical three years of participation, a registrant, as noted earlier, could participate in the expanded voluntary program by submitting tagged risk/return summary information over a shorter period or even just once as the registrant chooses.

[81] 55 documents per year × 43 hours per submission = 2,365 hours.

[82] This cost increase is estimated by multiplying the increase in annual internal hour burden (1,774) by the estimated hourly wage rate of $222.00. The estimated wage figure is based on published rates for compliance attorneys and programmer analysts, modified to account for an 1800-hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead, yielding effective hourly rates of $261 and $209, respectively. *See* Securities Industry Association, *Report on Management & Professional Earnings in the Securities Industry 2006* (Sept. 2006) (''SIA Report''). The estimated wage rate is further based on the estimate that compliance attorneys would account for one quarter of the hours worked and programmer analysts would account for the remaining three quarters, resulting in a weighted wage rate of $222.00 (($261 × .25) + ($209 × .75)). The wage rates used in the Proposing Release were based upon the Securities Industry Association, *Report on Management & Professional Earnings in the Securities Industry 2005* (Sept. 2005), and the total internal and external burden increases converted to dollars differs from the estimates in the Proposing Release due to changes in wage rates in the 2006 SIA Report.

[83] 591 hours × $256.00 per hour = $151,296. The estimated wage figure is based on published rates for attorneys and senior programmers, modified to account for an 1800-hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead, yielding effective hourly rates of $292 and $244, respectively. *See* SIA Report, *supra* note 82. The estimated wage rate is further based on the estimate that attorneys will account for one quarter of the hours worked and senior programmers will account for the remaining three quarters, resulting in a weighted wage rate of $256.00 (($292 × .25) + ($244 × .75)).

[84] $333 per participant × 55 participants = $18,315. The estimated annual cost of the software comes from our previous PRA estimate for the current voluntary program. *See* XBRL Adopting Release, *supra* note 12, 70 FR at 6563 and n. 113. That estimate was based on our discussions with software providers and others familiar with XBRL. We estimated that the cost of licensing software will range from $200 to $3,000 each year, with the majority of companies licensing less complex software in the $200 to $500 range. We set our software cost estimate at $500, which is the highest cost for the simpler XBRL software license, and we assumed that the first year license fee will be waived (based upon our understanding that software providers indicated that they will provide these products for free in the initial stages of the voluntary program). Because the PRA estimates represent the average burden over a three-year period, we estimated the average burden for software license costs to be $333 per year. *Id.*

[85] This annual total consists of $151,296 in outside professional costs plus $18,315 in software costs.

accuracy of that data. Additionally, the expanded voluntary program may benefit funds and the public by permitting experimentation with data tagged using the risk/return summary taxonomy.

In the future, the availability of potentially more accurate tagged information about mutual funds could also reduce the cost of research and analysis and create new opportunities for companies that compile, provide, and analyze data to produce more value added services. Enhanced access to tagged information also has the potential to allow retail investors (or financial advisers assisting such investors) to perform more personalized and sophisticated analyses and comparisons of mutual funds, which could result in investors making better informed investment decisions, and therefore in a more efficient distribution of assets by investors among different funds. This may, in turn, also contribute to increased competition among mutual funds and result in a more efficient allocation of resources among competing investment products. Although it is not possible to quantify precisely the beneficial effects of more efficient allocation of investors' assets and increased competition, they may be significant, given the size of the mutual fund industry.

In the Proposing Release, we sought comments on our cost-benefit analysis,[86] and several commenters discussed the potential benefits resulting from the expansion of the interactive data voluntary reporting program and from interactive data in general. Two commenters stated that interactive data will increase the accuracy of information.[87] One commenter also noted the potential for increased timeliness of critical data that investors require to make informed investment decisions.[88] Another commenter stated that a prospectus tagged using the risk/return summary taxonomy will allow automated, instantaneous extraction of every fact disclosed in the risk/return summary.[89] Further, commenters stated that allowing funds to file tagged risk/return summary information would serve the objective of providing investors with more user-friendly access to key fund information.[90] Commenters also noted potential cost savings of interactive data which would benefit investors.[91] Finally, one commenter noted that the investment analysis process would become more efficient and effective through the increased use of automation and reduced human intervention that would result from the use of interactive data.[92]

B. Costs

The expansion of the voluntary program will lead to some additional costs for funds choosing to submit tagged documents containing risk/return summary information as exhibits to their Form N–1A filings. For purposes of the PRA, we estimated that the increase in annual internal burden hours to the industry will be 1,774 hours, which will amount to approximately $393,828 and that the increase in annual external costs will amount to approximately $169,611 for a total estimated increase of $563,439 on an annual basis.[93]

We based these cost estimates upon, among other things, experience with filers who have submitted tagged financial information in the current voluntary program.[94] Due to the ongoing nature of the project to develop the risk/return summary taxonomy, however, we have limited data to quantify the cost of implementing the use of interactive data tags applied to risk/return summary information. In the Proposing Release, we sought comments and supporting data on our cost estimates with regard to the proposed amendments.[95] We did not receive any comments or supporting data specific to our cost estimates.[96]

In the future, there may be additional costs to current users of EDGAR data. For example, companies that currently provide tagging and dissemination of EDGAR data may experience decreased demand for their services. These entities have developed certain products and services based on data in EDGAR; many entities disseminate, repackage, analyze, and sell the information. Allowing mutual funds to submit tagged risk/return summary information, even voluntarily, may have an impact on entities providing EDGAR-based services and products. Because the Commission does not regulate all these entities, it is currently not feasible to accurately estimate the number or size of these potentially affected entities. The limited, voluntary nature of the program will help the Commission assess the effect, if any, on these entities. In addition, the availability of mutual fund tagged data on EDGAR may provide these companies with alternative business opportunities.

V. Promotion of Efficiency, Competition, and Capital Formation

Section 2(c) of the Investment Company Act[97] and section 2(b) of the Securities Act[98] require the Commission, when engaging in rulemaking that requires it to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.

The amendments will extend the interactive data voluntary reporting program to enable mutual funds voluntarily to submit tagged information contained in the risk/return summary section of their prospectuses on EDGAR as exhibits to Form N–1A filings. The expansion of the voluntary program is intended to help us evaluate the usefulness to investors, third-party analysts, mutual funds, the Commission, and the marketplace of data tagging and, in particular, of tagging mutual fund information. Because compliance with the amendments will be voluntary, the Commission estimates that the impact of the amendments will be limited. However, because the tagging of risk/return summary information has the potential to facilitate analysis of that information, we believe that the amendments could promote efficiency by allowing us and others to gain experience with tagged mutual fund information in Commission filings.

Further, tagging of the risk/return summary information has the potential to help streamline the delivery of mutual fund information, and provide investors and others with improved tools to compare funds based upon, among other things, costs, investment objectives, strategies, and risks. We believe that the potential to streamline the delivery of mutual fund information and to provide investors and others with improved mutual fund comparison tools could promote efficiency and competition through more efficient allocation of investments by investors and more efficient allocation of assets among competing funds. In the future,

[86] *See* Proposing Release, *supra* note 6, 72 FR at 6684.

[87] *See* letters from Confluence and Hamscher, *supra* note 19.

[88] *See* letter from PWC, *supra* note 19.

[89] *See* letter from Hamscher, *supra* note 19.

[90] *See* letters from ICI and PWC, *supra* note 19.

[91] *See* letters from Confluence and PWC, *supra* note 19.

[92] *See* letter from PWC, *supra* note 19.

[93] *See supra* Section III.

[94] *See supra* note 78.

[95] *See* Proposing Release, *supra* note 6, 72 FR at 6684.

[96] One commenter noted that it is difficult to estimate the likely cost of participation in the voluntary program at this time but noted that it may wish to provide cost data to the Commission in the future. *See* letter from ICI, *supra* note 19.

[97] 15 U.S.C. 80a–2(c).

[98] 15 U.S.C. 77b(b).

companies that currently provide tagging and dissemination of EDGAR data may experience decreased demand for their services. The availability of mutual fund tagged data on EDGAR, however, may provide these companies with alternative business opportunities. We do not anticipate that the amendments will have a significant impact on capital formation. Finally, because the amendments are designed to permit mutual funds to provide information in a format that we believe will be more useful to investors, we believe that the amendments are appropriate in the public interest and for the protection of investors.

We requested comment on whether the proposed amendments would promote efficiency, competition, and capital formation. We received no comment on this issue.

VI. Final Regulatory Flexibility Analysis

This Final Regulatory Flexibility Analysis was prepared in accordance with 5 U.S.C. 604 and relates to the amendments we are adopting that will expand the current interactive data voluntary reporting program to enable mutual funds voluntarily to submit tagged information contained in the risk/return summary section of their prospectuses on EDGAR as exhibits to Form N–1A filings. An Initial Regulatory Flexibility Analysis (''IRFA''), which was prepared in accordance with the 5 U.S.C. 603, was published in the release proposing the amendments.

A. Need for the Amendments

The purpose of the amendments is to help us evaluate the usefulness to investors, third-party analysts, mutual funds, the Commission, and the marketplace of data tagging and, in particular, of tagging mutual fund information. We believe that the expanded voluntary program will enable us to study further the extent to which interactive data tags enhance the comparability of that data, the usefulness of data tags for dissemination, and our staff's ability to review and assess the accuracy and adequacy of that data. The expanded voluntary program will also help us assess the effect of interactive data tags on the quality and transparency of risk/return summary information, as well as the compatibility of data tagging with the Commission's disclosure requirements.

More specifically, we believe that the expanded voluntary program will better enable us to study the extent to which interactive data enhances the:

- Search capability of the EDGAR database to allow more efficient and effective extraction and analysis of specific data,
- Capability to perform comparisons among mutual funds, and
- Ability to perform analyses of mutual fund data and whether it would reduce the resources needed for data analysis.

In addition, we believe that the expanded voluntary program will enhance our ability to evaluate the:

- Impact on the staff's ability to review filings on a more timely and efficient basis,
- Use of tagged data for risk assessment and surveillance procedures, and
- Compatibility of interactive data with reporting quality, transparency, and other Commission reporting requirements.

B. Significant Issues Raised by Public Comment

In the IRFA for the proposed amendments, we requested comment on the number of small entities that would be affected by the proposed amendments, the existence or nature of the potential effect of the proposals on small entities, how to quantify the effect of the proposals, how different procedures could be provided for small entities, and we asked commenters to provide any empirical data supporting the extent of the impact. We received no comment letters specifically addressing the IRFA in the Proposing Release; however, one commenter suggested that the Commission could lower the barrier for participation for small funds by providing a ''literal'' or structured form using some commonly used software applications.[99]

C. Small Entities Subject to the Rules

The expansion of the voluntary program may have an effect on mutual fund participants in the voluntary program. Under Rule 0–10 under the Investment Company Act, an investment company is a small entity if it, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less as of the end of its most recent fiscal year.[100] We estimate that there are approximately 131 mutual funds that meet this definition. A smaller subset of those issuers may voluntarily submit tagged risk/return summary information under the voluntary program, but, because submitting risk/return summary information will be voluntary, we anticipate that only complexes with sufficient resources will elect to participate. To date, no small entity mutual funds have elected to participate in the current voluntary program.

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements

The voluntary program is designed to assist us in assessing the feasibility of using interactive data on a broader basis. Experience with the current voluntary program indicates that the cost of participating in the expanded program, the associated burden on the EDGAR system, and the possible effect of the expanded voluntary program on those entities that use the EDGAR data will be minimal. Nevertheless, the impact of the amendments remains somewhat speculative at this point.

No registrant will be required to submit tagged documents under the expansion of the voluntary program. The submission of tagged risk/return summary information will require a participating mutual fund to tag the risk/return summary section of its prospectus using the risk/return summary taxonomy and potentially develop extensions and to submit exhibits to its filing. Volunteers may also need to purchase software or retain a consultant to assist in tagging data. For purposes of the PRA, we estimated that each volunteer, including small entities, would incur approximately 43 burden hours and $333 in software costs annually.

E. Agency Action To Minimize Effect on Small Entities

The Regulatory Flexibility Act directs us to consider significant alternatives that would accomplish the stated objective, while minimizing any significant adverse impact on small entities. The purpose of the amendments is to help us evaluate the usefulness to investors, third-party analysts, mutual funds, the Commission, and the marketplace of data tagging and, in particular, of tagging mutual fund information. Submitting documents containing tagged risk/return summary information is entirely voluntary. We have considered different or simpler procedures for small entities, including:

- The establishment of different compliance or reporting requirements or timetables;
- The clarification, consolidation, or simplification of the proposed requirements;
- The use of performance rather than design standards; and
- Exemption from coverage.

[99] *See* letter from Hamscher, *supra* note 19.

[100] 17 CFR 270.0–10.

For tagged data to provide benefits such as ready comparability, however, the data tagging system cannot have alternative procedures. Similarly, in order to achieve the benefits of interactive data tagging, use of a single data tagging technology is necessary. Additionally, providing structured input forms, as suggested by one commenter,[101] is not appropriate at this time given the cost of deploying and maintaining such forms and the difficulty of permitting extensions to be used with a structured input form. If we determine to require data tagging in the future, we will look to the results of the voluntary program, including those of the expansion of the program to risk/return summary information, in considering alternatives to minimize any burden on small entities.

VII. Statutory Authority

The Commission is adopting the rule amendments outlined above under Sections 5, 6, 7, 10, 19(a), and 28 of the Securities Act [15 U.S.C. 77e, 77f, 77g, 77j, 77s(a), and 77z–3] and Sections 6(c), 8, 24(a), 30, and 38 of the Investment Company Act [15 U.S.C. 80a–6(c), 80a–8, 80a 24(a), 80a–29, and 80a–37].

List of Subjects

17 CFR Parts 232 and 239

Reporting and recordkeeping requirements, Securities.

17 CFR Parts 270 and 274

Investment Companies, Reporting and recordkeeping requirements, Securities.

Text of Rule and Form Amendments

■ For the reasons set forth above, the Commission amends title 17, Chapter II of the Code of Federal Regulations as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The general authority citation for Part 232 is revised to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll, 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, and 7201 et seq.; and 18 U.S.C. 1350.

* * * * *

■ 2. Amend § 232.401 by:

■ a. Revising the first sentence of paragraph (a);

■ b. Removing the word ''or'' at the end of paragraph (b)(1)(ii);

■ c. Removing the phrase ''(§ 239.15A and § 274.11A of this chapter)'' in paragraph (b)(1)(iii);

■ d. Removing the period at the end of paragraph (b)(1)(iii) and adding in its place ''; or'';

■ e. Adding new paragraph (b)(1)(iv); and

■ f. Revising paragraphs (d)(1)(i) and (d)(2)(i).

The addition and revisions read as follows:

§ 232.401 XBRL-Related Document submissions.

(a) An electronic filer that participates in the voluntary XBRL (eXtensible Business Reporting Language) program may submit XBRL-Related Documents (§ 232.11) in electronic format as an exhibit to: The filing (other than a Form N–1A (§ 239.15A and § 274.11A of this chapter) filing) to which the XBRL Related Documents relate; an amendment to such filing, but, in the case of a Form N 1A filing, an amendment made only after the effective date of the Form N–1A filing to which the XBRL-Related Documents relate; or if the electronic filer is eligible to file a Form 8–K (§ 249.308 of this chapter) or a Form 6–K (§ 249.306 of this chapter), a Form 8–K or a Form 6–K, as applicable, that references the filing to which the XBRL-Related Documents relate if such Form 8–K or Form 6–K is submitted no earlier than the date of that filing. * * *

(b) * * *

(1) * * *

(iv) The risk/return summary information set forth in Items 2 and 3 of Form N 1A provided that, in the case of a Form N 1A filing that includes more than one series (as that term is used in rule 18f–2(a) under the Investment Company Act (§ 270.18f 2(a) of this chapter), a filer may include in mandatory content complete risk/return summary information for any one or more of those series.

* * * * *

(d) * * *

(1) * * *

(i) That the financial information contained in the XBRL-Related Documents is ''unaudited'' or ''unreviewed,'' as applicable (but only if the mandatory content contained in the XBRL-Related Documents contains information other than risk/return summary information submitted under paragraph (b)(1)(iv) of this section);

* * * * *

(2) * * *

(i) The exhibit index of a Form 10–K (§ 249.310 of this chapter), 10–Q (§ 249.308a of this chapter), 10 (§ 249.210 of this chapter), 10–SB (§ 249.210b of this chapter), 10–KSB (§ 249.310b of this chapter), 10–QSB (§ 249.308b of this chapter), 20–F or N–1A and, in the case of risk/return summary information submitted under paragraph (b)(1)(iv) of this section, within the XBRL-Related Documents as a tagged data element;

* * * * *

3. Revise § 232.402(a)(1) to read as set forth below and amend § 232.402(b) by removing each reference to ''Item 401'' and adding in its place ''Rule 401''.

§ 232.402 Liability for XBRL-Related Documents.

(a) * * *

(1) Are not deemed filed for purposes of section 11 of the Securities Act (15 U.S.C. 77k), section 18 of the Exchange Act (15 U.S.C. 78r), or section 34(b) of the Investment Company Act (15 U.S.C. 80a–33(b)), or otherwise subject to the liabilities of these sections, and are not part of any registration statement to which they relate;

* * * * *

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

■ 4. The general authority citation for Part 239 is revised to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77sss, 78c, 78l, 78m, 78n, 78o(d), 78u–5, 78w(a), 78ll, 78mm, 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–24, 80a–26, 80a–29, 80a–30, and 80a–37, unless otherwise noted.

* * * * *

PART 270—GENERAL RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

■ 5. The authority citation for Part 270 continues to read in part as follows:

Authority: 15 U.S.C. 80a–1 *et seq.*, 80a–34(d), 80a–37, and 80a–39, unless otherwise noted.

* * * * *

■ 6. Revise § 270.8b–33 to read as follows:

§ 270.8b–33 XBRL-Related Documents.

A registrant that participates in the voluntary XBRL (eXtensible Business Reporting Language) program may submit, in electronic format as an exhibit to a filing on Form N–1A (§§ 239.15A and 274.11A of this chapter), Form N–CSR (§§ 249.331 and 274.128 of this chapter), or Form N–Q (§§ 249.332 and 274.130 of this chapter) to which they relate, XBRL Related Documents (§ 232.11 of this chapter). A registrant that submits XBRL Related Documents as an exhibit to a form must name each XBRL Related Document

[101] *See supra* note 99.

''EX 100'' as specified in the EDGAR Filer Manual and submit the XBRL Related Documents in such a manner that will permit the information for each series and, for any information that does not relate to all of the classes in a filing, each class of an investment company registrant and each contract of an insurance company separate account to be separately identified. A registrant may submit such exhibit with, or in an amendment to, the Form N–CSR or Form N–Q filing to which it relates, or in an amendment to the Form N–1A filing to which it relates, in accordance with rule 401 of Regulation S–T (§ 232.401).

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

■ 7. The authority citation for Part 274 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78l, 78m, 78n, 78o(d), 80a–8, 80a–24, 80a–26, and 80a–29, unless otherwise noted.

* * * * *

■ 8. Amend General Instruction B.4.(b) of Form N 1A (referenced in §§ 239.15A and 274.11A) by revising ''8b–32 [17 CFR 270.8b–1—270.8b–32]'' to read ''8b–33 [17 CFR 270.8b–1—270.8b–33]''.

Note: The text of Form N–1A will not appear in the Code of Federal Regulations.

Dated: July 11, 2007.

By the Commission.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–13738 Filed 7–16–07; 8:45 am]

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Federal Register

Vol. 72, No. 136

Tuesday, July 17, 2007

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Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**
TTY for the deaf-and-hard-of-hearing	**741–6086**

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FEDERAL REGISTER PAGES AND DATE, JULY

35907–36336 2
36337–36588 3
36589–36858 5
36859–37096 6
37097–37418 9
37419–37628 10
37629–37990 11
37991–38462 12
38463–38746 13
38747–38996 16
38997–39300 17

CFR PARTS AFFECTED DURING JULY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
8158 36587
8159 37095
8160 38461
8161 38995
8162 38997
Executive Orders:
13338 36587
13381 (Amended by 13436) 36337
13436 36337
13437 36339
Administrative Orders:
Memorandums:
Memorandum of June 26, 2007 36335
Memorandum of June 28, 2007 35907
Memorandum of July 3, 2007 37627
Presidential Determinations:
No. 2007-23 of June 28, 2007 37419
No. 2007-24 of June 28, 2007 37421
No. 2007-25 of July 5, 2007 38747

6 CFR

5 ..... 38749, 38750

7 CFR

2 36859
301 35909
305 35909
353 35915
922 37991
924 38463
925 37423
928 38465
959 37993
1170 36341
1214 38467
1220 37995
Proposed Rules:
301 39018
305 36629
340 39021
354 39025
915 38037
922 38496
981 36900
984 38498
1755 39028
1767 38511

9 CFR

309 38700
310 38700
318 38700
331 38467
381 38467

10 CFR

72 38468
Proposed Rules:
50 ..... 37470, 38030
71 37471

12 CFR

26 38753
205 36589
212 38753
348 38753
563f 38753
Proposed Rules:
1 36550
2 36550
3 36550
4 36550
5 36550
7 36550
9 36550
10 36550
11 36550
12 36550
16 36550
19 36550
21 36550
22 36550
23 36550
24 36550
26 36550
27 36550
28 36550
31 36550
32 36550
34 36550
37 36550
40 36550
701 37122

14 CFR

25 37425
39 ..... 36860, 36861, 36863, 36866, 37997, 37999, 38000, 38002, 38004, 38006
71 ..... 36345, 36346, 36593, 36868, 37430, 37431, 37629, 38999
73 35917
97 ..... 38469, 38755
Proposed Rules:
25 38732
39 ..... 36370, 36373, 36378, 36380, 36385, 36391, 36901, 36905, 36907, 36912, 36914, 36916, 36920, 36925, 37122, 37124, 37126, 37130, 37132, 37472, 37475, 37477, 37479, 37484, 38527, 38529, 38532, 38797, 38800, 39039
71 ..... 36397, 37487, 37488,

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT JULY 17, 2007

COMMERCE DEPARTMENT

Industry and Security Bureau

Export administration regulations:

Commerce Control List—

Microelectronic circuits; export licensing jurisdiction; published 7-17-07

STATE DEPARTMENT

International Traffic in Arms Regulations:

U.S. Munitions List, Category XV; radiation-hardened microelectric circuits; coverage and performance characteristics; published 7-17-07

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Apricots grown in Washington; comments due by 7-23-07; published 7-13-07 [FR E7-13581]

AGRICULTURE DEPARTMENT

Animal and Plant Health Inspection Service

Plant-related quarantine, domestic:

Citrus canker; comments due by 7-23-07; published 6-21-07 [FR E7-12041]

AGRICULTURE DEPARTMENT

Federal Crop Insurance Corporation

Crop insurance regulations:

Tobacco crop insurance provisions; comments due by 7-23-07; published 5-23-07 [FR E7-09775]

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

Americans with Disabilities Act; implementation:

Accessibility guidelines—

Emergency transportable housing Federal advisory committee; intent to establish; comments due by 7-25-07; published 6-25-07 [FR E7-12205]

Passenger Vessel Emergency Alarms Advisory Committee; intent to establish; comments due by 7-25-07; published 6-25-07 [FR E7-12196]

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:

Northeastern United States fisheries—

Emergency closure due to presence of toxin causing paralytic shellfish poisoning; comments due by 7-27-07; published 6-27-07 [FR E7-12432]

West Coast States and Western Pacific fisheries—

Highly migratory species; comments due by 7-27-07; published 6-27-07 [FR E7-12430]

International fisheries regulations:

Nations whose fishing vessels are engaged in illegal, unreported, or unregulated fishing or bycatch of protected living marine resources; certification; comments due by 7-26-07; published 6-11-07 [FR E7-11254]

Marine mammals:

Taking and importing—

U.S. Navy operations of surveillance towed array sensor systems low frequency active sonar; comments due by 7-24-07; published 7-9-07 [FR 07-03329]

Ocean and coastal resource management:

Marine sanctuaries—

Channel Islands National Marine Sanctuary, CA; comments due by 7-23-07; published 5-24-07 [FR E7-10096]

COMMODITY FUTURES TRADING COMMISSION

Special calls for information; comments due by 7-23-07; published 6-22-07 [FR E7-11984]

Traders reports:

Books and records maintenance; comments due by 7-23-07; published 6-22-07 [FR E7-12045]

DEFENSE DEPARTMENT

Defense Acquisition Regulations System

Acquisition regulations:

Contract profit/fee policies; comments due by 7-23-07; published 5-22-07 [FR E7-09754]

Leasing; vessels, aircraft, and combat vehicles; comments due by 7-23-07; published 5-22-07 [FR E7-09744]

DEFENSE DEPARTMENT

Grants and agreements:

Nonprocurement debarment and suspension; OMB guidance, implementation; comments due by 7-26-07; published 6-26-07 [FR 07-03086]

EDUCATION DEPARTMENT

Special education and rehabilitative services:

Infants and Toddlers with Disabilities Early Intervention Program; comments due by 7-23-07; published 5-9-07 [FR 07-02140]

ENVIRONMENTAL PROTECTION AGENCY

Air programs; State authority delegations:

Arizona and Nevada; comments due by 7-23-07; published 6-21-07 [FR E7-12044]

Air quality implementation plans:

Preparation, adoption, and submittal—

Interstate ozone transport and nitrogen oxides reduction; petition for reconsideration findings for Georgia; comment request; comments due by 7-23-07; published 6-8-07 [FR E7-11036]

Air quality implementation plans; approval and promulgation; various States:

Delaware; comments due by 7-23-07; published 6-21-07 [FR E7-12051]

Idaho and Washington; comments due by 7-26-07; published 6-26-07 [FR E7-12234]

Iowa; comments due by 7-26-07; published 6-26-07 [FR E7-12237]

Pesticide programs:

Tolerance reassessment decisions—

Methamidophos, etc.; comments due by 7-23-07; published 5-23-07 [FR 07-02561]

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:

Crop Grouping Program; expansion; comments due by 7-23-07; published 5-23-07 [FR E7-09595]

Famoxadone; comments due by 7-23-07; published 5-23-07 [FR E7-09823]

Propanil, etc.; comments due by 7-23-07; published 5-23-07 [FR E7-09912]

FEDERAL TRADE COMMISSION

Industry guides:

Fuel economy advertising for new automobiles; comments due by 7-23-07; published 5-9-07 [FR E7-08886]

Select leather and imitation leather products; comments due by 7-23-07; published 5-23-07 [FR E7-09965]

HEALTH AND HUMAN SERVICES DEPARTMENT

Centers for Medicare & Medicaid Services

Medicare:

Medicare Advantage and Part D prescription drug contract determinations, appeals, and intermediate sanctions processes; revisions; comments due by 7-24-07; published 5-25-07 [FR 07-02579]

Prescription drug benefit; policy and technical changes; comments due by 7-24-07; published 5-25-07 [FR 07-02577]

HEALTH AND HUMAN SERVICES DEPARTMENT

Privacy Act regulations:

Systems of records exemptions; comments due by 7-24-07; published 5-25-07 [FR E7-10143]

HOMELAND SECURITY DEPARTMENT

Coast Guard

Anchorage regulations:

Maine; comments due by 7-23-07; published 5-24-07 [FR E7-09968]

Merchant marine officers and seamen:

Large passenger vessels; crew requirements; comments due by 7-23-07; published 4-24-07 [FR E7-07696]

Oceanographic research vessels:

Alternative Compliance Program; comments due by 7-23-07; published 5-22-07 [FR E7-09840]

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

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S. 277/P.L. 110–47

Grand Teton National Park Extension Act of 2007 (July 13, 2007; 121 Stat. 241)

Last List July 10, 2007

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