

for such treatment and maintenance of records on such drugs.

These statutory mandates have been reflected in treatment regulations that have been enforced by the Food and Drug Administration (FDA) since 1972. FDA has approved over 900 "narcotic treatment programs" under these regulations. Up until 1993, methadone was the only narcotic treatment medication approved for use under these regulations. In 1993, the regulations were revised to add regulatory standards for the use of levo-alpha-acetyl-methadol (LAAM), following review and approval of a New Drug Application (NDA) for this use by FDA.

FDA has received and is reviewing NDAs for two new narcotic treatment medications, buprenorphine and buprenorphine/naloxone (buprenorphine/nx). If approved, both products must be the subject of treatment standards.

The Secretary recognizes that partial or mixed agonist medications, are different than full agonists, such as methadone and LAAM. The Secretary has, therefore, determined that these differences warrant a different treatment standard model:

The Secretary notes that there are new medications under development for the treatment of opioid addiction. While still under investigation and review, it is conceivable that these new medications will present safety and effectiveness profiles that differ from the existing approved treatment medications, methadone and LAAM. A new medication, for example, could rely on weak or partial agonist properties or on mixed agonist-antagonist properties, with pharmacokinetic and pharmacodynamic properties that would minimize the risk of deliberate abuse through injection and, in turn, would minimize the overall risk of diversion. As such, it may be appropriate to tailor the Federal opioid treatment standards to the specific characteristics of these future medications. (See **Federal Register**, July 22, 1999, 64 FR 39810.)

Because of their special characteristics, partial agonist medications should be the subject of specific treatment standards. Indeed, partial agonist medications' pharmacological properties and safety profiles warrant a new paradigm in narcotic addiction treatment, office-based treatment. Therefore, the Department of Health and Human Services is announcing its intent to develop and issue a proposed rule that will address the use of partial agonist treatment medications in the office-based treatment of narcotic addiction.

II. Office-Based Treatment of Narcotic Addiction

The Department is preparing a proposed rule for publication in the near future that will address the use of approved narcotic partial agonist treatment drugs controlled in Schedules III-V, in office-based settings. The proposed rule will include standards and procedures for determining the training and experience necessary to safely and effectively treat opiate addicts with partial agonist treatment medications in an office-based setting. This may include limits on the number of patients that may be treated by any one office-based physician. In addition, the proposal will include standards that relate to medical and psychosocial services, including counseling, that should be available to patients that are determined to need them. The proposed rule will include standards respecting the quantities of medications that may be prescribed, dispensed or administered to patients for unsupervised use.

In anticipation of the availability of partial agonist treatment medications, a Subcommittee on Buprenorphine was formed as part of SAMHSA's Center for Substance Abuse Treatment (CSAT) National Advisory Council. The Subcommittee considered the available research base on buprenorphine, office-based settings, and Federal oversight during two public meetings. The full CSAT National Advisory Council, after deliberation, adopted the Subcommittee's findings and recommendations which were subsequently conveyed to CSAT by the Council on June 11, 1999, in the form of a comprehensive report. The report may be obtained by notifying the CSAT contact listed above. The report is also available at the SAMHSA website (www.samhsa.gov).

SAMHSA believes that a key feature of office-based treatment will be the ability of the office-based physician to prescribe partial agonist treatment medications to patients in treatment. Without the ability to prescribe, office-based physicians would have to store and dispense medications directly to patients. These practices could be expensive and impractical for the patient and office-based physician. Current regulations enforced by the Drug Enforcement Administration (21 CFR 1306.07(a)) prohibit prescriptions for narcotic drugs used in the treatment of narcotic addiction. However, DEA is preparing a separate proposed rule to rescind this prohibition as it pertains to narcotic treatment drugs controlled in Schedules III-V.

III. References

1. Using Buprenorphine for Office-Based Treatment of Opiate Addiction, Recommendations to the Center for Substance Abuse Treatment.

Dated: December 29, 1999.

Nelba Chavez,

Administrator, Substance Abuse and Mental Health Services Administration.

Dated: March 30, 1999.

Donna E. Shalala,

Secretary, Health and Human Services.

[FR Doc. 00-10969 Filed 5-3-00; 8:45 am]

BILLING CODE 4162-20-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 00-44; FCC 00-93]

Extension of the Filing Requirement for Children's Television Programming Reports (FCC Form 398)

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The document proposes to amend the FCC's rules to continue indefinitely the requirement that commercial broadcast television licensees file with the Commission, on an annual basis, their quarterly Children's Television Programming Reports (FCC Form 398). The Commission's rules currently state that such reports shall be filed on an annual basis for an experimental period of three years, from January 1998 through January 2000. Continuation of the annual filing requirement will permit the Commission to continue to enforce the Children's Television Act of 1990 ("CTA"), and its rules implementing the CTA, by monitoring the amount and quality of educational television programming for children and industry compliance with the FCC's children's educational programming requirements.

DATES: Comments are due on or before June 12, 2000; reply comments are due on or before July 12, 2000.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW, Room TW-A306, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Kim Matthews, Policy and Rules Division, Mass Media Bureau, (202) 418-2154.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking* ("NPRM"), MM 00-44; FCC 00-93, adopted March 9, 2000; released April 6, 2000. The full

text of the Commission's *NPRM* is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room TW-A306), 445 12 St. SW, Washington, DC. The complete text of this *NPRM* may also be purchased from the Commission's copy contractor, International Transcription Services (202) 857-3800, 1231 20th St., NW, Washington, DC 20036.

Synopsis of Notice of Proposed Rulemaking

I. Introduction

1. This *NPRM* proposes to amend § 73.3526(e)(11)(iii) of the Commission's rules to continue indefinitely the requirement that commercial broadcast television licensees file with the Commission, on an annual basis, their quarterly Children's Television Programming Reports (FCC Form 398). The Commission's rules currently state that such reports shall be filed on an annual basis for an experimental period of three years, from January 1998 through January 2000. Continuation of the annual filing requirement will permit the Commission to continue to enforce the Children's Television Act of 1990 ("CTA"), and its rules implementing the CTA, by monitoring the amount and quality of educational television programming for children and industry compliance with the Commission's children's educational programming requirements.

II. Background

2. The CTA requires the Commission, in its review of each television broadcast license renewal application, to "consider the extent to which the licensee . . . has served the educational and informational needs of children through the licensee's overall programming, including programming specifically designed to serve such needs." In enacting the CTA, Congress found that, while television can benefit society by helping to educate and inform children, there are significant market disincentives for commercial broadcasters to air children's educational and informational programming. The objective of Congress in enacting the CTA was to increase the amount of educational and informational programming available on television. The CTA accomplished that objective by placing on every television licensee an obligation to provide such programming, including programming specifically designed to educate and inform children, and by requiring the FCC to enforce that obligation.

3. The Commission's initial rules implementing the CTA, adopted in

1991, included a very flexible definition of educational programming and did not establish quantitative guidelines regarding the amount of educational programming licensees were required to provide. In addition, these initial rules did not include measures designed to inform the public about educational programming. Within a few years after these initial rules took effect, questions began to be raised regarding the effectiveness of the new rules, and in particular about the content of the programs stations claimed were educational.

4. In August 1996, the Commission adopted its current educational programming rules to strengthen its enforcement of the CTA (61 FR 43981, August 27, 1996). The Commission's rules include several measures to improve public access to information about the availability of programming "specifically designed" to serve children's educational and informational needs (otherwise known as "core" programming). These measures include a requirement that licensees identify core programming at the time it is aired and in information provided to publishers of television program guides. Licensees are also required to designate a children's liaison at the station responsible for collecting comments on the station's compliance with the CTA. In addition, the rules also establish a definition of "core" programming as well as a three-hour per week processing guideline pursuant to which broadcasters airing at least three hours per week of programming that meets the definition of "core" will receive staff-level approval of their license renewal applications.

5. One of the most important public information measures adopted by the Commission in 1996 is the requirement that licensees complete a Children's Television Programming Report (FCC Form 398) each calendar quarter. Among other things, these Reports identify the educational and informational programs aired by the licensee over the previous quarter and the days and times these programs were regularly scheduled, the age of the target child audience for each program, and the average number of hours per week of core programming broadcast over the past quarter. Licensees must include in the Reports an explanation of how each core program meets the definition of "core" programming adopted by the Commission. Stations must also identify in their Reports the core programs the station plans to air during the next calendar quarter.

6. The Reports are prepared on a quarterly basis and must be placed in the station's public inspection file. Stations are required to publicize the existence and location of the reports. In addition, as noted above, the rules currently provide that, "for an experimental period of three years" these Reports must be filed with the Commission on an annual basis (four quarterly reports filed jointly once a year) on the following dates: January 10, 1998, January 10, 1999, and January 10, 2000. The Reports must be filed with the Commission electronically, and the Commission posts the Reports on the FCC's Internet home page where they can be readily accessed by the public. The address for the Commission's home page is: <http://www.fcc.gov>. The Commission also encourages broadcasters to make these Reports available on their own websites.

III. Discussion

7. The public information initiatives adopted in 1996 are an integral part of the children's programming rules. These measures are designed to ensure that the public, and especially parents, has access to information regarding the educational programming being aired by broadcasters so that parents and others can help achieve the goal of the CTA to increase the amount of educational programming available on television. In adopting the public information initiatives as part of its revised educational programming rules, the Commission explained their purpose as follows:

8. We conclude that the market inadequacies that led Congress to pass the Children's Television Act can be addressed, in part, by enhancing parents' knowledge of children's educational programming. One way to encourage licensees to provide such programming is to encourage and enable the public, especially parents, to interact with broadcasters. Easy public access to information permits the Commission to rely more on marketplace forces to achieve the goals of the CTA and facilitates enforcement of the statute by allowing parents, educators, and others to actively monitor a station's performance. As CBS "wholeheartedly" agrees, "judgments of the quality of a licensee's programming, educational or otherwise, are best made by the audience, not the federal government." Thus, our rules should facilitate easy access to information regarding children's educational programming in the community.

9. Facilitating public access to the information contained in the Children's Television Programming Reports helps

the marketplace to achieve the goals of the CTA in a number of ways. Parents who have access to information about educational programming, such as the titles of the programs, the times they are regularly scheduled to air, and the age for which the programs are intended, can select such programming for their children to watch, thereby increasing the audience for such programs and the incentive of broadcasters to air, and producers to supply, more such programs. Better information also helps parents in working with broadcasters in their local communities to improve children's educational programming without government intervention. The information contained in the Reports can be used by parents, educators, and others interested in educational programming to monitor a station's performance in complying with the CTA and the Commission's rules. The Commission encourages parents and others to communicate directly with stations and program producers regarding the shows stations claim meet the FCC's definition of "core" programming. In this way, the public can play an active role in helping to enforce children's programming requirements. Finally, requiring broadcasters to identify programming they rely upon to meet their obligation to air educational programming makes broadcasters more accountable to the public. Improving broadcaster accountability minimizes the need for government involvement to enforce the CTA and helps to ensure that broadcasters, with input from the public, rather than the Commission determine which television programs serve children's educational needs.

10. The requirement that broadcasters file their Children's Television Programming Reports with the Commission was initially adopted, on an experimental basis, for a period of three years. To date, Reports have been filed for two successive years, January 10, 1998 and January 10, 1999. Under the current rules, the filing requirement expires after Reports for 1999 are filed January 10, 2000. We believe that the requirement that broadcasters file these Reports with the FCC should be continued. Therefore, we propose to retain the filing requirement indefinitely, and request comment on this proposal.

11. Anecdotal evidence suggests that organizations devoted to informing parents and community members about children's programming use the reports as a primary data source. For example, the Center for Research on the Influences of Television on Children at the University of Texas reviews local

broadcasters' reports as part of an annual evaluation of children's programming in the Austin, Texas market. The Center for Media Education uses the reports to develop tools for parents. Other organizations, including the National Institute on Media and the Family and the Annenberg Public Policy Center at the University of Pennsylvania, use the reports to track national trends in children's television programming. The filing requirement is an important part of the emphasis placed by the rules on improving the flow of information to the public about educational programming. Filing permits the Commission to place the Reports on its website, making this information easily accessible in one central location. Members of the public can view Reports from a number of stations easily, and compare results, without having to contact each station individually. Continuation of the filing requirement is also important to ensure that the Commission itself has access to information regarding licensee compliance with the children's programming rules. Without the annual filing requirement, licensees would be required to report on their station's children's programming only once every eight years, at the end of the license term. Extension of the license term to eight years necessarily places a heavier emphasis on facilitating public monitoring of licensee compliance with the rules, to assist the FCC in its enforcement role. Among other things, the Commission has relied upon information in the Reports to evaluate industry practices in connection with preemption of children's programming. A review of the Children's Television Programming Reports filed with the Commission for 1998 indicates that, of the 4,964 quarterly reports filed, 63 reported less than 3 hours of core children's educational and informational programming, 2,116 reported exactly 3 hours of core programming, and 1,832 reported 4 or more hours of core programming. In adopting the children's programming rules, the Commission stated it would monitor the broadcast industry's children's educational programming performance for three years based upon the Children's Television Programming Reports filed with the Commission, and would review the reports at the end of the three-year period and take appropriate action as necessary to ensure that stations are complying with the rules and guidelines. The Commission will commence that review after January 10, 2000, the filing due date for the last Children's Television

Programming Reports of the three-year period.

12. We also request comment on whether our rules should be revised to require that Reports be filed quarterly, at the time they are prepared, rather than once a year. As broadcasters must prepare the Reports quarterly, requiring Reports to be filed on a quarterly basis is unlikely to impose a significant additional burden on licensees, especially now that Reports are required to be filed electronically and transmission to the Commission should require only a few additional keystrokes. Finally, we ask commenters to address whether any changes should be made to FCC Form 398 to make the Reports more informative or easier to prepare. For example, are there revisions to Form 398 that would make it easier for the reader to determine the number of times core programs are preempted and to obtain information about the rescheduling of any preempted episodes?

IV. Administrative Matters

13. *Comments and Reply Comments.* Pursuant to 47 CFR 1.415 and 1.419 of the Commission's rules, interested parties may file comments on or before June 12, 2000 and reply comments on or before July 12, 2000. Comments may be filed using the Commission's Electronic Filing System (ECFS) or by filing paper copies. See Electronic Filing of Documents in Rulemaking Proceedings (63 FR 24121, May 1, 1998).

14. Comments filed through the ECFS can be sent as an electronic file via the Internet to <<http://www.fcc.gov/e-file/ecfs.html>>. Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, postal service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to ecfs@fcc.gov, and should include the following words in the body of the message, "get form, <your e-mail address>." A sample form and directions will be sent in reply.

15. Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appear in the caption of this proceeding, commenters must submit two additional

copies for each additional docket or rulemaking number. All filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 445 Twelfth Street, SW; TW-A325, Washington, DC 20554.

16. Parties who choose to file by paper should also submit their comments on diskette. These diskettes should be submitted to: Kim Matthews, 445 Twelfth Street, SW; 2-C225, Washington, DC 20554. Such a submission should be on a 3.5 inch diskette formatted in an IBM compatible format using WordPerfect 5.1 for Windows or compatible software. The diskette should be accompanied by a cover letter and should be submitted in "read only" mode. The diskette should be clearly labeled with the commenter's name, proceeding (including the docket number (MM Docket No. 00-44), type of pleading (comment or reply comment), date of submission, and the name of the electronic file on the diskette. The label should also include the following phrase "Disk Copy—Not an Original." Each diskette should contain only one party's pleadings, preferably in a single electronic file. In addition, commenters must send diskette copies to the Commission's copy contractor, International Transcription Service, Inc., 445 Twelfth Street, SW; CY-B402, Washington, DC 20554.

17. *Ex Parte Rules*. This is a permit-but-disclose notice and comment rulemaking proceeding. Ex parte presentations are permitted except during the Sunshine Agenda period, provided they are disclosed as provided in the Commission's Rules. See generally 47 CFR 1.1202, 1.1203, and 1.1206(a).

18. *Initial Regulatory Flexibility Analysis*. With respect to this Notice, and Initial Regulatory Flexibility Analysis ("IRFA") is contained in Appendix A. As required by Section 603 of the Regulatory Flexibility Act, the Commission has prepared an IRFA of the expected impact on small entities of the proposals contained in this Notice. Written public comments are requested on the IRFA. In order to fulfill the mandate of the Contract With America Advancement Act of 1996 regarding the Final Regulatory Flexibility Analysis, we ask a number of questions in our IRFA regarding the prevalence of small business in the television broadcasting industry. Comments on the IRFA must be filed in accordance with the same filing deadlines as comments on the Notice, but they must have a distinct heading designating them as responses to the IRFA. The Secretary shall send a copy of this Notice, including the IRFA,

to the Chief Counsel for Advocacy of the Small Business Administration in accordance with Section 603(a) of the Regulatory Flexibility Act, Public Law No. 96-354, 94 Stat. 1164, 5 U.S.C. 601 et seq. (1981), as amended.

19. *Authority*. This Notice is issued pursuant to authority contained in Sections 4(i), 303, and 307 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 303, and 307.

VII. Initial Regulatory Flexibility Analysis

20. *Initial Paperwork Reduction Act of 1995 Analysis*. This *NPRM* proposes to continue indefinitely the requirement that broadcast television licensees file with the Commission their Children's Television Programming Reports on FCC Form 398. In addition, the *NPRM* invites comment on whether these filings should be required on a quarterly, rather than an annual, basis, and on whether revisions should be made to Form 398 to reduce the burden on licensees. As part of our continuing effort to reduce paperwork burdens, we invite the general public and the Office of Management and Budget (OMB) to take this opportunity to comment on the information collections contained in this *NPRM*, as required by the Paperwork Reduction Act of 1995, Public Law No. 104-13. Public and agency comments are due at the same time as other comments on this Notice; OMB comments are due 60 days from the date of publication of this Notice in the **Federal Register**. Comments should address: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Judy Boley, Federal Communications Commission, 445 Twelfth Street, SW; 1-C8004, Washington, DC 20554, or via the Internet to jboley@fcc.gov and to Timothy Fain, OMB Desk Officer, 10236 NEOB, 725 17th Street, NW, Washington, DC 20503 or via the Internet to fain_t@al.eop.gov.

21. *Initial Regulatory Flexibility Act Analysis*. As required by the Regulatory

Flexibility Act, 5 U.S.C. 603 ("RFA"), the Commission has prepared an Initial Regulatory Flexibility Analysis ("IRFA") of the expected impact on small entities of the proposals contained in this *NPRM*. Written public comments are requested with respect to the IRFA. These comments must be filed in accordance with the same filing deadlines for comments on the rest of the *NPRM*, but they must have a separate and distinct heading, designating the comments as responses to the IRFA. The Commission shall send a copy of this *NPRM*, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with the RFA, 5 U.S.C. 603(a).

22. *Reasons Why Agency Action is Being Considered*. Our goals in commencing this proceeding and in formulating the proposals in the *NPRM* are to ensure that the FCC and the public have adequate information regarding educational programming for children and licensee compliance with the CTA and the FCC's rules.

23. *Need For and Objectives of the Proposed Rule Changes*. Our goal in commencing this proceeding and in formulating the proposals in the *NPRM* is to ensure that the public continues to have access to information regarding the educational programming being aired by television broadcast licensees to assist parents in selecting educational programming for their children and to assist the public in monitoring the performance of stations in complying with the CTA and the FCC's rules. Our goal is also to ensure that the FCC receives adequate information to enforce the CTA and its rules, and to permit it to provide a central location for access to Children's Television Reports on the FCC's Internet website.

24. *Legal Basis*. Authority for the actions proposed in the *NPRM* may be found in Sections 4(i) and 303 and 307 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 303, and 307.

25. *Recording, Recordkeeping, and Other Compliance Requirements*. The *NPRM* proposes to continue indefinitely existing filing requirements, and invites comments on whether licensees should be required to file Children's Television Programming Reports on a quarterly rather than an annual basis.

26. *Federal Rules that Overlap, Duplicate, or Conflict with the Proposed Rules*. The rules proposed in this proceeding do not overlap, duplicate, or conflict with any other rules.

27. *Description and Estimate of the Number of Small Entities to Which the Rules Would Apply*. Under the RFA,

small entities may include small organizations, small businesses, and small governmental jurisdictions. 5 U.S.C. 601(6). The RFA, 5 U.S.C. 601(3), generally defines the term "small business" as having the same meaning as the term "small business concern" under the Small Business Act, 15 U.S.C. 632. A small business concern is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration ("SBA"). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies "unless an agency after consultation with the Office of Advocacy of the SBA and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**. There are approximately 1,240 existing commercial television broadcasters of all sizes that may be affected by the proposals contained in this *NRPM*.

28. Any Significant Alternatives Minimizing the Impact on Small Entities and Consistent with the Stated Objectives: This *NPRM* solicits comment on a number of proposals, including continuation of the existing requirement to file Children's Television Programming Reports with the Commission. We seek comment in the *NPRM* on this proposal as well as on other issues, and on whether there is a significant economic impact on any class of small licensees as a result of any of our proposals. Any significant alternatives presented in the comments will be considered.

List of Subjects in 47 CFR Part 73

Television broadcasting.

Federal Communications Commission.

Magalie Roman Salas,
Secretary.

[FR Doc. 00-11098 Filed 5-3-00; 8:45 am]

BILLING CODE 6712-01-P

ENVIRONMENTAL PROTECTION AGENCY

48 CFR Parts 1503 and 1552

[FRL-6588-2]

Acquisition Regulation

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is issuing this rule to amend the EPA Acquisition Regulation (EPAAR) to add a contract clause to Agency contracts whereby contractors, under contracts exceeding \$1,000,000, are required to display EPA Office of the Inspector General Hotline posters within contractor work areas.

DATES: Comments should be submitted not later than July 3, 2000.

ADDRESSES: Comments must be submitted to Larry Wyborski, U.S. Environmental Protection Agency, Office of Acquisition Management (3802R), 1200 Pennsylvania Avenue NW, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Larry Wyborski, U.S. Environmental Protection Agency, Office of Acquisition Management (3802R), 1200 Pennsylvania Avenue NW, Washington, DC 20460; (202) 564-4369, wyborski.larry@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

A. Background Information

EPA's Office of Inspector General (OIG) requested that contractor personnel under EPA contracts have access to information for contacting the OIG in the event they wish to report waste, fraud or abuse under an EPA contract. The information will be available in an EPA OIG Hotline Poster. A contract clause will notify the contractor of the requirement to display the hotline posters and will provide a reference for obtaining the posters.

B. Executive Order 12866

This is not a significant regulatory action for purposes of Executive Order 12866; therefore, no review is required at the Office of Information and Regulatory Affairs, within the Office of Management and Budget (OMB).

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this rule does not contain information collection requirements for the approval of OMB under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, et seq.).

D. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute, unless the agency certifies that the rule will not have a significant impact on a substantial

number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impact of this rule on small entities, small entity is defined as: (1) A small business that meets the definition of a small business found in the Small Business Act and codified at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any *adverse* economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives "which minimize any significant economic impact of the proposed rule on small entities." 5 U.S.C. Sections 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. This direct final rule does not have a significant impact on a substantial number of small entities. The requirements under the rule impose no reporting, record-keeping, or compliance costs on small entities.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) Public Law 104-4, establishes requirements for Federal agencies to assess their regulatory actions on State, local and Tribal governments and the private sector. This rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. Any private sector costs for this action relate to paperwork requirements and associated expenditures, which would be far below the level established for UMRA applicability. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.